PASS information

Title	Assessment of the effectiveness of additional Risk Minimisation Measures (aRMMs) among pharmacists for provision of desogestrel 75 microgram film-coated tablets in a community pharmacy setting
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Product Reference	ATC G03AC09
Procedure Number	PL 42807/0002 PL 17836/0015
Marketing Authorisation Holders	Maxwellia Ltd Laboratoire HRA Pharma
Joint PASS	Yes
Research questions and objectives	To evaluate the effectiveness of desogestrel 75 microgram film-coated tablets aRMMs by: • Demonstrating that the aRMMs are effective in enabling pharmacists to make appropriate decisions to supply based on contraindications and special warnings; this includes awareness and mitigation of safety concerns; • Identifying whether there are particular contraindications or warnings for which pharmacists consistently make the wrong supply decision; • Establishing ease of access to and ease of use of the aRMMs.
Country of Study	UK
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1. Abstract

Title:

Assessment of the effectiveness of additional Risk Minimisation Measures (aRMMs) among pharmacists for provision of desogestrel 75 microgram film-coated tablets in a community pharmacy setting.

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Keywords:

Desogestrel, Contraception, Lovima, Hana

Rationale and background:

Desogestrel 75 microgram film-coated tablets was reclassified to a pharmacy only (P) medicine in the UK separately by Maxwellia Ltd and Laboratoire HRA Pharma in July 2021. To support the safe supply of the products via pharmacy, both companies have independently developed a Pharmacy Training Guide and an optional Pharmacy Checklist as additional Risk Minimisation Measures (aRMMs). The content of the materials has been aligned and approved by the MHRA .

This post-authorisation safety study (PASS) sets out to assess the effectiveness of the approved aRMMs for desogestrel 75 microgram film-coated tablets as a P medicine, six months after the UK market launch. The study, conducted at the request of the MHRA, included the aRMMs from two brands, Hana (Laboratoire HRA Pharma) and Lovima (Maxwellia).

The research was carried out among UK community pharmacists who had conducted consultations on P-desogestrel in the last six months, and had received and read the aRMMs. The PASS used a series of patient scenarios designed to test the knowledge of pharmacists about when to supply or not supply the product, and for what reason. Key performance indicators (KPIs) were set at 80% giving correct answers regarding the decision to supply or not supply desogestrel in eight scenarios (Table 9-3) to adjudge the target audience who were adequately trained on risk minimisation measures.

Research question and objectives:

The overall objective of the study was to evaluate the effectiveness of the aRMMs in mitigating the risks of incorrect supply of desogestrel 75 microgram film-coated tablets to patients in a community pharmacy. Specifically, the goals of the study were to:

1. Demonstrate that the training provided by each company is effective in enabling pharmacists to make appropriate decisions to supply desogestrel 75 microgram film-coated tablets based on contraindications and special warnings; this includes awareness and mitigation of safety concerns
2. Identify whether there are particular contraindications or warnings for which pharmacists consistently make the wrong supply decision

3. Establish ease of access to and ease of use of the aRMMs.

Study design:

The study was a cross sectional, non-interventional web-based survey at six months post the first product launch following MHRA approval of the reclassification.

Setting:

The survey was distributed across the United Kingdom (UK) to a representative mix of independent and multiple ownership pharmacies.

Subjects and study size, including dropouts:

Pharmacists who had read the aRMM materials and had conducted at least one consultation during the previous six months were eligible to participate. To ensure representative data, a mix of independent and multiple ownership pharmacies, including those in urban, small town and rural settings were recruited to participate. The target sample size was 200 completed surveys. The sample size chosen for this study was dependent on statistical and feasibility considerations.

Variables and data sources:

The survey collected information about pharmacists' understanding of the key safety messages in the risk minimisation measures using eight multi-parameter scenarios. The scenarios were designed to evaluate pharmacists' ability to make correct supply/do not supply decisions, and as a secondary measure, through multiple safety parameters, to establish their level of understanding of the reasons behind the correct decision.

It also collected information about potential pharmacist behaviour with regard to communicating important safety information to patients, as well as their demographic characteristics and clinical experience.

The KPI was set at 80% for those making appropriate decisions to supply or not supply desogestrel and also for pharmacists giving the right reason for their decision in each of the eight scenarios. The key objective of this study (objective 1) was satisfied by the supply/not supply question in each scenario. The measure of choice of reason for the decision was a secondary objective (objective 2). This very high bar was set as a 'best in class' objective, and was well above the 70% target set in many PASS studies.

In this survey, the data source was a panel of 33,175 UK retail pharmacy staff who had previously opted-in to participate in research with CIG Research.

Results

Discussion

The materials most likely to have been read to help minimise risk when having consultations regarding the supply of desogestrel 75 microgram film-coated tablets without a prescription were the Pharmacy Training Guide and the Consultation/Supply Aid Checklist (Table 10-7). In terms of the usefulness of the materials used in consultations, 87% rated them as extremely or very useful.

The research demonstrated that the pharmacy training material provided was effective in enabling pharmacists to make correct decisions to supply or not supply desogestrel and consequently the materials have adequately minimised the risk of inappropriate supply.

The materials for both brands were rated as easily accessible to pharmacists when giving consultations, and for all four of the materials included (the Pharmacy Training Guide, Consultation/supply aid checklist, SmPC and Pack Copy).

Across the total sample, in seven of the eight scenarios, the option to supply or not supply desogestrel reached the threshold of 80% set as a KPI.

Regarding secondary consideration of the reason to supply or not supply P desogestrel, it fell short of the high KPI objective that 80% of pharmacists would select the correct reason for their decision in four of the eight scenarios. This was primarily due to the complexity of the multi-parameter scenarios, and particularly two of the scenarios where an incorrect reason was selected by 48.4% of respondents in one case and 62.5% in the other.

Despite this, the level of pharmacist confidence in providing correct advice and making the right decision about supplying the product was very high. 98% of all pharmacists were at least fairly confident about advising patients and 60.5% were very or completely confident. It was also important that the level of confidence increased with the number of consultations pharmacists had given in the first six months since the launch of the two products. Despite their reported confidence, pharmacists, when unsure, tended to become conservative, recommending not to supply desogestrel and to refer patients to their GP – effectively a low risk option (see scenario 6, Table 10-13).

Pharmacists participating in this study had conducted at least one consultation on P-desogestrel in the last six months, and on average had only conducted 15 consultations over the time period. Given that the research took place only six months after the launch of the product, the level of appropriate decision-making was relatively high. In view of the early stage at which this research was conducted following the launch of both brands, it is fair to assume that increased experience of consultations, and use of the aRMMs, will improve the proportion of pharmacists giving the correct reason for supply or not to supply, rather than referring to a GP, even in the complex multi-parameter situations presented in these scenarios.

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2. List of abbreviations

AE	Adverse Event
aRMMs	additional Risk Minimisation Measures
CI	Confidence Intervals
CIG	Communications International Group
DIA	Drug Information Association
DSG	Desogestrel
GDPR	General Data Protection Regulation
GP	General Practitioner
GSL	General Sales List medicine
GXP	Good Practice
hCG	human Chorionic Gonadotrophin
HCP	Healthcare Professional
KPI	Key Performance Indicator
LARCs	Long-Acting Reversible Contraceptives
KRMs	Key Risk Messages
MAH	Marketing Authorisation Holder
MHRA	Medicines and Healthcare products Regulation Agency
MRP	Mutual Recognition Procedure
NIS	Non-Interventional Study
OC	Oral Contraception
OTC	Over The Counter
P	Pharmacy medicine
PASS	Post-Authorisation Safety Study
PGD	Patient Group Directions
POM	Prescription Only Medicine
POP	Progestin-only Pill
RM	Risk Management
RMP	Risk Management Plan
SAP	Survey Analysis Plan
SmPC	Summary of Product Characteristics
SSRI	Selective Serotonin Reuptake Inhibitor
STI	Sexually Transmitted Disease
URL	Uniform Resource Locator

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Shared responsibility statement

This is a joint PASS submission and there is a shared responsibility between Laboratoire HRA Pharma and Maxwellia Ltd for the management and reporting of Adverse Events.

In the course of this study, no adverse events were reported by pharmacists in relation to either brand.

5. Milestones

Milestone	Planned date	Actual date	Comments
DSG reclassification approval	8th July 2021	8th July 2021	
Launch of product in pharmacy	July 2021	July 2021	
Roll out of aRMMs	July 2021	July 2021	
MHRA protocol approval	2nd September 2021	15th September 2021	
User testing (launch)	w/c 20th September 2021	22th September 2021	
Registration in the EU PAS Register®	30th September 2021	28th September 2021	
Pilot study launch	w/c 11th October 2021	12th October 2021	
Pilot study data collection and results reporting	w/c 1st November 2021	27th October 2021	
Submission of changes made to the protocol and questionnaire to MHRA	w/c 29th November 2021	1st December 2021	
MHRA updated protocol approval	w/c 10th January 2022	12th January 2022	
Main study launch	w/c 17th January 2022	20th January 2022	
End of data collection	w/c 14th February 2022	2nd February 2022	
Publication of final study report	w/c 18th April 2022		

6. Rationale and background

Desogestrel 75 microgram film-coated tablets (DSG) was reclassified from a prescription only (POM) to a pharmacy only (P) medicine in the UK separately by Maxwellia Ltd and Laboratoire HRA Pharma. Both applications for non-prescription 75 microgram desogestrel (marketed as Lovima 75 microgram film-coated tablets and Hana 75 microgram film-coated tablets retrospectively) were approved in July 2021.

To support the safe supply of the products via pharmacies and correct advice is provided by pharmacists, , both companies independently developed a Pharmacy Training Guide and an optional Pharmacy Checklist as additional Risk Minimisation Measures (aRMMs). The content of the aRMMs between Laboratoire HRA Pharma and Maxwellia, was aligned and approved by the MHRA.

This survey was designed to assess pharmacists' understanding of the aRMMs (Pharmacy Training Guide and Pharmacy Checklist) with respect to potential risks including but not limited to venous thromboembolism, arterial thromboembolism, disturbances of liver function, breast cancer, benign and malignant liver tumours, and drug interactions. It also assessed the communication of additional information for pharmacists to consider, including but not limited to, alternative contraception options to ensure women can make informed choices, safeguarding and consent, information on how to take DSG, counselling advice on potential side effects of DSG, quick starting and managing potential off-label use and managing a missed or forgotten pill.

7. Research questions and objectives

This study evaluated the effectiveness of P desogestrel 75 microgram tablet aRMMs. Specifically, the primary objectives were to:

- Demonstrate that the aRMMs are effective in enabling pharmacists to make appropriate decisions to supply based on contraindications and special warnings; this includes awareness and mitigation of safety concerns
- Identify whether there are particular contraindications or warnings for which pharmacists consistently make wrong supply decisions
- Establish ease of access to and ease of use of the aRMMs.

8. Amendments and updates

Number	Date	Section of study report	Amendment or update	Reason
None				

9. Research methods

This section presents the methods that have been employed to evaluate the effectiveness of the P desogestrel 75 microgram aRMMs in the UK.

9.1. Study design

This observational study was a UK national cross-sectional web-based survey.

9.2. Setting

The survey was conducted in the UK at six months post product launch for the two brands, following MHRA approval of the reclassification.

Pharmacists who had read the aRMMs for at least one of the brands and had conducted at least one consultation regarding the supply of P desogestrel 75 microgram film-coated tablets during the six months prior to the survey were eligible to participate. A mix of independent and multiple ownership pharmacies, including those in urban, small town and rural settings were recruited to participate in the survey from CIG Research's opt-in panel of 35,175 UK community pharmacists.

Table 9-1: Sample quotas set, and quotas achieved

The distribution of pharmacists in the UK formed the basis of quotas set for this survey for geographical distribution and outlet type, and is based on CIG Research's database of UK community pharmacies and staff. Classification by neighbourhood type is not a standard classification variable and quotas were set based on a series of previous surveys conducted by CIG Research in the UK between 2015 and 2020.

	Quotas set proportion (+/-5%)	Quotas achieved
Single outlet independent	15%	12%
Group branch independents 2-49 outlets	35%	38%
Multiples (50 plus outlets)	50%	51%
Pharmacist Proprietor	10%	5%
Pharmacist Manager / Supervisor	30%	33%
Pharmacist	40%	44%
Locum Pharmacist	20%	18%
Urban	50%	56%
Suburban	35%	31%
Rural	15%	13%
London and South East/South West	45%	43%
Midlands and East of England	20%	23%
North East/North West	25%	22%
Scotland, Wales, Northern Ireland	10%	12%

The study was conducted as a non-interventional web-based survey, which allowed respondents to participate at a time and location that was convenient to them. The research panel is used to completing surveys in this environment and no other data collection method was necessary to facilitate acceptable completion rates.

Invitations
Pharmacists based in community pharmacies across the UK were invited to participate in this survey in January and February 2022. A total of 35,175 pharmacy staff were invited to take part. Invitations were sent in three stages to randomly selected members of CIG Research panel:

1. Soft launch to established CIG Research panel members (six months-plus membership)
    - 20.01.2022: initial invitation sent to 2,305 CIG Research panel members
    - 22.01.2022: first reminder sent to 2,106 members from the first group
    - 24.01.2022: second reminder sent to 2,026 members from the first group
    - 28.01.2022: final reminder sent to 2,005
2. Second group of randomly selected CIG Research panel members
    - 22.01.2022: initial invitation to 632 CIG Research panel members
    - 24.01.2022: first reminder to 621 members from the second group
    - 28.01.2022 final reminder to 618
3. Full launch to total list of 32,238 opt-in research participants
    - 26.01.2022: initial invitation to 32,238 pharmacists
    - 28.01.2022: first reminder to 30,109 pharmacists
    - 29.01.2022: second reminder to 29,604 pharmacists
    - 1.02.2022: final reminder to 19,181 Pharmacists

9.3. Subjects

Eligible UK-registered pharmacists from CIG Research's opt-in panel who responded to the survey invitation made up the study population.

9.3.1. Inclusion criteria

Pharmacists were required to meet the following criteria for inclusion in the survey:

- Qualified pharmacist working in a community pharmacy in the UK
- Have read at least one of the aRMM materials and held at least one consultation with a female customer regarding the supply of P desogestrel 75 microgram film-coated tablets in the six months prior to the study

The sample also aimed to be representative of community pharmacists by age, gender, outlet size, and by region within the UK, including Northern Ireland.

9.3.2. Exclusion criteria

Pharmacists not meeting the following criteria were not permitted to take part in the survey:

- Have not received and read the aRMM materials supplied for the products in the UK, or do not recall having received or read them
- Have participated in the user testing of the draft questions for the survey (described in Section 9.4.4 of the PASS Protocol: User and pilot testing of the survey questions)
- Are employed in full-time research, GP practices or hospitals (i.e., not community-based pharmacists)
- Work only as online pharmacists and do not provide consultations
- Have been in the employment of or contracted to the MHRA, Maxwellia Ltd, Laboratoire HRA Pharma, Communications International Group or Consensio LLP in the last 12 months.

9.4. Variables

The survey contained a total of 40 questions relating to: Agreement to participate (2), eligibility (6), demographics (6), awareness and behaviours pertaining to pharmacist consultations and use of educational materials (4), attitudes towards the educational materials and their use (6), questions assessing pharmacists' knowledge of the correct decision to supply or not supply desogestrel (16).

The questionnaire is provided in Annex 3 of the protocol [Appendix 1.1 of this document].

The following survey questions provided the variables needed to address the study objectives:

- Q3, Q10, Q11, Q13 Scenarios 1-8: Demonstrate that the aRMMs are effective in enabling pharmacists to make appropriate decisions to supply based on contraindications and special warnings; this includes awareness and mitigation of safety concerns
- Q13 Scenarios 1-8: Identify whether there are particular contraindications or warnings for which pharmacists consistently make wrong supply decisions
- Q10, Q11, Q12: Establish ease of access to and ease of use of the aRMMs.

9.5. Data sources and measurement

In order to target the desired population, invitations were sent by email to pharmacists from CIG Research's opt-in panel of 35,175 UK community pharmacy staff. Response rates of 2-3% are typical in studies of this type and length, which would have returned between 704 and 1,055 responses. For this survey, a response rate of 2.45% was achieved; eligibility among those starting the survey was 26.12%, and completion rate 22.53%.

Respondents accessed the survey by means of a secure URL link provided in the email invitation sent to CIG Research's opt-in panel of pharmacists. Each respondent could access the survey only once, which was controlled by unique account identifiers within the survey software. The sample of 200 respondents to the survey was quota controlled to be nationally representative of community pharmacists in the UK.

Pharmacists were screened to ensure they had received and read the aRMMs from at least one of the brands and conducted at least one consultation on desogestrel 75 microgram film-coated tablets without a prescription in the last six months (Q1, Q2, Q3). The scenario section of the questionnaire was designed to present multi-factor safety scenarios, even though these would not be typical of most consultations, in which pharmacists could choose to refer to information sources during consultations. As the pharmacist might be completing the survey away from their usual place of consultation and might not have access to the materials they would usually use, an instruction was given that they could make use of any of the aRMMs they would normally use to help them complete the survey. The decision was taken not to provide a direct electronic link to these materials during the survey, as this would be be unlikely to happen in real-life.

Information on the CIG Research opt-in panel is held on CIG's cloud-based servers and updated continuously to ensure all unsubscribes are removed and new participants wishing to join the panel are classified according to their job title, location and outlet type. When invitations were sent out for this survey, the panel stratification classification was used to boost responses from under-represented segments in collected responses, by encouraging pharmacists in those segments to take part. CIG Research compensated pharmacists for their time spent completing the survey in the form of reward points, which can be redeemed for vouchers. This remuneration programme is independent of Maxwellia Ltd and Laboratoire HRA Pharma and is governed by UK laws and regulations.

A structured, self-administered questionnaire comprised of closed and open-ended questions or statements with multiple response choices (i.e. questions or statements asking the pharmacists to choose from a defined list of responses) was used to collect the survey data.

The PASS protocol was subject to the following amendments before the launch of the main study:

Prior to finalisation of the study questionnaire, the proposed questions were peer reviewed and the functionality of the online survey was user tested with five pharmacists in the UK to identify any ambiguity and estimate survey completion time. This was conducted to ensure that the questionnaire flowed well and that question wording did not generate bias or misunderstanding among respondents. The user testing was performed on September 22nd 2021 on the survey questions by sampling five pharmacists from the CIG Research panel who met the inclusion criteria. The report on this user testing was appended to the PASS Protocol submitted to the MHRA on December 1st 2021.
Across the five users, an average of 12 minutes was taken to complete the survey, with a range of between 10 and 27 minutes.

One of the survey questions, and its associated answer options, was amended following results of the user testing:

- The filter question 'which, if any of these organisations have you worked for or been contracted to in the last year' was amended to 'Which, if any, of these organisations have you been employed by or contracted to in the last year'

(full report available in Appendix 1.2 of this document).

The amended survey was piloted with a further 30 pharmacists from the CIG Research panel who met the inclusion criteria. This was conducted between 12th and 27th October 2021 and the report was appended to the PASS Protocol submitted to the MHRA on December 1st 2021.

The pilot assessed both the flow of the questionnaire and the meaningfulness of the results from this sample.

It concluded that:

- Eligibile completions represented one in three of those commencing the survey, leading to a forecast of the requirement for 600 respondents to achieve a 200 sample in the full survey
- A slider scale used to measure numbers of consultations held had been set at 1 to 500-plus at intervals of 20. This was amended to be 1 to 200-plus at intervals of 1, to better reflect the fact that in many cases fewer than 20 consultations had taken place
- The level of correct responses to the scenarios was short of the 80% KPI target, but not at a statistically significant level, and the target was kept, given that this pilot took place only four months after the product launch.

The full report from the pilot is available in Appendix 1.2 of this document.

The PASS Protocol was amended and re-submitted to the MHRA. It was approved by the MHRA on 12th January 2022.

- A two-step process for answering each scenario was agreed – supply/do not supply, and then reasons for supply
- A balance of two 'supply' reasons and two 'do not supply' reasons was made for each scenario

The final questionnaire is available in Annex 3, Appendix 1.1 of this document.

Participation in this study was voluntary. The questionnaire collected data on pharmacist characteristics (i.e., job title, outlet type, region) and their responses to the scenario-based risk knowledge questions. The data collected from the survey was used to evaluate the effectiveness of the aRMMs. Any personal, identifying information used for processing compensation had previously been provided to CIG Research by pharmacy panellists for this purpose and was not collected within this survey.

The collection of any personal, identifying information (e.g., first name, last name, address) from respondents was only used for processing of compensation, as allowed by local laws and country regulations, and such information was stored in a separate database.

9.6. Bias

A number of controls were in place to ensure that the survey was conducted in a professional manner and to minimise bias, including the following:

The questionnaire was designed such that all biases in question wording, scale responses and order effect were mitigated. This included the use of:

- Balanced scales
- Randomisation of response options
- Non-leading question phraseology
- Survey flow, routing and question logic designed to maximise the respondents' efficient and considered responses.

The internet survey was programmed to ensure that questions were asked in the appropriate sequence, and all questions were presented in a standard order to reduce exposure bias.

Respondents could not skip ahead or go back to a question once it was answered. All questions presented were required to be answered in order to complete the survey.

Respondents were only allowed to complete the survey once, as controlled by the survey software and panel management system, QuestionPro, to minimise exposure bias and fraud.

9.7. Study size

The sample size chosen for this study was dependent on statistical and feasibility considerations. On the basis of the maximum feasible sample size achievable within the scope of this study, and the relative precision of this dataset, a sample of 200 pharmacists was chosen. For 200 completed surveys, results would be precise to within ±6.9%, based on confidence intervals around a 50% estimate with 95% confidence limits, and ±5.5% at the 80% KPI level. For 1,600 responses (200 sample x 8 case studies per respondent), results would be precise to within ±2.5% at the 50% mark, and ±1.4% at the 80% mark.

Because precision varies based on the proportion who respond correctly, Table 9-2 provides a range of expected precision, based on the normal approximation of the binomial CI, for several proportions as well as sample sizes. The greatest variance and, therefore, the least precision, occurs when the observed proportion of responses is 50%

$P(-1.96 < Z < 1.96) = 0.95$, i.e., there is a 95% probability that a standard normal variable, Z, will fall between -1.96 and 1.96.

The margin of error is 1.96 times the standard error (the standard deviation of the point estimate from the sample), and 1.96 reflects the fact that a 95% confidence level was selected. So, the general form of a confidence interval is:

point estimate + Z SE (point estimate)

where Z is the value from the standard normal distribution for the selected confidence level (e.g., for a 95% confidence level, Z=1.96).

In practice, we often do not know the value of the population standard deviation (σ). However, if the sample size is large (n > 30), then the sample standard deviations can be used to estimate the population standard deviation.

For the 200 completed surveys, results are precise to within ±6.9% at the 50% mark. Note that although the sample size is based on the requirements set in the study, the proportion of correct responses cannot be known ahead of time. Since precision depends on both the sample size and the proportion of correct responses, a range of possible precision is presented for different proportions at relevant sample sizes below. For analyses by segment, where around 100 pharmacists are included, the precision of results lies within ±10% at worst. In the full tables appended, margins of error are quoted for individual percentages within the total sample and for individual sub-sample sizes, but not for individual percentages within segments, where samples are too small to compare statistically.

The precision of the estimate calculations is based on the following assumptions:

- The confidence intervals (CIs), also referred to as margins of error, around the estimate are two-sided
- The probability of type-I error (alpha) is 5%
- The table below provides precision of the estimate (with 95% CI around the estimate) for a range of sample sizes and percentages.

Table 9-2: Estimated precision by sample size

Sample size	Proportion of correct responses observed (%)	Statistical precision/margin of error (+/-%)
40	20	12.4
40	50	15.5
40	70	14.2
80	20	8.8
80	50	11.0
80	70	10.0
100	20	7.8
100	50	9.8
100	70	9.0
200	10	4.2
200	20	5.5
200	50	6.9
200	80	5.5
1,600 (total case studies)	80	± 1.4

*95% confidence interval, 2-sided.

9.8. Data transformation

All data collected during the study is held confidentially by CIG Research using an electronic data collection system called QuestionPro. This system encrypts all identifiable information, and respondent identifiers are stored separately from survey responses.

To minimise data entry errors and skip logic for certain questions as well as the ability to mark only one response or multiple responses as appropriate forms part of the survey programming. There were no follow-up queries to respondents for this project.

9.9. Statistical methods

9.9.1. Main summary measures

Statistical analyses were descriptive – i.e., no formal hypothesis was tested. Counts and percentages of the correct responses were calculated for each question/item in the questionnaire. All CIs around the percentages are exact two-sided 95% CIs calculated according to the method of Clopper-Pearson (Clopper and Pearson, 1934[1]). The survey contained skip patterns – i.e., some questions were skipped depending on the answer to a previous question. Percentages were based on the population to whom a specific question was presented.

The analysis populations included:

All Respondents – The All Respondents population consisted of respondents who had accessed the survey and started it. These respondents were used as the denominator for percentages in survey administration statistics, unless otherwise specified, and in the survey eligibility results analysis.

Completed Surveys (Primary Population) – The population for all remaining analyses included only those with completed surveys. "Completed" was defined as an eligible respondent who had no missing data, with the exception of data from skip patterns. An eligible respondent was defined as one who completed all eligibility questions and met all inclusion criteria and none of the exclusion criteria.

9.9.2. Main statistical methods

Analysis of the primary objectives:

All responses to questions around the primary objectives were summarised by counts and percentages. Exact binomial two-sided 95% CIs (margins of error) were calculated for the proportion of respondents who gave the correct or desired responses. The primary objectives of the study are listed in Section 7.

The relevant questions to define success of understanding important safety information were combined into eight scenarios (Table 9-3). To be counted as demonstrating understanding of a specific scenario, pharmacists were required to answer two questions correctly – the supply/do not supply question followed by the correct reason for their choice out of four options. The number and percentages, including exact binomial two-sided 95% CIs, of respondents demonstrating understanding were calculated for each individual scenario and for all eight scenarios in aggregate.

The aRMMs were considered effective if at least 80% of respondents demonstrated understanding of each scenario by answering it correctly and if 80% of the total number of responses to the

scenarios (i.e., 1,280 out of a possible 1,600) were correct. These KPIs were subject to margin of error validation.

Table 9-3: aRMMs Informing Understanding of Important Safety Messages

Number	Answer	Risk/contraindication
Scenario 1	a. Incorrect	Contraindicated if there is unexplained vaginal bleeding and a recent history of liver disease
	b. Incorrect	Contraindicated if there is unexplained vaginal bleeding and a recent history of liver disease
	c. Incorrect	Contraindicated if there is unexplained vaginal bleeding and a recent history of liver disease
	d. Correct	Correct understanding of recent history of liver disease and unexplained vaginal bleeding
Scenario 2	a. Correct	Correct understanding of using desogestrel in depression and taking an Selective Serotonin Reuptake Inhibitor (SSRI)
	b. Incorrect	A maximum of 3 months treatment should be supplied for an initial supply
	c. Incorrect	Not contraindicated when taking an SSRI
	d. Incorrect	Depression is not a contraindication
Scenario 3	a. Incorrect	Contraindicated if taking a hepatic enzyme-inducing drug
	b. Incorrect	Contraindicated if taking a hepatic enzyme-inducing drug
	c. Incorrect	Contraindicated if taking a hepatic enzyme-inducing drug
	d. Correct	Correct understanding of the effect of hepatic enzyme-inducing drugs on desogestrel
Scenario 4	a. Incorrect	Additional contraceptive measures should be used for the first 7 days
	b. Correct	Correct understanding of the use of desogestrel in hypertension, while breastfeeding and starting to use desogestrel after giving birth
	c. Incorrect	Hypertension is not a contraindication
	d. Incorrect	Breastfeeding is not a contraindication
Scenario 5	a. Incorrect	Diabetes is a contraindication History of thrombosis is not a contraindication Acute VTE is a contraindication
	b. Incorrect	Diabetes is a contraindication
	c. Incorrect	Diabetes is a contraindication History of thrombosis is not a contraindication
	d. Correct	Correct understanding of using desogestrel in diabetes and a history of thrombosis
Scenario 6	a. Correct	Correct understanding of periods, side-effects, pregnancy and maximum quantity that can be supplied for < 18 years old
	b. Incorrect	A maximum of 3 months treatment can be supplied to a female under the age of 18
	c. Incorrect	Not contraindicated unless bleeding is after sex or becomes bothersome
	d. Incorrect	Not contraindicated if pregnancy can be excluded
Scenario 7	a. Incorrect	A history of sex steroid-sensitive malignancies is a contraindication
	b. Incorrect	A history of sex steroid-sensitive malignancies is a contraindication
	c. Correct	Correct understanding of using desogestrel in breast cancer (sex steroid-sensitive malignancies) and migraine
	d. Incorrect	A history of sex steroid-sensitive malignancies is a contraindication Migraine is not a contraindication

Scenario 8	a. Incorrect	Desogestrel should not be started immediately after taking ulipristal acetate
	b. Correct	Correct understanding of emergency contraception and excluding pregnancy
	c. Incorrect	Not contraindicated if pregnancy can be excluded
	d. Incorrect	Smoking is not a contraindication

Analysis of additional survey questions:

Additional questions in the survey included questions to determine respondent eligibility, prescribing status, demographic information, and clinical experience. The number and percentage of respondents were summarised by their responses to each question.

Subgroup analysis:
The following subgroup analyses were performed for each of the questions related to the primary objectives of the study for all completed surveys, as applicable:

Outlet type
- Independents (pharmacists working in small chains of 1-49 outlets)
- Multiples (pharmacists working in chains of 50+ outlets)

Location
- Urban (pharmacists working in city or town centre pharmacies)
- Suburban/Rural (pharmacists in suburbs, villages or rural locations)

Age
- Pharmacists aged under 40 years
- Pharmacists aged 40 plus

Gender (excluding those choosing 'other' or 'prefer not to say')
- Male pharmacists
- Female pharmacists

Job title
- Pharmacists (those with title Proprietor, Manager or pharmacist)
- Locums (those with title Locum Pharmacist)

Consultation status
- High consultations (≥10 patients in last 6 months)
- Medium consultations (3-9 patients in the last 6 months)
- Low consultations (1-2 patients in the last 6 months)

Note that the cut-off between low, medium and high consultations was not determined a priori and was instead based on the distribution of consultation frequency in the completed surveys. The goal was to have similar sample sizes in all subgroups.

9.9.3. Missing values

In order to minimise bias, the survey was programmed to ensure respondents could not skip ahead and only allowed for missing data caused by skip patterns. In instances where there was missing data not due to skip patterns (i.e., the respondent did not complete the survey), the respondent was not considered in the analysis.

9.9.4. Sensitivity analyses

All percentages based on the total sample and the totals for segments were sensitivity tested to establish margins of error at each percentage level. These are presented in the tables, as exact binomial two-sided 95% CIs.

9.9.5. Amendments to the Survey Analysis Plan

There were no unforeseen analyses or deviations from the Survey Analysis Plan (SAP). No analysis was completed until survey collection had ended.

9.10. Quality control

The study was conducted in accordance with all applicable regulatory requirements. The testing was also conducted in accordance with all applicable subject privacy requirements (including European General Data Protection Regulation - GDPR), and the guiding principles of the current version of the Declaration of Helsinki.

Documentation of all data management activities allowed step-by-step retrospective assessment of data quality and performance. Management of data was performed in accordance with applicable standards (including MHRA *'Good Practice - GXP' Data Integrity Guidance and Definitions*[2]) and data cleaning procedures to ensure the integrity of the data (e.g., removing errors and inconsistencies in the data).

The survey data was collected using a secure online data entry system. The proposed system was validated as secure for receiving and storing survey data. A cloud-based data repository was used to warehouse survey data and other relevant programme information. This platform ensured compliance with Annex 11 *EudraLex The Rules Governing Medicinal Products in the European Union*[3] for the entry, storage, manipulation, analysis and transmission of electronic information.

The system was integrated with dashboard reporting services to enable real time access to data collected online. All data entered was single data entered by the respondent. Data was checked in real time against the programmed edit specifications as they were entered to ensure that data was being entered according to acceptable parameters and requirements. Data exported into Excel for the purposes of generating presentation charts for reporting was aggregated and not manipulated in any way that altered the results of the survey, and matched the data held within the secure online data entry system. All versions generated were dated, kept with accompanying documentation and archived. This archived data is available for independent audit.

10. Results

10.1. Participants

Survey administration statistics for pharmacists invited to participate in the survey are presented in Table 10-1.

Table 10-1: Survey administration statistics

	Number	%
Universe (CIG Research pharmacy staff database)	35,175	100.0
Viewed the invitation during the fieldwork period	8,343	23.7
Eligible to take part based on demography	518	1.5
Those who had held at least one consultation regarding the supply of desogestrel 75 microgram film-coated tablets (DSG) in the last 6 months	280	0.8
Those who had received and read training materials or consultation checklists regarding the supply of desogestrel 75 microgram film-coated tablets (DSG) without a prescription to help minimise risk when having consultations	247	0.70
Completed the survey (and passed all quality control checks)	200	0.6

In order to achieve 200 responses, 35,175 pharmacy staff were invited to take part and received three reminder invitations over the course of two weeks (see Appendix 1.3 table 1.1.1). Fieldwork was completed between January 20th and February 2nd 2022, during which 8,343 opened the invitation and 922 began the survey, 852 agreed to take part and 16 immediately dropped out, stating that they did not want to proceed.

819 (88.9% of those starting the survey) agreed to report any AEs (although in the event, none were reported), and 86.8% had not in the last year worked with any of the five organisations chosen for elimination. 61.4% were eligible on job title, while the remainder were eliminated as non-pharmacist staff. 55.6% were eligible on the basis of their outlet type (excluded were those working in hospitals and non-community pharmacies or online only).

280 (57.8%) of those 518 pharmacists eligible on demographic grounds had held at least one consultation regarding the supply of desogestrel 75 microgram film-coated tablets (DSG) in the last six months. This was far lower a number than had been predicted at the time of submission of the Protocol (80%).

247 (88.1%) of those eligible as having conducted consultations had received and read training materials or consultation checklists regarding the supply of desogestrel 75 microgram film-coated tablets (DSG) without a prescription to help minimise risk when having consultations. A further 5.6% had received the materials but had not read them; 6.3% had neither received nor read the materials.

37 respondents, having qualified for the survey on all quotas, dropped out before completing the questionnaire. Given that the requirement was for the survey to be completed within one hour, and that many community pharmacists complete surveys while at work in busy pharmacies, this was not unexpected.

Finally, of the 210 who completed the survey, 10 responses didn't pass quality control requirements for three reasons:

- 5 had completed the study from outside the UK. This could have involved UK respondents on short-term travel, but could also have involved non-UK panel members
- 1 did not answer the open ended questions in full
- 4 had responded by repetitively answering the same answer across many questions (and consequently finishing in a very short time).

10.1.1. Length of survey

The invitation to the survey indicated that respondents should take their time to respond, and that the survey would take in the region of 15 minutes. This was based on the average length of response during the Pilot study of 30 pharmacists. The average length of time taken among the 200 respondents completing this survey was 19.0 minutes, with the range from 308 seconds to 3479 seconds.

Time taken (seconds)	Number	%
308-540 (5-9 mins)	32	16.0
541-720 (9-12 mins)	30	15.0
721-900 (12-15 mins)	36	18.0
901-1080 (15-18 mins)	25	12.5
1081-1800 (18-30 mins)	26	13.0
1801 plus (30 mins plus)	26	13.0

It is important to note that analysis of the key questions, and specifically the answers given to the eight scenarios, established that length of survey completion showed no correlation with correct answers. There was no evidence that taking longer to complete the survey led to a greater number of correct answers. On that basis, segmentation by length of completion has been excluded from the analysis.

10.2. Descriptive data

Among the 922 who started the survey, 59.3% were pharmacists and 15.8% locums – the remainder were ineligible on the basis of job title, or were excluded because they did not want to report AEs or had worked for one of the six organisations chosen for exclusion.

Among those completing the survey, pharmacists constituted 80.5% and locums 19.5%. Of the 561 who answered the type of outlet question, 55.1% were working in independent outlets (small chains of up to 49 outlets) and the rest were working in multiples. When the completed surveys were analysed, the ratio was 48.5% independents to 51.5% multiples.

Quotas were set within the target sample based on CIG Research panel composition, since national statistics across all pharmacists are not available, and are skewed by the size of the outlet. The following quotas taken from the panel of 35,175 pharmacy staff were closely matched by the achieved sample, with the exception of the number of proprietor pharmacists – this cohort was slightly under-represented.

Table 10-2: Sample quotas set and quotas achieved

	Quotas set proportion (+/-5%)	Quotas achieved
Single outlet independent	15%	12%

Group branch independents 2-49 outlets	35%	38%
Multiples (50 plus outlets)	50%	51%
Pharmacist Proprietor	10%	5%
Pharmacist Manager / Supervisor	30%	33%
Pharmacist	40%	44%
Locum Pharmacist	20%	18%
Urban	50%	56%
Suburban	35%	31%
Rural	15%	13%
London and South East/South West	45%	43%
Midlands and East of England	20%	23%
North East/North West	25%	22%
Scotland Wales, N Ireland	10%	12%

Within the multiples, a large range of outlet brands were included. 33.0% of the 103 working in multiples worked in Boots, and 17.5% in LloydsPharmacy – as many as worked in supermarket pharmacies. The 'Other multiples' included:

- Lincolnshire Co-op
- Cohens
- Tesco
- Asda
- Avicenna Group
- Knights
- Paydens
- Peak pharmacy

Table 10-3: Description of pharmacists: job title, outlet type, multiple

Total number of respondents	N=922 Started	%	N=200 Completed	%
What is your job title?				
Pharmacist Proprietor	28	3.7	10	5.0
Pharmacist Manager / Supervisor	158	21.1	63	31.5
Pharmacist	258	34.5	88	44.0
Locum Pharmacist	118	15.8	39	19.5
Other (discontinued)	186	24.9		
What type of outlet do you work in?				
One shop independent	85	15.2	23	11.5
Group branch shop (2 to 5 outlets)	93	16.6	41	20.5
Group branch shop (6 to 9 outlets)	28	5.0	9	4.5
Group branch shop (10 to 49 outlets)	48	8.6	24	12.0
Group branch shop (50 plus outlets)	228	40.6	98	49.0
Multiple head office	24	4.3	5	2.5
Other (discontinued)	55	9.8		
Which multiple do you work in?				
			N=103	%
Boots			34	33.0%
LloydsPharmacy			18	17.5%

Superdrug	5	4.9%
Rowlands Pharmacy	2	1.9%
Well Pharmacy	11	10.7%
Day Lewis	1	1.0%
Supermarket Pharmacy	18	17.5%
Other	14	13.6%

While 52.4% of respondents completing the survey worked in community pharmacies based in city or town centres, 33.0% worked in suburban outlets, and the remainder in villages or rural settings. For analysis purposes, suburban pharmacists were grouped with those working in village and rural settings. The sample was spread across the UK in line with the market, with Greater London (21.0%), the South East (14.0%) and South West (8.0%) constituting the largest share of the market and consumer population.

Table 10-4: Description of pharmacists: location

Question	N=200	%
Where is your pharmacy?		
Scotland	9	4.5
Northern Ireland	5	2.5
Wales	11	5.5
North East	13	6.5
North West	16	8.0
Yorkshire and the Humber	11	5.5
West Midlands	24	12.0
East Midlands	19	9.5
South East	28	14.0
South West	16	8.0
East of England	6	3.0
Greater London	42	21.0

Among the 200 pharmacists, 53.1% were men, 44.1% women and the remainder preferred not to answer, or classified themselves as 'other'. There were more women pharmacists working in multiples (58.3%) than in independents (30.9%).

The average age of the pharmacists was 40.6 years, with the women (39.4 years) slightly younger than the men (43.9 years). The average number of years that the 200 pharmacists had been qualified for was 15.9. Men tended to have been qualified for longer (17.4 years) than women (14.1 years), in line with their relative ages. The age profile of those conducting consultations on desogestrel, having received and read the aRMMs (approximately one third of all pharmacists in the UK) is no different from average ages typically achieved on samples drawn by CIG Research on all pharmacist surveys conducted without these quota controls.

10-5: Description of pharmacists: age

Question	N=200	%
What is your age?		
Under 25	9	4.5
25-29	5	2.5
30-34	11	5.5
35-39	13	6.5

40-44	16	8.0
45-49	11	5.5
50-54	24	12.0
55-59	19	9.5
60-64	28	14.0
65 plus	16	8.0
Mean age		40.6
For how many years have you been qualified as a pharmacist?		
Mean number of years	200	15.88

Among pharmacists eligible to participate in this research on demographic grounds, 57.8% had conducted consultations on desogestrel (DSG), and of these, 88.1% had received and read the training materials or checklists. The penetration of pharmacists conducting consultations in independent community pharmacies and multiple outlets did not differ significantly, and the proportion of those conducting consultations in these two cohorts who had also received and read the aRMMs did not differ significantly.

10-6: Responses to questions about desogestrel consultations and materials – completed surveys

Base (those eligible on demographic grounds	Total sample 467	%	Independents N=254	Multiples N=252
In the last six months, have you held any consultations regarding the supply of desogestrel 75 microgram film-coated tablets (DSG) in the pharmacy without a prescription?				
Yes	270	57.8%	55.3%	60.4%
No (discontinued)	197	42.1%	44.7%	39.6%
In the last six months, have you received and read training materials or consultation checklists regarding the supply of desogestrel 75 microgram film-coated tablets (DSG) without a prescription to help minimise risk when having consultations?				
Yes, received and read	237	88.1%	90.1%	86.2%
Yes, received but not read (discontinued)	15	5.6%	4.6%	6.5%
No (discontinued)	17	6.3%	5.3%	7.3%

10.3. Main results

10.3.1. Reading and utilising of each of the aRMMs

The materials most likely to have been read to help minimise risk when having consultations regarding the supply of desogestrel 75 microgram film-coated tablets (DSG) without a prescription were the Pharmacy Training Guide (statistically more likely to have been supplied by Hana than by Lovima) and the Consultation/Supply Aid Checklist (more likely to have been supplied by Hana than Lovima). These were followed by the Summary of Product Characteristics (SmPC) and the pack copy, both of which were read by around six in 10 (Hana) and four in 10 (Lovima) pharmacists. Around one in 10 pharmacists had read each of these materials, but could not recall the brand associated with them.

Table 10-7: Responses to questions about materials used to help minimise risk – completed surveys

Question	N=200	%	Precision or Margin of Error (±%)
Which, if any, of these materials have you read to help minimise risk when having consultations regarding the supply of desogestrel 75 microgram film-coated tablets (DSG) without a prescription?			
Pharmacy training guide			
Hana	170	85.0	5.0
Lovima	120	60.0	6.8
Brand unknown	18	9.0	4.0
Consultation/ supply aid checklist			
Hana	164	82.0	5.3
Lovima	111	55.5	6.9
Brand unknown	20	10.0	4.2
SmPC			
Hana	126	63.0	6.7
Lovima	81	40.5	6.8
Brand unknown	23	11.5	4.4
Pack copy			
Hana	120	60.0	6.8
Lovima	81	40.5	6.8
Brand unknown	14	7.0	3.5
Other			
Hana	29	14.5	4.9
Lovima	17	8.5	3.9
Brand unknown	16	8.0	3.8

While in most cases there was no difference between the materials which were read in independents or in multiples, it was clear that the Lovima branded Consultation/supply aid checklist was more likely to be read in independents than in multiples and the Hana SmPC more likely to be read in multiples than in independents (Table 10-7).

The utilising of these materials during consultations was reported by pharmacists in a second question and varied between the two brands also. As with the previous table, it is clear that Hana branded materials were more likely than Lovima branded materials to have been used in conjunction with consultations, and while more pharmacists had read the Pharmacy Training Guide than the supply aid checklist, it was the checklist which was most likely to be used in conjunction with consultations (Table 10-8).

While Hana branded materials were equally likely to be used in conjunction with consultations by men and women pharmacists, Lovima materials were more likely to be used by men than by women – in the case of the SmPC, more than twice as likely. Hana branded materials were equally likely to be used in conjunction with consultations by younger and by older pharmacists, while the Lovima branded Pharmacy Training Guide and supply aid checklist were more likely to be used by older than younger pharmacists (Appendix 1.3 Table 4.1).

Table 10-8: Responses to questions about materials used in conjunction with consultations – completed surveys

Question	Base (read materials)	N	%	Precision or Margin of Error (±%)
Which, if any, of these materials have you used in conjunction with consultations regarding the supply of desogestrel 75 microgram film-coated tablets (DSG) without a prescription?				
Pharmacy training guide				
Hana	198	130	65.7	6.6
Lovima	198	80	40.4	6.8
Brand unknown	198	18	9.1	4.0
Consultation/ supply aid checklist				
Hana	195	148	75.9	6.0
Lovima	195	86	44.1	7.0
Brand unknown	195	19	9.7	4.2
SmPC				
Hana	155	80	51.6	7.9
Lovima	155	54	34.8	7.5
Brand unknown	155	22	14.2	5.5
Pack copy				
Hana	142	81	56.3	8.2
Lovima	142	53	36.8	7.9
Brand unknown	142	17	11.8	5.3
Other				
Hana	47	26	55.3	14.2
Lovima	47	15	31.9	13.3
Brand unknown	47	11	23.4	12.1
After using the materials for consultations regarding the supply of desogestrel 75 microgram film-coated tablets (DSG) without a prescription, how useful did you find them?				
Extremely useful	200	81	40.5	6.8
Very useful	200	93	46.5	6.9
Somewhat useful	200	23	11.5	4.4
Not useful	200	0	0.0	0.0
No opinion	200	3	1.5	1.7
Mean score (+5 to +1)	200		4.2	Std.dev. 0.77

In terms of the usefulness of the materials used in consultations, 87% rated them as extremely or very useful. This level of positivity was seen equally among male and female pharmacists, and was higher among the older pharmacists (92%) than the younger pharmacists (84%). The mean age of pharmacists in independents (40.8 years) did not differ significantly from that of those working in multiples (40.3). (Full results are in Table 2, appendix 1.3). The mean usefulness rating among those based in independents (4.3) also did not differ from the rating among those based in multiples (4.2)

A question was posed for those who reported that the materials were not useful to them. In the event, nobody reported this, so there were no responses to this question.

10.3.2. Numbers of consultations held

This survey was conducted six months after the launch of the two brands, so it was reasonable to consider whether pharmacists had had much experience in the consultation process. Given that the sample consisted of those who had conducted consultations and had read the aRMMS, it was also relevant to examine the effect of more consulting experience on the correct decisions being made regarding supply. Across the total sample, the average number of consultations conducted was 15.27 – equivalent to approximately one every two weeks, although this mean hides a wide range of responses from 1 to 200-plus.

Table 10-9: Number of consultations pharmacists had with patients – completed surveys

Question	N=200	%	Precision or Margin of Error (±%)
How many consultations do you estimate that you have had with patients about non-prescription desogestrel 75 microgram film-coated tablets in the pharmacy in the last six months?			
Mean number of consultations	15.27	Range 1-200	Std dev. 14.31

Of the 200 respondents who had conducted consultations and read the appropriate materials, 21.5% had conducted only one consultation in six months, and 67.5% had conducted fewer than 10. Only 3.5% had conducted more than 100.

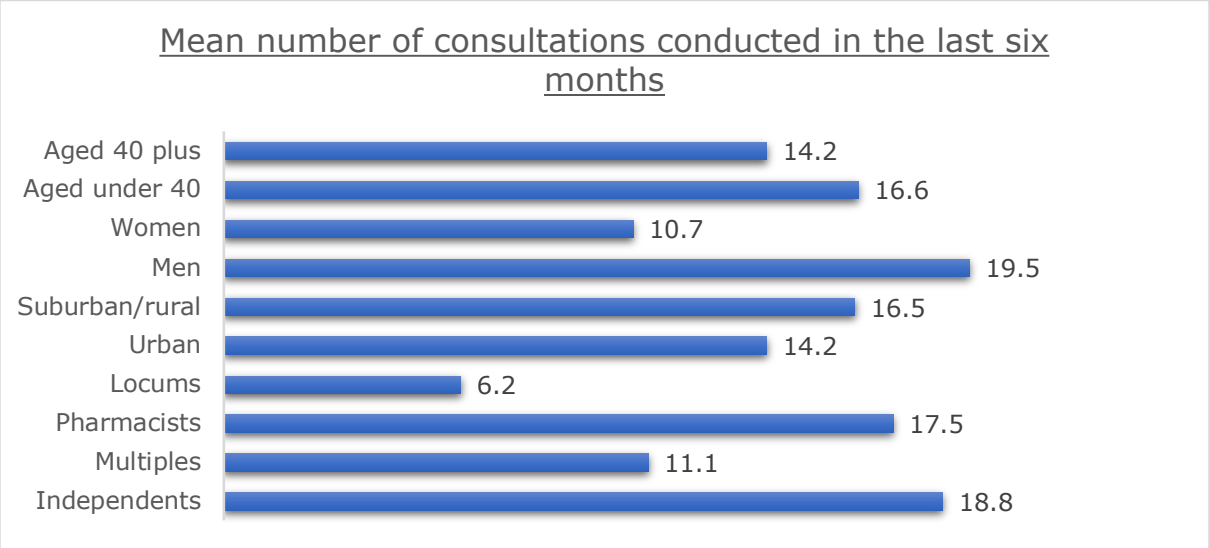
The sample was split into three approximately equal sized groups for analysis of their understanding of the scenarios, and their levels of confidence in advising and supplying desogestrel (Table 10-10).

Table 10-10: Distribution of number of consultations held – completed surveys

Number of consultations held in the last six months	N=200	(%)
1	43	21.5
2	18	9.0
3-4	36	18.0
5-9	38	19.0
10-19	26	13.0
20-30	19	9.5
31-60	6	3.0
61-100	7	3.5
101-200	7	3.5

The number of consultations conducted varied by segment, with male pharmacists conducting the most (19.5 in six months), followed by those in independent outlets (18.8) and those with the job title Pharmacist (17.5), while locum pharmacists (6.2) and women pharmacists (10.7) averaged the fewest.

Illustration 1



10.3.3. Use of consulting facilities and ease of access to aRMMs in pharmacy during consultation

Pharmacists conducting consultations reported that 84.4% of their consultations took place in a private consultation area in the pharmacy, and 14.5% at the pharmacy counter. This ratio did not vary significantly between independent and multiple outlets.

The materials for both brands were rated as easily accessible to pharmacists when giving consultations, and for all four of the materials included (the Pharmacy Training Guide, Consultation/supply aid checklist, SmPC and Pack Copy).

Table 10-11: Responses to questions about consultations in the pharmacy – completed surveys

Question	N=200 (figures are % of consultations)	%	Precision or Margin of Error (±%)	Independents N=97 (%)	Multiples N=103 (%)
Where in the pharmacy are these consultations conducted? (percentage of consultations total = 100%)					
In a private consultation area	84.36	84.4	5.0	86.7%	82.2%
At the pharmacy counter	14.21	14.2	4.9	12.1%	16.2%
Elsewhere	1.425	1.4	1.6	1.3%	1.6%
Were the materials easily accessible to you when giving consultations? Yes.					
Pharmacy training guide					
Hana	153	85.3	4.9	68 (79.1%)	89 (90.8%)
Lovima	123	66.8	6.5	62 (70.5%)	61 (63.5%)
Consultation/ supply aid checklist					

Hana	152	86.4	4.8	73 (83.0%)	79 (89.8%)
Lovima	117	65.0	6.6	59 (67.0%)	58 (63.0%)
SmPC					
Hana	136	80.0	5.5	62 (72.9%	74 (87.1%)
Lovima	109	62.3	6.7	51 (62.2%)	58 (62.4%)
Pack copy					
Hana	140	79.1	5.6	66 (77.6%)	74 (80.4%)
Lovima	99	56.6	6.9	51 (60.0%)	48 (53.3%)
Other					
Other	50	27.9	6.2	19 (21.3%)	31 (34.4%

10.3.4. Scenarios relating to understanding of aRMMs

10.3.4.1. Decision to supply or not supply (Table 10-12)

For each scenario, two questions were asked:

1. Whether to supply or not supply desogestrel
2. Which reason was the most suitable reason for supplying or not supplying (from a multiple choice of four).

KPI-aligned results

On average, taking all 1,600 responses across the eight scenarios into account, the average correct response level was 82.6% (+/- 1.8%). This exceeded the KPI of 80% set for the primary objective:

> *Demonstrate that the aRMMs provided by each company is effective in enabling pharmacists to make appropriate decisions to supply desogestrel 75 microgram film-coated tablets (DSG) based on contraindications and special warnings; this includes awareness and mitigation of safety concerns.*

Across the total sample, in seven of the eight scenarios, the option to supply or not supply desogestrel reached the threshold of 80% set as a KPI.

In the case of scenario 6, 66.0% (+/- 6.6%) of pharmacists took the correct decision regarding supply of P desogestrel. The 34% choosing the 'do not supply' answer, were choosing a conservative option choosing the incorrect answer of 'do not supply' were choosing a conservative option which minimised risk of incorrect supply (see Section 10, Table 10-17 for more detail).

Illustration 2

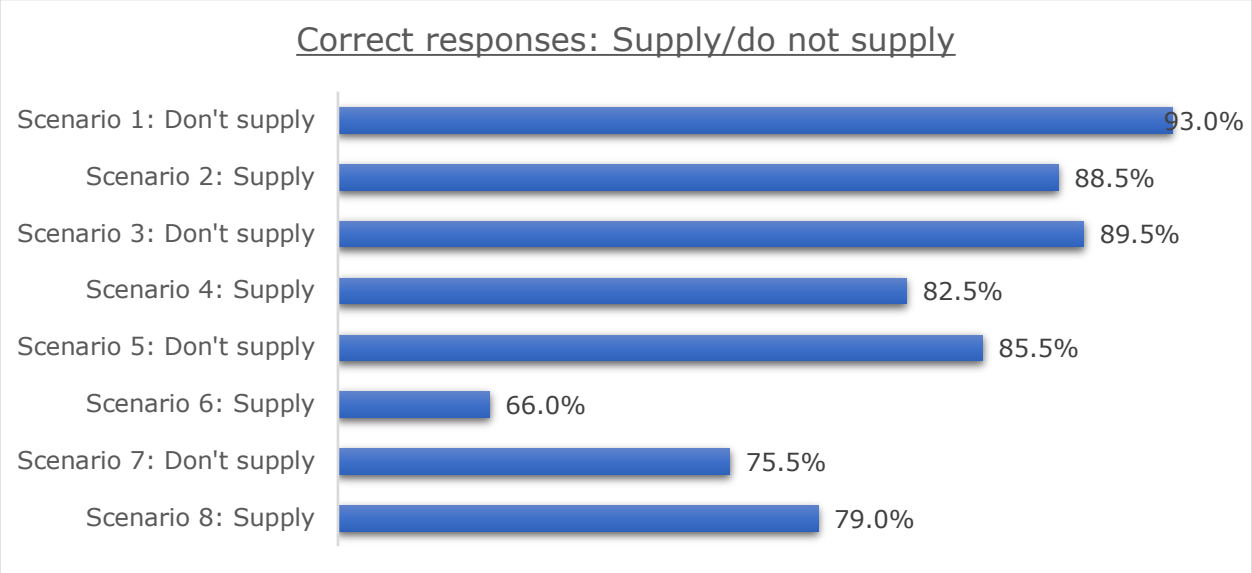


Table 10-12: Responses to scenarios relating to aRMMs – completed surveys

Scenario	Supply/ Don't supply	Correct (%)	Margin of error (+/-%)
1	Don't supply	93.0%	3.5
2	Supply	88.5%	4.3
3	Don't supply	89.5%	4.2
4	Supply	82.5%	5.2
5	Don't supply	85.5%	4.8
6	Supply	66.0%	6.6
7	Don't supply	75.5%	5.9
8	Supply	79.0%	5.6
	MEAN	82.6% (N=1600)	1.8

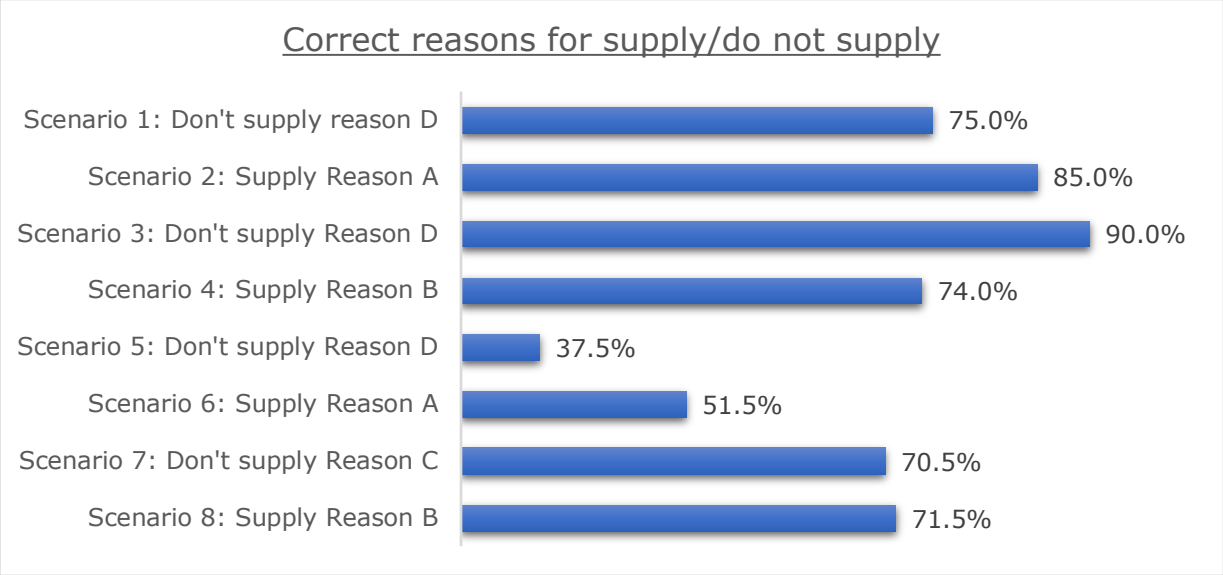
10.3.4.2. Reasons for decision (Table 10-13)

Respondents were presented with four possible reasons for supply/do not supply (two for each) and were required to choose the one they felt best described the reason. In scenarios 1-4, the proportions giving the right reason for supply or not supply of desogestrel (DSG) met the KPI of 80%, subject in each case to margins of error. In scenarios 5-8, the threshold was not met, although both scenarios 7 and 8 fell only slightly short of the threshold (70.5% +/- 6.3% and 71.5% +/- 6.2% respectively).

The two scenarios which fell far short of the KPI were scenario 5 (37.5% correct +/- 6.7%) and scenario 6 (51.5% correct +/- 6.9%). In the case of scenario 5, 85.5% of all pharmacists had chosen the correct 'do not supply' answer, but the majority of these people (56%) chose the wrong reason (reason C rather than reason D). Those not clear about which was the correct reason for not supplying were taking the correct decision of non-supply, mitigating incorrect supply risk.

In scenario 6, the correct response was to supply (chosen by 66.0% +/- 6.6%), and only 51.5% +/- 6.9% gave the right reason. 33.5% of pharmacists chose – incorrectly – the "do not supply " response on this scenario. As this scenario was complex it was probably not clearly understood. Importantly, when pharmacists were unsure of the correct response, they chose the "do not supply" option, ie the conservative choice. This was because it was important for them to ensure that a consumer was not inappropriately exposed to the product. This behaviour may be viewed as being correct.

Ilustration 3



Regarding secondary consideration of the reason to supply or not supply P desogestrel (DSG), it fell short of the high KPI objective that 80% of pharmacists would select a correct reason for their decision in each of the eight scenarios provided. This was primarily due to the complexity of the multi-parameter scenarios, and particularly two of the scenarios where the correct answer was selected by 51.5% in one case and 37.5% in the other.

Table 10-13: Questions relating to the understanding of the aRMMs – completed surveys

Scenario	Correct A-D	A N=200 (%)	B N=200 (%)	C N=200 (%)	D N=200 (%)	% Correct	Margin of error (+/-%)
1	D	3 (1.5%)	9 (4.5%)	38 (19.0%)	150 (75.0%)	75.0%	6.0
2	A	170 (85.0%)	9 (4.5%)	14 (7.0%)	7 (3.5%)	85.0%	4.9
3	D	7 (3.5%)	5 (2.5%)	8 (4.0%)	180 (90.0%)	90.0%	4.2
4	B	20 (10.0%)	148 (74.0%)	9 (4.5%)	23 (11.5%)	74.0%	6.1
5	D	24 (12.0%)	6 (3.0%)	95 (47.5%)	75 (37.5%)	37.5%	6.7
6	A	103 (51.5%)	30 (15.0%)	57 (28.5%)	10 (5.0%)	51.5%	6.9
7	C	26 (13.0%)	25 (12.5%)	141 (70.5%)	8 (4.0%)	70.5%	6.3

8	B	13 (6.5%)	143 (71.5%)	40 (20.0%)	4 (2.0%)	71.5%	6.2
					Mean	69.6%	2.2

The four scenarios not reaching the KPI threshold are examined in more detail in section 10.3.4.4

10.3.4.3. Reasons for decision by segment

While there were some differences between those working in independents and multiples, with those in multiples more likely to choose correct answers, these were not statistically significant. Women were more likely to give correct answers than men. Again, these differences were non-significant, and interestingly, locums were slightly more likely than pharmacists to give correct answers (Table 10-14).

Analysis of time taken to complete the survey showed that there was no difference in accuracy of responses to the questions between the faster and slower respondents. Likewise, analysis of those having conducted more consultations over the last six months compared to those conducting fewer showed no difference currently in the level of accuracy in answering the scenario questions (Table 11.3, appendix 1.3).

Table 10-14: Questions relating to the understanding of the aRMMs – completed surveys by segment: outlet type, gender, role

Scenario	Correct A-D	Independents N=97 % Correct	Multiples N=103 % Correct	Men N=104 % Correct	Women N=90 % Correct	Pharmacists N=161 % Correct	Locums N=39 % Correct
1	D	72.2%	77.7%	69.2%	83.3%	73.9%	79.5%
2	A	82.5%	87.4%	81.7%	88.9%	85.1%	84.6%
3	D	90.7%	89.3%	86.5%	93.3%	88.2%	97.4%
4	B	76.3%	71.8%	71.2%	75.6%	73.3%	76.9%
5	D	34.0%	40.8%	34.6%	40.0%	36.7%	41.0%
6	A	48.5%	54.4%	52.9%	51.1%	55.1%	51.3%
7	C	70.1%	70.9%	66.4%	63.3%	70.2%	71.8%
8	B	70.1%	72.8%	73.1%	68.9%	72.7%	66.7%
	Mean	68.1%	71.4%	67.0%	70.6%	69.40%	71.15%

Those working in a suburban, village or rural setting were more likely than those working in urban pharmacies to give correct answers, especially the correct answer to scenarios 5 and 6. While it might be construed that those working in suburban, village and rural settings were under less pressure and better able to respond to the questions, there is no evidence for this. While the mean for suburban/rural is 72.9% +/- 3.2%, the mean for urban is 66.6% +/- 1.7% (Table 10-15).

Younger pharmacists were slightly more likely to give correct answers than older pharmacists, although this was a not statistically significant difference (Table 10-15).

Table 10-15: Questions relating to the understanding of the aRMMs – completed surveys by segment: urban/suburban, age

Scenario	Correct A-D	Urban N=106 (%)	Suburban/ rural N=94 (%)	Under 40 years old N=90	Aged 40 plus N=100
1	D	78.3%	71.3%	77.8%	72.7%
2	A	82.1%	88.3%	78.9%	90.0%
3	D	86.8%	93.6%	90.0%	90.0%
4	B	72.6%	75.5%	74.4%	73.6%
5	D	32.1%	43.6%	35.6%	39.1%
6	A	47.2%	56.4%	58.9%	45.5%
7	C	65.1%	76.6%	73.3%	68.2%
8	B	68.9%	77.5%	74.4%	69.1%
	Mean	66.6%	72.9%	70.4%	68.5%

An additional table comparing numbers of consultations conducted (Table 11.3) is included in appendix 1.3.

10.3.4.4. Analysis of the four scenarios which did not meet the KPI

Regarding secondary consideration of the reason to supply or not the P desogestrel, it fell short of the high KPI objective that 80% of pharmacists would select a correct reason for their decision in four of the eight scenarios provided. This was primarily due to the complexity of the multi-parameter scenarios, and particularly two of the scenarios where an incorrect reason was selected by 48.4% of respondents in one case and 62.5% in the other. This section examines in more detail the four scenarios where the secondary consideration of choosing reasons for supply/not supply fell short of the KPI of 80%.

Scenario 5 (Table 10-16)
A woman in her 30s asks to have a chat to find out if desogestrel (DSG) would be a suitable contraceptive for her. She has been with her partner for over 10 years and previously had a contraceptive implant, but had it removed a couple of months ago. She and her partner have been using condoms since she had her implant removed. She says her periods are regular and she has no bleeding between her periods or after sex. She has type 2 diabetes, which is well controlled; she is taking metformin. She had a deep vein thrombosis about five years ago, but has not had a recurrence. She has a BMI of >30.

This scenario was designed to check pharmacists' understanding of medical conditions where a supply of desogestrel (DSG) would be inappropriate; more specifically, their understanding of using DSG if a woman is overweight, has diabetes and a history of thrombosis. However it wasn't specified if the woman had previously had desogestrel on prescription.

85% of the pharmacists took the correct decision and did not supply DSG to this hypothetical patient.

However, the correct reason for not supplying (D - Do not supply desogestrel and refer her to her doctor as she has type 2 diabetes) was only chosen by 37.5%. The incorrect reason (C - Do not supply desogestrel and refer her to her doctor as she has a history of thrombosis) was selected by 47.5% of respondents.

The correct reason for not supplying is that the woman has diabetes and she is initiating desogestrel; women with diabetes should be carefully monitored during the first few months of use and it is recommended that women are referred to their doctor or nurse when they are initiating P desogestrel 75 microgram.

While DSG is contraindicated in women with an active or suspected thrombosis, it is not contraindicated in women with a history of thrombosis. It is important to note that when reading a scenario and not actually seeing a patient in the pharmacy, it is often difficult to differentiate the two, so caution is not unreasonable.

As seen in Table 10-16, within the segments, there were few differences in the levels of correct reasons, and in all cases except those working in suburban and rural settings, the incorrect reason (C) was more prevalent than the correct reason (D).

Despite pharmacists' increased confidence in advising and correctly supplying DSG being correlated to more experience of consultations (from 54% feeling completely or very confident about advising patients and 51% feeling completely or very confident about correctly supplying desogrestrel for those having conducted 1 or 2 consultations to 7.8% and 72.3% respectively among those who have conducted ten mor more consultations), the increased number of consultations did not result in a

larger proportion of correct answers to scenario 5. 42.6% of those conducting 1-2 consultations were correct and 36.9% of those who had conducted at least ten consultations were correct (Table 11.3 appendix 1.3).

In this scenario, 85.5% of pharmacists correctly chose the 'do not supply' option and referred the woman back to her doctor, which was the correct response. We do not have information as to why they believed thrombosis should be the major reason in a woman with diabetes who is overweight. We cannot conclude that their reasoning was wrong and indeed it appears medically reasonable, given the risk factors.

Table 10-16: Response to scenario 5 – completed surveys by segment: outlet type, gender, role, urban/suburban, age, number of consultations

D Correct - Do not supply desogestrel and refer her to her doctor as she has type 2 diabetes	Correct answer D %	Precision or Margin of Error (±%)	Incorrect answer C %
Total	37.5	6.7	47.5
Independents	34.0	9.4	48.5
Multiples	40.8	9.5	46.6
Men	34.6	9.1	50.0
Women	40.0	10.1	45.6
Pharmacists	36.7	7.4	47.8
Locums	41.0	15.4	46.2
Urban	32.1	8.9	53.8
Rural	43.6	10.0	40.4
Aged under 40	35.6	9.9	50.0
Aged 40 plus	39.1	9.6	45.5
Conducted 1-2 consultations	42.6	12.4	42.6
Conducted 3-9 consultations	33.8	10.9	51.4
Conducted 10 plus consultations	36.9	11.7	47.8

Scenario 6 (Table 10-17)
A 16 year old woman asks for a further supply of DSG. She has been taking DSG for three months. She says that she has been experiencing some spotting and her periods haven't been as regular as they used to be, but this isn't bothering her. She has been taking DSG as directed every day and hasn't missed a dose. She has no medical conditions and is not taking any other medicines. She asks if she can have more than a three month supply.

This scenario was designed to check pharmacists' understanding that a maximum of three months' supply of DSG should be made to women under 18 years of age. This is to ensure there is a regular opportunity to assess safeguarding, compliance and counselling on sexual health.

In this scenario, 66% of pharmacists made the correct decision to supply DSG and 34% took the more conservative decision and opted for no supply.

Among the 66% taking the correct decision, the majority (78%) did so for the correct reason (A - Supply desogestrel (3 month supply maximum) and advise her to consult her GP if the spotting is after sex or the irregular periods become bothersome) and 22% selected the correct answer to supply, but with incorrect reason (B - Supply desogestrel (12 month supply maximum) and advise her to consult her GP if the spotting is after sex or the irregular periods become bothersome).

The most prevalent answer after A (the correct answer) was C (C - Do not supply desogestrel as she is experiencing spotting and irregular periods). Given that the correct response was to supply DSG, pharmacists unsure of the right answer were more likely to choose a do not supply option in order to minimise risk of incorrect supply.

Of those who said they would not supply desogestrel, the most common reason for not supplying was that the woman was experiencing spotting and was having irregular periods. Menstrual irregularity is the most commonly reported side effect of DSG; while irregular bleeding may be uncomfortable for some women, it does not represent a safety issue. Unless bleeding occurs after sexual intercourse or becomes troublesome, DSG can be supplied.

Pharmacists are not medically trained to differentiate spotting from more significant bleeding and indeed both would be reportable as an AE. To therefore refer back for a medical opinion is not unreasonable.

The level of correct response did not vary by segment, although those who had conducted only one or two consultations in the last six months were less likely than those who had conducted more to get this answer correct, and more likely to be correct for the wrong reason (Table 11.3 Appendix 1.3).

Table 10-17: Response to scenario 6 – completed surveys by segment: outlet type, gender, role, urban/suburban, age, number of consultations

A Correct: Supply desogestrel (3-month supply) and advise her to consult her GP if the spotting is after sex or the irregular periods become bothersome	Correct answer A %	Precision or Margin of Error (±%)	Incorrect answer B %
Total	51.5	6.6	15.0
Independents	48.5	9.9	13.4
Multiples	54.4	9.6	16.5
Men	52.9	9.6	11.5
Women	51.1	10.3	18.9
Pharmacists	55.1	7.7	15.5
Locums	51.3	15.7	12.8
Urban	47.2	9.5	16.0
Rural	56.4	10.4	13.8
Aged under 40	58.9	10.2	14.4
Aged 40 plus	45.5	9.8	15.5
Conducted 1-2 consultations	45.9	12.1	18.0
Conducted 3-9 consultations	54.1	11.4	16.2
Conducted 10 plus consultations	53.9	12.5	10.8

Scenario 7 (Table 10-18)
A woman in her 40s asks if she can buy DSG. She and her husband have been using condoms and spermicide for contraception since she had breast cancer, but he doesn't really like using condoms. She asks if DSG would be suitable for her as she had breast cancer nearly 10 years ago and gets occasional migraines. Apart from this, she has no other medical conditions and isn't taking any prescription medicines. Her periods are regular and she hasn't experienced any bleeding between her periods or after sex.

For scenario 7, 75.5% +/-5.9% correctly chose the do not supply option, fulfilling the KPI.

Regarding the reason for their correct do not supply decision, 70.5% +/- 6.3% of pharmacists (just short of the 80% KPI), correctly chose option C (C - Do not supply desogestrel as she has a history of breast cancer). The proportion choosing the incorrect option D (Do not supply desogestrel as she gets occasional migraines) the right decision to not supply, but for the wrong reason) was just 4.0%.

Within the segments, women were more likely to give the correct answer than were men (based on margins of error). The same is true for Locums compared to pharmacists and Rural pharmacists compared to those in Urban settings. However, it should be borne in mind that these are relatively small numbers on which to draw conclusions. Again, there was no evidence that having more experience of consultations led to more correct answers (Table 11.3, appendix 1.3).

Table 10-18: Response to scenario 7 – completed surveys by segment: outlet type, gender, role, urban/suburban, age, number of consultations

C Correct: Do not supply desogestrel as she has a history of breast cancer	Correct answer C %	Precision or Margin of Error (±%)	Incorrect answer D %
Total	70.5	6.6	4.0
Independents	70.1	9.9	4.1
Multiples	70.9	9.6	3.9
Men	66.4	9.6	4.8
Women	73.3	10.3	3.3
Pharmacists	70.2	7.7	3.1
Locums	71.8	15.7	7.7
Urban	65.1	9.5	4.7
Rural	76.6	10.4	3.1
Aged under 40	73.3	10.2	4.4
Aged 40 plus	68.2	9.8	4.6
Conducted 1-2 consultations	68.9	11.6	0.0
Conducted 3-9 consultations	71.6	10.3	8.1
Conducted 10 plus consultations	70.8	11.1	3.1

Scenario 8 (Table 10-19)
A woman in her 30s asks to speak to you in private. She explains that she had unprotected sex a couple of days ago and would like to buy emergency contraception. She has taken ulipristal acetate in the past and would like to take the same tablet again as she didn't experience any side-effects. You determine that she is suitable for ulipristal acetate and provide her with a pack. She says that she has just started a new relationship and would also like to start taking regular contraception. You discuss contraceptive options with her, including long-acting reversible contraceptives (LARCs), and explain that only barrier methods such as condoms will protect her from Sexually Transmitted Diseases (STIs). She decides she would like to start taking DSG. She isn't taking any other medication, has no medical conditions and her periods are regular. She mentions that she smokes.

79.0% +/- 5.6% of pharmacists correctly chose the supply option for this scenario, meeting the KPI.

Regarding the reason for their correct supply decision, 71.5% +/-6.2% of pharmacists chose option B correctly (B - supply desogestrel and advise her to start taking it on day one of her next menstrual period and to use additional contraceptive measures (abstinence or barrier methods) until then) and a further 6.5% chose option A (supply desogestrel and advise her to start taking it straight away). This option was a correct decision to supply DSG, but with an incorrect reason. Therefore, scenario 8 fell just short of the 80% KPI target.

If a woman wishes to start DSG after using emergency contraception, it is advisable to start taking it on day one of her natural cycle. While pharmacists can judge it necessary to start sooner (referred to as quick starting), she should wait five days (120 hours) after taking ulipristal acetate before starting DSG as concomitant use of ulipristal acetate and DSG may result in reduced efficacy of both ulipristal acetate and DSG and is therefore not recommended.

The majority of segments provided answers correctly within the margins of error set. Women pharmacists, those in urban pharmacies and those aged 40 plus performed slightly worse (Table 11.1 appendix 1.3).

There was no evidence that those with more experience of consultations were more likely to be correct on this scenario (Table 11.3 appendix 1.3).

Table 10-19: Response to scenario 8 – completed surveys by segment: outlet type, gender, role, urban/suburban, age, number of consultations

B Correct: Supply desogestrel and advise her to start taking it on day 1 of her next menstrual period and to use additional contraceptive measures (abstinence or barrier methods) until then	Correct answer B %	Precision or Margin of Error (±%)	Incorrect answer A %
Total	71.5	6.6	6.5
Independents	70.1	9.9	8.3
Multiples	72.8	9.6	4.9
Men	73.1	9.6	6.7
Women	68.9	10.3	5.6
Pharmacists	72.7	7.7	3.7
Locums	66.7	15.7	18.0
Urban	68.9	9.5	8.5
Rural	77.5	10.4	4.3
Aged under 40	74.4	10.2	6.7
Aged 40 plus	69.1	9.8	6.4
Conducted 1-2 consultations	72.1	11.3	9.8
Conducted 3-9 consultations	75.7	9.8	5.4
Conducted 10 plus consultations	66.2	11.5	4.6

10.3.5. Confidence and self-rated knowledge

As shown in Table 10-20, 60.5% of all respondents reported feeling completely or very confident about advising patients on the use of desogestrel 75 microgram film-coated tablets. This rose to 68.2% among those aged 40 plus, compared to only 51.1% among younger pharmacists. Men and women had a similar level of confidence as each other. Locums (51.3%) were somewhat less confident than pharmacists (62.7%), and those working in urban pharmacies (65.1%) were more confident than those working in rural pharmacies (54.4%).

Similarly, 61.5% of all pharmacists felt completely or very confident about correctly supplying DSG without a prescription, rising to 76.4% among older pharmacists (compared to 54.5% among under 40s). Men and women showed equal levels of confidence (Table 10, Appendix 1.3). Pharmacists (63.4%) were more confident than locums (53.8%) about supplying DSG (Table 10.1, Appendix 1.3).

Those who had only conducted one or two consultations in the last six months (52%) were less confident about correctly supplying DSG than those who had conducted three to nine consultations (59.5%). Those who had conducted at least 10 consultations were the most confident (72.3% were completely or very confident in correctly supplying DSG). This suggests that the process of correctly supplying desogestrel will become easier and will perhaps be more likely to be correct as the non-prescription supply becomes more established (Table 10.1, Appendix 1.3).

Table 10-20: Responses to questions relating to confidence – completed surveys by segment: age, gender

Question	Total sample N=200	%	Precision or Margin of Error (±%)	Under 40 years old N=90	Aged 40 plus N=100	Men N=104	Women N=90
How confident do you feel about advising patients on the use of desogestrel 75 microgram film-coated tablets?							
Completely (5)	38	19.0	5.4	13.3%	23.6%	21%	16.7%
Very (4)	83	41.5	6.8	37.8%	44.6%	39%	42.2%
Fairly (3)	75	37.5	6.7	46.7%	30.0%	38%	38.9%
Not very (2)	4	2.0	2.0	2.2%	1.8%	2%	2.2%
Not at all (1)	0	0.0	0.0	0.0%	0.0%	0%	0.0%
Mean score (+5 to +1)	200	3.8	Std.dev. 0.77	3.6	3.9	3.8	3.7
And how confident are you about correctly supplying desogestrel 75 microgram film-coated tablets without a prescription?							
Completely (5)	35	17.5	5.3	12.2%	26.4%	20%	13.3%
Very (4)	88	44.0	6.9	42.2%	50.0%	42%	44.4%
Fairly (3)	72	36.0	6.6	42.2%	21.8%	36%	38.9%
Not very (2)	5	2.5	2.2	3.3%	1.8%	2%	3.3%
Not at all (1)	0	0.0	0	0.0%	0.0%	0%	0.0%
Mean score (+5 to +1)	200	3.8	Std. dev. 0.76	3.6	4.0	3.8	3.7

Self-rated knowledge about desogrestrel

Pharmacists were asked to rate their own knowledge about desogestrel, and 73% of them rated their knowledge as excellent or very good for its mode of action, 74% for its side-effects, 89% for its recommended dosage and frequency, 71% for its use with concomitant medication and 73% for its exclusion of pregnancy. This picture pertains across the segments, with older pharmacists more positive about their levels of knowledge than younger pharmacists (Table 10-21).

Table 10-21 also shows that a small number of pharmacists considered themselves to have poor or very poor levels of knowledge. Slightly more of those aged under 40 than those aged 40 plus considered themselves so, while there were no gender differences in levels of knowledge.

Table 10-21: Responses to questions relating to self-rated knowledge – completed surveys by segment: age, gender

Question	Total sample N=200	%	Precision or Margin of Error (±%)	Under 40 years old N=90	Aged 40 plus N=100	Men N=104	Women N=90
How would you rate your own level of knowledge about desogestrel 75 microgram film-coated tablets: Its mode of action							
Excellent	45	22.5	5.8	14.4%	29.1%	26%	18.9%
Good	101	50.5	6.9	52.2%	49.1%	48%	51.1%
Fair	46	23.0	5.8	27.8%	19.1%	22.0%	25.6%
Poor	7	3.5	2.5	4.4%	2.7%	4.0%	3.3%
Very poor	1	0.5	1.0	1.1%	0.0%	0.0%	1.1%
How would you rate your own level of knowledge about desogestrel 75 microgram film-coated tablets: Its side effects							
Excellent	39	19.5	5.5	11.1%	26.4%	20%	20.0%
Good	109	54.5	6.9	60.0%	50.0%	52%	54.4%
Fair	47	23.5	5.9	25.6%	21.8%	26.0%	22.2%
Poor	3	1.5	1.7	1.1%	1.8%	1.9%	1.1%
Very poor	2	1.0	1.4	2.2%	0.0%	0.0%	2.2%
How would you rate your own level of knowledge about desogestrel 75 microgram film-coated tablets: Recommended dosage, frequency							
Excellent	86	43.0	6.9	36.7%	48.2%	42%	44.4%
Good	92	46.0	6.9	53.3%	40.0%	43%	47.8%
Fair	21	10.5	4.2	8.9%	11.8%	14.4%	6.7%
Poor	0	0.0	0	0.0%	0.0%	0.0%	0.0%
Very poor	1	0.5	1.0	1.1%	0.0%	0.0%	1.1%
How would you rate your own level of knowledge about desogestrel 75 microgram film-coated tablets: Its use with concomitant medication							
Excellent	37	18.5	5.4	13.3%	22.7%	21%	16.7%
Good	105	52.5	6.9	47.8%	56.4%	50%	52.2%
Fair	54	27.0	6.2	34.4%	20.9%	26.9%	28.9%
Poor	4	2.0	1.9	4.4%	0.0%	1.9%	2.2%
Very poor	0	0.0	0	0.0%	0.0%	0.0%	0.0%
How would you rate your own level of knowledge about desogestrel 75 microgram film-coated tablets: Exclusion of pregnancy							
Excellent	55	27.5	6.2	23.3%	30.9%	31%	24.4%
Good	100	50.0	6.9	50.0%	50.0%	43%	55.6%
Fair	42	21.0	5.6	25.6%	17.3%	23.1%	20.0%
Poor	3	1.5	1.7	1.1%	1.8%	2.9%	0.0%
Very poor	0	0.0	0	0.0%	0.0%	0.0%	0.0%

Those who had conducted more consultations tended to be more confident in their knowledge of DSG than those who had only conducted one or two consultations (Table 10-22):

- Those considering their knowledge of the mode of action of DSG to be excellent or good (63%) after 1-2 consultations comparedto 80% of those having completed at least 10 consultations considering this to be so

- Those considering their knowledge of the side effects of DSG to be excellent or good (63%) after 1-2 consultations compared to 82% of those having completed at least 10 consultations considering this to be so
- Those considering their knowledge of the exclusion of pregnancy of DSG to be excellent or good (74%) after 1-2 consultations comparedto 83% of those having completed at least 10 consultations considering this to be so.

Table 10-22: Responses to questions relating to self-rated knowledge – completed surveys by segment: role, urban/suburban, number of consultations

Question	Pharmacists N=161 (%)	Locums N=39 (%)	Urban N=106 (%)	Suburban/ rural N=94 (%)	1-2 consults N=61 (%)	3-9 consults N=74 (%)	10+ consults N=65 (%)
How would you rate your own level of knowledge about desogestrel 75 microgram film-coated tablets: Its mode of action							
Excellent	23.0%	20.5%	21.7%	23.4%	21.3%	17.6%	29.2%
Good	48.4%	59.0%	51.9%	48.9%	44.3%	55.4%	50.8%
Fair	23.6%	20.5%	22.6%	23.4%	26.2%	23.0%	20.0%
Poor	4.3%	0.0%	2.8%	4.3%	8.2%	2.7%	0.0%
Very poor	0.6%	0.0%	0.9%	0.0%	0.0%	1.4%	0.0%
How would you rate your own level of knowledge about desogestrel 75 microgram film-coated tablets: Its side effects							
Excellent	18.6%	23.1%	20.8%	18.1%	14.8%	20.3%	23.1%
Good	57.8%	41.0%	55.7%	53.2%	47.5%	56.8%	58.5%
Fair	20.5%	35.9%	20.8%	26.6%	32.8%	21.6%	16.9%
Poor	1.9%	0.0%	0.9%	2.1%	3.3%	1.4%	0.0%
Very poor	1.2%	0.0%	1.9%	0.0%	1.6%	0.0%	1.5%
How would you rate your own level of knowledge about desogestrel 75 microgram film-coated tablets: Recommended dosage, frequency							
Excellent	42.2%	46.2%	46.2%	39.4%	50.8%	37.8%	41.5%
Good	46.0%	46.2%	43.4%	48.9%	37.7%	52.7%	46.2%
Fair	11.2%	7.7%	9.4%	11.7%	9.8%	9.5%	12.3%
Poor	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Very poor	0.6%	0.0%	0.9%	0.0%	1.6%	0.0%	0.0%
How would you rate your own level of knowledge about desogestrel 75 microgram film-coated tablets: Its use with concomitant medication							
Excellent	19.3%	15.4%	15.1%	22.3%	16.4%	21.6%	16.9%
Good	52.2%	53.8%	53.8%	51.1%	54%.1	51.4%	52.3%
Fair	26.1%	30.8%	29.2%	24.5%	26.2%	25.7%	29.2%
Poor	2.5%	0.0%	1.9%	2.1%	3.3%	1.4%	1.5%
Very poor	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
How would you rate your own level of knowledge about desogestrel 75 microgram film-coated tablets: Exclusion of pregnancy							
Excellent	27.3%	28.2%	27.4%	27.7%	31.1%	25.7%	26.2%
Good	49.7%	51.3%	49.1%	51.1%	42.6%	50.0%	56.9%
Fair	21.7%	17.9%	20.8%	21.3%	21.3%	24.3%	16.0%
Poor	1.2%	2.6%	2.8%	0.0%	4.9%	0.0%	0.0%
Very poor	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

10.4. Other analyses

10.4.1. Reasons why some consultations did not result in the supply of desogestrel

The open ended question asking pharmacists why some of their consultations did not result in the supply of DSG delivered a variety of responses, which were collated according to the following codes. Besides the 30.5% who claimed that all their consultations had resulted in the supply of DSG, the single most prevalent comment was that patients declined to buy the DSG after consultation because they had expected it to be free because prescriptions are free, or because they were not prepared to pay the cost (19.5% +/- 5.5%). 16.5% of respondents reported that they'd had consultations which didn't result in supply because the patient had contra-indications for DSG, based on their medical history or other medication they were taking, which indicated co-morbidities.

Table 10-23: Reasons some consultations didn't result in supply – completed surveys

Question	N=200	%	Precision or Margin of Error (±%)
When these consultations did not result in the supply of desogestrel 75 microgram film-coated tablets, what were the main reasons for this?			
Not applicable/all resulted in supply	61	30.5	6.4
Cost/patient not willing to pay	39	19.5	5.5
Contra-indications with medical history/age/ co-morbidity	33	16.5	5.1
Patient changed their mind/unsure/wanted time to think about it	15	7.5	3.7
Specific symptoms indicated unsuitability	12	6.0	3.3
Required referral to GP	8	4.0	2.7
Possibility of pregnancy	7	3.5	2.5
Other answers	7	3.5	2.5
Out of stock/lack of availability	6	3.0	2.4
Not suitable (reasons not specified)	5	2.5	2.2
Patient wanted a combined oral contraceptive	4	2.0	2.0
Patient already on contraception	3	1.5	1.7
Patient outside appropriate time period	3	1.5	1.7
Pharmacy too busy to fully consult patient	3	1.5	1.7
Patient wanted more/larger supply	2	1.0	1.4
Patient unsure of medical details	1	0.5	1.0
Don't remember	1	0.5	1.0

A full list of verbatim responses to this question is appended in Appendix 1.4.

10.5. Adverse events/adverse reactions

This survey did not generate any pharmacovigilance issues and no AEs were reported.

11. Discussion

11.1. Key results

The objectives for this survey were three-fold:

1. To demonstrate that the aRMMs are effective in enabling pharmacists to make appropriate decisions to supply based on contraindications and special warnings; this includes awareness and mitigation of safety concerns
2. To identify whether there are particular contraindications or warnings for which pharmacists consistently make the wrong supply decision
3. To establish ease of access to and ease of use of the aRMMs.

The survey demonstrated that the aRMMs were effective in minimising the risk of wrong supply and enabling pharmacists to make appropriate decisions to supply or not supply, on complex and multi-safety parameter scenarios. Those not clear about which was the correct reason for not supplying were anyway taking the correct decision of non-supply, mitigating incorrect supply risk.

The materials for both brands were rated as easily accessible to pharmacists when giving consultations, and for all four of the materials included (the Pharmacy Training Guide, Consultation/supply aid checklist, SmPC and Pack Copy).

On average, taking all 1,600 responses across the eight scenarios into account, the correct decision to supply/not supply desogestrel was 82.6% (+/- 1.8%), and exceeded the KPI of 80%.

Respondents were then presented with four possible reasons for supply/do not supply (two for each) and were required to choose the one they felt best described the reason. In the cases of scenarios 1-4, the proportions giving the right reason for supply or not supply of DSG met the KPI of 80%, subject in each case to margins of error.

For scenarios 5-8, the threshold was not met, although scenarios 7 and 8 fell only slightly short of the threshold (70.5% +/- 6.3% and 71.5% +/- 6.2% respectively). Pharmacists' answers were generally not to supply when supply could have taken place, hence minimal risk to the patient.

The two scenarios which fell far short of the KPI were scenario 5 (37.5% correct reason +/- 6.7%) and scenario 6 (51.5% correct reason +/- 6.9%).

Scenario 5 was designed to check pharmacist understanding of using DSG if a woman has diabetes or a history of thrombosis. 85.5% of all pharmacists chose the correct 'do not supply' answer, but 56% of them chose the wrong reason for doing so. Those not clear about which was the correct reason for not supplying were taking the conservative route of non-supply, mitigating incorrect supply risk.

Scenario 6 was designed to check pharmacist understanding that a maximum of three months' supply of DSG should be made to women under 18 years of age, to ensure a regular opportunity to assess safeguarding, compliance and counselling on sexual health.

In this scenario, the correct response was to supply (chosen by 66.0% +/- 6.6%), for which 51.5% +/- 6.9% gave the right reason. Again, where pharmacists were unsure of the correct answer, given that making a mistake presented greater risk because it could have meant incorrect supply, 33.5% chose a more conservative do not supply answer.

60.5% of all respondents reported feeling completely or very confident about advising patients on the use of desogestrel 75 microgram film-coated tablets. Importantly, levels of confidence in advising patients increased with the number of consultations conducted.

Pharmacists participating in this study had conducted at least one consultation on DSG in the last six months, and on average had only conducted 15 consultations. Given that the research took place only six months after the launch of the product, the level of appropriate decision-making was relatively high.

In view of the early stage at which this research was conducted following the launch of both brands, it is fair to assume that increased experience of consultations and use of the aRMMs will improve the proportion of pharmacists giving the correct reason to supply or not to supply, rather than refer to a GP, even in the complex multi-parameter situations presented in these scenarios.

Those who had conducted more consultations tended to be more confident in their knowledge of DSG than those who had only conducted one or two consultations. This implies that as more time elapses and the average number of consultations increases, the levels of knowledge about DSG will increase and with it there will be an increase in the proportion of correct reasoning for supply/do not supply.

11.2. Limitations

It is a limitation that the participating pharmacists were self-selected since respondents voluntarily responded to the invitation to participate. However, the survey recruitment strategies were intended to recruit a representative sample. The sample was representative of the demographic profile of pharmacists in the UK and so it can be assumed that the complete survey represented the state of understanding and use of aRMMs in all pharmacies where they have been received and read, and in conjunction with consultations.

All data from the survey was self-reported and therefore susceptible to possible reporting bias. There could be discrepancies between what pharmacists reported about their practices and their actual behaviours, given that this survey was based on recall of a six month period of consultations. In this case, it would be difficult to validate whether pharmacists' responses to practice-related questions completely concur with their actual behaviours since this was a self-reported survey.

The survey results Table 10-6 indicates that a significant proportion of pharmacists (6.3% of those eligible to participate) did not receive the aRMM tools and that 5.6% received them but did not read them. Reliance on the respondent's recall of whether or not the aRMMs were received is an inherent limitation of the study methodology. If the respondent says they did not receive a particular tool, the risk minimisation programme is evaluated as not optimally disseminating material.

A secondary limitation inherent in the survey research is the reliance on the respondent's recall of whether or not the aRMM materials were read and utilised. If respondents said they did not read and utilise the aRMMs, they were screened out. It is possible that pharmacists may simply not recall the tools that were received and read, although few claimed not to remember the brand sponsoring each item. Removing those who did not recall reading the aRMMs reduced the overall sample size, and in order to achieve 200 eligible responses, 922 pharmacy staff were required to attempt to take part in the survey.

The objective of this PASS is to measure the effectiveness of the pharmacy training materials. The study looked at two process indicators: a) reaching the target population and b) assessing clinical knowledge. These process indicators were intended to provide insight into the extent to which the

dissemination of pharmacy materials had been executed as planned and whether the intended measures impacted the correct decision to supply or not supply DSG.

11.3. Interpretation

With regard to the reported tool utilisation, data indicate that 87% of pharmacists found the tools extremely or very useful. Further, 11.5% found them somewhat useful and nobody considered them not useful.

Although an a priori threshold of 80% correct per risk question was used to define the success of the study, the selection of this threshold for success is subjective and not based on prior knowledge, experience or established scientific criteria in the education or risk communication literature (as acknowledged by EMA: 7 May 2015 PRAC Rapporteur PASS Protocol Assessment Report; Procedure no.: EMEA/H/C/000387/MEA 087.2[4]). In this case, the choice of an 80% threshold for the KPI was in line with 'best in class' practice for PASS. Had a lower threshold of 70% been chosen (in line with many similar studies), it would have resulted in the KPI across all eight scenarios being achieved (69.6% +/- 2.2%).

11.4. Generalisability

The CIG Research panel of 35,175 pharmacy staff contains a majority of all registered UK pharmacists (currently 42,990), and can be assumed to be reasonably representative of the universe. However, from the panel, just 0.6% completed the survey, and these were only 21.7% of the total number attempting the survey who were eligible. On this basis, it is not likely that the findings generated are completely representative of the universe of UK community pharmacists. In the case of the margin of error on each scenario, figures as high as +/- 10-12% for various segments indicate that the results only approximate to that representation.

12. Other information

Not applicable

13. Conclusions

The results of this survey show that:

- The aRMMs were effective in minimising the risk of wrong supply and enabling pharmacists to make appropriate decisions to supply or not supply DSG in complex and multi-safety parameter scenarios, achieving the 80% predefined KPI.
- The key safety messages outlined in the aRMMs were effectively communicated to pharmacists, but the expected reason for supply was not consistently chosen in two of the eight scenarios. This specific parameter therefore fell short of the pre-defined KPI. However, there may be legitimate reasons why a different medical rationale was chosen in order to make the correct supply/not supply decision, given the complexity of the scenarios
- Where pharmacists were unsure about their reasons for choosing to supply DSG, there was a tendency towards the safer option of non-supply and referring patients to a doctor, thus minimising the risk of incorrect supply. Referring a decision to a more experienced colleague, in the face of uncertainty, is common medical practice and ensures patient safety is maintained and should not be considered as “incorrect”.
- As would be expected, the degree of confidence in advising patients and choosing to supply DSG increased with the number of consultations conducted
- All decisions of “no supply” in women who were not suitable, were correct and met the 80% KPI.
- The aRMMs were easily accessed by pharmacists for both Lovmia and Hana.

Based upon this current evaluation of knowledge, understanding and behaviours, the aRMMs were determined to be effective in minimizing the risk of providing P-desogestrel. Corrective action plans and materials are to be provided by each company to improve correct reasoning for supply/no supply of P-desogestrel.

14. References

1. Clopper, CJ, Pearson, ES. The Use of Confidence or Fiducial Limits Illustrated in the Case of the Binomial. Biometrika. 1934;26(4):404-413.
2. MHRA *'GXP' Data Integrity Guidance and Definitions* letter (publishing.service.gov.uk)
3. EudraLex: The Rules Governing Medicinal Products in the European Union, Volume 4 *Good Manufacturing Practice Medicinal Products for Human and Veterinary Use*, Annex 11: Computerised Systems Annex 11 Final 0910 (europa.eu)
4. EMA: *7 May 2015 PRAC Rapporteur PASS Protocol Assessment Report; Procedure no.: EMEA/H/C/000387/MEA 087.2*

Annex 1. List of standalone documents

No.	Document Reference No	Date	Title
1.	Appendix 1.1	Jan 2022	Protocol
2.	Appendix 1.2	Sept 2021, Oct 2021	User test and pilot report
3.	Appendix 1.3	Feb 2022	Final Tables and Listings
4.	Appendix 1.4	Feb 2022	Verbatim responses to Q5

Appendix 1.1: NON-INTERVENTIONAL STUDY (NIS) PROTOCOL

NON-INTERVENTIONAL STUDY (NIS) PROTOCOL
Post-Authorisation Safety Study (PASS) Information

Title	Assessment of the effectiveness of additional Risk Minimisation Measures (aRMMs) among pharmacists for provision of desogestrel 75 microgram film-coated tablets in a community pharmacy setting
Protocol version identifier	CIG021221.3
Date of last version of protocol	Tuesday, 11 January 2022
EU Post Authorisation Study register number	Study not yet registered. Registration will be performed upon Medicines and Healthcare Products Regulatory Agency (MHRA) approval of this protocol
Active Substance	Desogestrel
Medicinal Product	Lovima 75 microgram film-coated tablets Hana 75 microgram film-coated tablets
Product Reference	ATC G03AC09
Procedure Number	PL 42807/0002 PL 17836/0015
Marketing Authorisation Holders	Maxwellia Ltd Laboratoire HRA Pharma
Joint PASS	Yes
Research questions and objectives	To evaluate the effectiveness of desogestrel 75 microgram film-coated tablets aRMMs by: • demonstrating that the aRMMs are effective in enabling pharmacists to make appropriate decisions to supply based on contraindications and special warnings; this includes awareness and mitigation of safety concerns; • identifying whether there are particular contraindications or warnings for which pharmacists consistently make the wrong supply decision; • establishing ease of access to and ease of use of the aRMMs.
Country of Study	UK
Author	Adrian Wistreich, Consensio LLP (trading as CIG Research), Linen Hall, 162-168 Regent Street, London, W1B 5TB UK
Marketing Authorisation Holders	Laboratoire HRA Pharma Maxwellia Ltd
Marketing Authorisation Contact	Alexandra Trehane, Head of Innovation, regulatory@maxwellia.com

1. Contents

LIST OF TABLES

LIST OF STAND-ALONE DOCUMENTS

I. Hana Training Materials

1. Hana Pharmacy Guide
2. Hana Pharmacy Supply Aid Checklist

II. Lovima Training Materials

3. Lovima Pharmacy Training Guide
4. Lovima Pharmacy Consultation/ Supply Aid Checklist

2. List of Abbreviations

AE	Adverse Event
aRMMs	additional Risk Minimisation Measures
CI	Confidence Intervals
CIG	Communications International Group
DIA	Drug Information Association
DSG	Desogestrel
GDPR	General Data Protection Regulation
GP	General Practitioner
GSL	General Sales List medicine
hCG	human Chorionic Gonadotrophin
HCP	Healthcare Professional
KPI	Key Performance Indicator
KRMs	Key Risk Messages
MAH	Marketing Authorisation Holder
MHRA	Medicines and Healthcare Products Regulation Agency
MRP	Mutual Recognition Procedure
NIS	Non-Interventional Study
OC	Oral Contraception
OTC	Over The Counter
P	Pharmacy medicine
PASS	Post-Authorisation Safety Study
PGD	Patient Group Directions
POM	Prescription Only Medicine
POP	Progestin-only Pill
RM	Risk Management
RMP	Risk Management Plan
SmPC	Summary of Product Characteristics
URL	Uniform Resource Locator

3. Responsible Parties

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Shared responsibility statement
This is a joint PASS submission and there is a shared responsibility between Laboratoire HRA Pharma and Maxwellia Ltd for the management and reporting of Adverse Events.

4. Abstract

This abstract provides a summary of study objectives and methodology. Detailed descriptions are included in corresponding sections in the main body of the protocol.

Rationale and Background

Desogestrel 75 microgram film-coated tablets was first authorised in Sweden in 1997 under the trade name Cerazette (Organon Pharmaceuticals) for oral contraception (OC) in women. It was then authorised in 1998 in other European countries, including the United Kingdom (UK), in the subsequent Mutual Recognition Procedure (MRP procedure number SE/H/0147/001, UK licence number PL 00025/0562).

Desogestrel 75 microgram film-coated tablets was reclassified to a pharmacy only (P) medicine in the UK separately by Maxwellia Ltd and HRA Pharma in July 2021. To support the safe supply of the products via pharmacy, both companies have independently developed a Pharmacy Training Guide and an optional Pharmacy Checklist as additional Risk Minimisation Measures (aRMMs). The training materials and consultation checklists together constitute important aRMMs for the non-prescription supply of the products, so that an appropriate decision is made by pharmacists to supply patients and correct advice is given. The content of the materials is aligned and has been agreed with the MHRA.

This post-authorisation safety study (PASS) will assess the effectiveness of the agreed aRMMs for desogestrel 75 microgram film-coated tablets.

Research Questions and Objectives

The overall objective is to evaluate the effectiveness of the aRMMs in mitigating the risks of incorrect supply of desogestrel 75 microgram film-coated tablets to patients in a community pharmacy. Specifically, the goals of the study are to:

- demonstrate that the training provided by each company is effective in enabling pharmacists to make appropriate decisions to supply desogestrel 75 microgram film-coated tablets based on contraindications and special warnings; this includes awareness and mitigation of safety concerns;
- identify whether there are particular contraindications or warnings for which pharmacists consistently make the wrong supply decision;
- establish ease of access to and ease of use of the aRMMs.

Study Design

The study will be a cross sectional, non-interventional web-based survey at six months post the first product launch following MHRA approval of the reclassification.

The survey will be distributed across the UK to a representative mix of independent and multiple ownership pharmacies with the aim of achieving a relevant sample size of pharmacists who have read the aRMM materials and conducted at least one consultation during the previous six months.

For this study, it will be important to ensure a representative mix of independent and multiple ownership pharmacies, including those in urban and small town settings.

The questionnaire has been designed such that all biases in question wording, scale responses and order effect are mitigated. This includes the use of:

- Balanced scales
- Randomisation of response options
- Non-leading question phraseology
- Survey flow, routing and question logic designed to maximise the respondent's efficient and considered response.

Prior to finalisation of the study questionnaire, the proposed questions were peer reviewed and the functionality of the online survey was user tested with 5 pharmacists in the UK to identify any ambiguity and estimate survey completion time.

A pilot study has run additionally with 30 pharmacists in order to evaluate the quality of the data produced by the respondents and ensure that it will lead to meaningful results.

Study Structure

The pharmacist survey will comprise two main sections, intended to:

1. Understand how the aRMMs are being used in practice. Pharmacists' feedback will be collected and analysed to determine whether changes to the aRMMs are required in order to support pharmacists more effectively when they are supplying desogestrel 75 microgram film-coated tablets;
2. Establish whether pharmacists can answer case study questions correctly and offer the correct advice to patients requesting desogestrel 75 microgram film-coated tablets for oral contraception from a pharmacy. Eight (8) case study scenarios are involved.

Pharmacists will be screened to ensure they have received and read at least one of the aRMMs and conducted a consultation on desogestrel 75 microgram film-coated tablets without a prescription in the last six months. The scenario section of the questionnaire is designed to mirror real life situations, in which pharmacists may choose to refer to information sources during consultations.

The pharmacist survey will take approximately 15 minutes to complete and will have to be completed in one sitting. However, the survey timer will be set for 60 minutes to allow respondents to take a break if required. During this time, the survey will remain open: respondents will not be able to save it and return to it later. Respondents will be informed about the length of the survey and allocated time to complete.

Data Sources

A structured, self-administered questionnaire comprised of closed and open ended questions or statements with multiple response choices (i.e. questions or statements asking the pharmacists to choose from a defined list of responses) will be used to collect the survey data. The questionnaire will collect data on pharmacist characteristics in addition to their responses pertaining to the effectiveness of the aRMMs.

Study Size

The survey will be distributed across the UK to a representative mix of pharmacists working in independent and multiple ownership community pharmacy businesses in city, urban, small town and

rural settings, with the aim of achieving a sample size of 200 pharmacists who have all read at least one company's aRMMs and conducted at least one consultation during the previous six months.

The sample size chosen for this study is dependent on statistical and feasibility considerations. The 200 responses will generate a combined response to 1600 case study scenarios, which will be taken together to measure the proposed success criteria.

Data Analysis

Previous analysis of comparable PASS studies has shown that receipt and use rates for risk management (RM) materials among healthcare professionals (HCPs) rarely exceed 80% (preliminary results of a cumulative systematic review and meta-analysis of risk minimisation survey studies presented at EMA/DIA Information Day, 2017),[3] whereas percentages of correct knowledge of key safety messages mostly lie between 70% and 90%. On this basis, a threshold of 80% has been set as an average across the eight case study scenarios, rather than on each one individually.

Data segmentation will be generated for key variables e.g. splitting the sample by gender and age, outlet type and job title.

Success Criteria

The aRMMs will be deemed effective if the following criteria are met:

- An average of at least 80% of pharmacists correctly advise whether to supply or not supply for each of the eight case study scenarios. The Key Performance Indicator (KPI) will be deemed achieved at 73.2% plus to allow 6.9% statistical precision (see table 2);
- The total number of correct answers across the scenarios exceeds 80%. The KPI will be deemed achieved at 77.6% plus to allow 2.5% statistical precision (see table 2). This means that 1242 correct answers out of the 1600 answers will be achieved.

Quality Control

The study will be conducted in accordance with all applicable regulatory and privacy requirements.

Documentation of all data management activities will allow step-by-step retrospective assessment of data quality and performance. Management of data will be performed in accordance with applicable standards and data cleaning procedures to ensure its integrity (e.g. removing errors and inconsistencies in the data).

Where the percentage of pharmacists answering a scenario question correctly is below the level defined to represent success, the training materials relating to that particular scenario will be reviewed and improved as appropriate in both sets.

5. Amendments and Updates

This is the second version of the protocol which has been revised to address areas identified in the pilot report and implement the respective changes.

Amendment or update number	Date	Section of Study Protocol	Amendment or Update	Reason
1.1	02 December 2021	9.1.1 Study Structure 9.4.4 User and pilot testing of the survey questions 9.4.5 Data collection process Annex 1 Annex 3 Annex 4	Updated length of the questionnaire Amended information about pilot study Amended invitation to participate in the survey Amended introductory text in the survey Removed 'Show image' option from the questionnaire Altered format of the question about number of consultations held in the last six months All scenarios split into two-part question with balanced number of supply / not supply options (2 each) and improved wording Amended table with risks assessed in case study scenarios	To address the issues identified in the pilot study report dated 27th October 2021
1.2	10 January 2022	Various 6. Milestones 9.4.4 User and pilot testing of the survey questions Annex 1 Annex 3	Version identifier CIG02122021.2 and date Change of dates Further information about user test and the pilot	In response to MHRA assessment of protocol update (following study pilot)

			Amended wording	
1.3	11 January 2022	Various Annex 3	Version identifier CIG02122021.3 and date Amended wording in the employment screening question Scenario 4 wording improved	In response to MHRA assessment of protocol update User test outcome In response to MHRA assessment of protocol update

6. Milestones

Milestone	Timelines
DSG reclassification approval	8th July 2021
Launch of product in pharmacy	July 2021
Roll out of aRMMs	July 2021
MHRA protocol approval	2nd September 2021
User testing	w/c 20th September 2021
Registration in the EU PAS Register®	30th September 2021
Pilot study launch	w/c 11th October 2021
Pilot study data collection and results reporting	w/c 1st November 2021
(If required) Submission of changes made to the protocol and questionnaire to MHRA	w/c 29th November 2021
(If required) MHRA updated protocol approval	w/c 10th January 2022
Main study launch	w/c 17th January 2022
End of data collection	w/c 14th February 2022
Publication of final study report	w/c 18th April 2022

7. Rationale and Background

Desogestrel 75 microgram film-coated tablets was first authorised in Sweden in 1997 under the trade name Cerazette (Organon Pharmaceuticals) for oral contraception (OC) in women. It was then authorised in 1998 in other European countries, including the United Kingdom (UK), in the subsequent Mutual Recognition Procedure (MRP procedure number SE/H/0147/001, UK licence number PL 00025/0562).

Desogestrel 75 microgram film-coated tablets (DSG) was reclassified to a pharmacy only (P) medicine in the UK separately by Maxwellia Ltd and Laboratoire HRA Pharma. Both applications for non-prescription (over the counter) 75 microgram desogestrel (to be marketed as Lovima 75 microgram film-coated tablets and Hana 75 microgram film-coated tablets retrospectively) were approved in July 2021.

To support the safe supply of the products via pharmacy, both companies have independently developed a Pharmacy Training Guide and an optional Pharmacy Checklist as additional Risk Minimisation Measures (aRMMs). The training materials and consultation checklists together constitute important aRMMs for the non-prescription supply of DSG, so that an appropriate decision is made by pharmacists to supply patients and correct advice is given. The content of the materials is aligned and has been agreed with the MHRA.

The MHRA has asked Maxwellia Ltd and Laboratoire HRA Pharma to confirm that the aRMMs for their desogestrel 75 microgram tablet products operate effectively in the community pharmacy setting by conducting a joint post-authorisation safety study (PASS).

Product information

Hana 75 microgram film-coated tablets[1]
Each film-coated tablet contains 75 microgram desogestrel
Licence holder: Laboratoire HRA Pharma

Lovima 75 microgram film-coated tablets[2]
Each film-coated tablet contains 75 microgram desogestrel
Licence holder: Maxwellia Ltd

Hana and Lovima tablets are oral contraceptives used for the prevention of pregnancy in women of childbearing age. Hana and Lovima tablets contain desogestrel (DSG), a progestogen-only oral contraceptive (also known as a POP or mini-pill).

The contraceptive effect of DSG is achieved primarily by inhibition of ovulation. Other effects include increased viscosity of cervical mucus.

One tablet must be taken every day at the same time so that the interval between two tablets is always 24 hours. The first tablet should be taken on the first day of menstrual bleeding. Thereafter, one tablet each day is to be taken continuously without taking any notice of possible bleeding. When a pack of pills is finished, a new pack should be started the next day, maintaining the same 24 hour interval between pills.

Like other POPs, Hana and Lovima can be used during breast-feeding and by women who cannot or do not want to use oestrogen.

Further product information can be found in the Summary of Product Characteristics (SmPCs) for Hana[1] and Lovima[2].

Laboratoire HRA Pharma and Maxwellia Ltd believe the launch of Hana and Lovima in the UK, and their availability as Pharmacy (P) medicines, will increase access for women of childbearing age to oral contraception.

Pharmacist role and training

Pharmacists have been identified as having an important role in facilitating and counselling patients to determine suitability of use of DSG, and in directing women for whom it is unsuitable to their doctors.

Pharmacists have experience in counselling patients on the supply and use of emergency hormonal contraception, which has been available in the UK as a Pharmacy (P) medicine since 2001. Some pharmacists also supply contraception via Patient Group Directions (PGDs) and/or online clinic services.

The companies have produced pharmacy training materials consisting of a Pharmacy Training Guide and a Pharmacy Supply Aid Checklist. The checklist can be completed by women prior to their consultation, and acts as an aide memoire for the pharmacist in determining if the medicine is suitable for supply. The woman will have the patient information leaflet and packaging to refer to: these contain the key safety messages for the products. As part of the consultation in the pharmacy, women will be informed of and signposted to information on all methods of contraception available, so that they can make an informed choice regarding the method most suitable for them.

The aRMMs are being offered in a variety of formats to ensure the widest opportunity for accessing learning. This includes online resources and printed materials.

Key Risk Messages for Pharmacists

The Pharmacy Training Guides and Pharmacy Supply Aid Checklists include risk messages for pharmacists to consider when determining the suitability of a patient for supply of Hana or Lovima and other important messages for pharmacists to consider during consultations.

The aRMMs have been generated to manage the following potential risks, which are detailed in the risk management plans (RMPs) for both companies' products:

- Venous thromboembolism
- Arterial thromboembolism
- Disturbances of liver function
- Breast cancer
- Benign and malignant liver tumours
- Drug interactions.

It is important that pharmacists consider the potential risks when identifying women suitable for supply of DSG. The pharmacy training materials address each of these risks and provide advice to pharmacists on how to manage these risks appropriately.

The pharmacy training materials also provide additional information for pharmacists to consider when ensuring safe supply of DSG. These include, but are not limited to:

- Alternative contraception options to ensure women can make informed choices
- Safeguarding and consent, particularly when supplying DSG to women under 16 years of age
- Information on how to take and how to start taking DSG
- Counselling advice on potential side effects of DSG
- Quick starting and managing potential off-label use
- Managing a missed or forgotten pill.

Study protocol objective

The objective of this protocol is to describe in detail the methods that will be employed to evaluate the effectiveness of the aRMMs in the UK and to outline the estimated timeline for the major study milestones (Section 6: Milestones). This non-interventional study is designated as a Post-Authorisation Safety Study (PASS) and is a commitment to the MHRA.

8. Research Questions and Objectives

The overall objective of this study is to evaluate the effectiveness of the aRMMs. Specifically, the primary objectives are to:

- Demonstrate that the aRMMs are effective in enabling pharmacists to make appropriate decisions to supply based on contraindications and special warnings; this includes awareness and mitigation of safety concerns;
- Identify whether there are particular contraindications or warnings for which pharmacists consistently make wrong supply decisions;
- Establish ease of access to and ease of use of the aRMMs.

9. Research Methods

This section presents the methods that will be employed to evaluate the effectiveness of the aRMMs in the UK.

9.1 Study Design

The study will be a cross sectional, non-interventional web-based survey that will be conducted in the UK at six months post the first product launch for at least one of the two brands following MHRA approval of the reclassification. The study will be conducted anonymously among pharmacists who have read the aRMMs for at least one of the brands and have conducted at least one consultation regarding the supply of desogestrel 75 microgram film-coated tablets during the previous six months.

For this study, it will be important to ensure a representative mix of independent and multiple ownership pharmacies, including those in urban and small-town settings.

The questionnaire has been designed such that all biases in question wording, scale responses and order effect are mitigated. This includes the use of:

- Balanced scales
- Randomisation of response options
- Non-leading question phraseology
- Survey flow, routing and question logic designed to maximise the respondents' efficient and considered responses.

Prior to finalisation, the study was subjected to user testing and a pilot study. Further details of these can be found in section 9.4.4.

9.1.1 Study Structure

The pharmacist survey will comprise two main sections, intended to:

1. Understand how the aRMMs are being used in practice. Pharmacists' feedback will be collected and analysed to determine whether changes to the aRMMs are required in order to support pharmacists more effectively when they are supplying the products. These questions are based on simple scales, single or multiple choices, and include two open ended questions. They cover the following areas:
    - aRMMs received and read prior to the study
    - Frequency of consultations
    - The setting within the pharmacy used for the consultation
    - aRMMs used during the consultation
    - Ease of access to the aRMMs
    - Level of pharmacist confidence in advising on the use of desogestrel 75 microgram film-coated tablets and correctly supplying.

2) Establish whether the pharmacists can answer questions correctly and offer the correct advice to customers requesting desogestrel 75 microgram film-coated tablets for oral contraception from a community pharmacy. Eight (8) case study scenarios are involved.

Pharmacists will be screened to ensure they have received and read the aRMMs from at least one of the brands and conducted a consultation on desogestrel 75 microgram film-coated tablets without a prescription in the last six months. The scenario section of the questionnaire is designed to mirror the real life situations, in which pharmacists may choose to refer to information sources during consultations. As the pharmacist may be completing the survey away from their usual place of

consultation and may not have access to the materials they would usually use, information on how to access the aRMMs will be provided after the screening process and before the scenario section of the questionnaire.

It will be possible to complete the survey on a desktop, tablet or mobile device. However, pharmacists will be advised to complete the survey on a desktop device for a better user experience.

The pharmacist survey will take approximately 15 minutes to complete and will have to be completed in one sitting. However, a survey timer will be set for 60 minutes to allow respondents to take a break if required. During this time, the survey will remain open: respondents will not be able to save it and return to it later. Respondents will be informed about the length of the survey and that it must be completed within one hour.

Pharmacists invited to participate in the study will agree to abide by the Adverse Events (AE) reporting requirements of both Maxwellia Ltd and Laboratoire HRA Pharma by submitting to Maxwellia Ltd or Laboratoire HRA Pharma an incident report, either anonymously or with their personal contact details. Participants will also agree to take part in the research voluntarily, supplying their information for the purposes of the study and within the CIG Research privacy rules.

The survey will be conducted online using proprietary market research questionnaire software. The survey has been designed with reference to both companies and scripted for completion by community pharmacists. The questionnaire will be accessed by means of a secure URL link, which will be sent in an email invitation to CIG Research's opt-in panel of pharmacists. The sample of 200 respondents to the survey will be quota controlled to be nationally representative of community pharmacists in the UK.

Both Maxwellia Ltd and Laboratoire HRA Pharma have provided aRMM tools to all UK pharmacies, so participants in the survey will have had access to and will recall reading the material provided by at least one of the two companies during the six months prior to the study. All participants will have conducted at least one consultation with a female customer for the supply of desogestrel 75 microgram film-coated tablets in the six months prior to the survey being conducted.

9.1.2 Success Criteria

The aRMMs will be deemed effective if the following criteria are met:

- An average of at least 80% of pharmacists correctly advise whether to supply or not supply DSG for each of the eight case study scenarios. In order to allow for ±<6.9% statistical precision (see table 2), the KPI will be deemed achieved at 73.2% plus;
- The total number of correct answers across all scenarios should exceed 80% . In order to allow for ±<2.5% statistical precision (see table 2), the KPI will be deemed achieved at 77.6% plus. This means that 1242 correct answers out of the 1600 answers will be achieved.

Table 1. Example of success criteria analysis

	Answered correctly	Answered incorrectly
Scenario 1	170 (85%)	30 (15%)
Scenario 2	190 (95%)	10 (5%)

Scenario 3	150 (75%)	50 (25%)
Scenario 4	180 (90%)	20 (10%)
Scenario 5	160 (80%)	40 (20%)
Scenario 6	200 (100%)	0 (0%)
Scenario 7	140 (70%)	60 (30%)
Scenario 8	190 (95%)	10 (5%)
TOTAL	1380	220
Average	86.25%	13.75%

The above example shows that aRMMs are effective because, on average, 86.25% of the pharmacists provided correct answers across all scenarios, equivalent to 1380 out of 1600 correct answers. While the average correct answer rate is above the 80% (±<2.5%) threshold across the eight scenarios, there is one (scenario7) which is below the threshold. In this instance, detailed analysis of which segment of pharmacists underperformed will be conducted, including e.g.:

- How many consultations these respondents estimate that they have conducted
- How they differ (if at all) from the main sample in terms of their demography, location, length of service and outlet type. Given that this may be based on small sub-samples (in the above example, at scenario 7, it is 60 respondents), this will be a qualitative analysis
- Level of confidence about advising patients and about supplying desogestrel 75 microgram film-coated tablets relative to the sample average
- Self-rated knowledge of the product
- Usefulness rating of the materials.

Should any scenario fall below the 80% (>-6.9%) answering correctly threshold, appropriate changes will be made to the aRMM tools. In the above example, scenario 7 did not pass the threshold, so the information relating to this scenario in the training materials would be amended. Any changes will take account of which wrong answer is selected by those giving incorrect answers in each scenario where the threshold is not met. Scenario 3 met the criteria as 75% is within the 6.9% statistical error for 80% threshold on 200 sample (73.2% plus).

9.2 Setting

Desogestrel 75 microgram film-coated tablets received its product licence in the UK in 1998 and has been available as a prescription only (POM) medicine since then. Since July 2021, it has been available as a pharmacy (P) medicine for women to purchase from pharmacies under the brand names Hana and Lovima. As a P medicine, desogestrel 75 microgram film-coated tablets can only be supplied through registered pharmacies under the personal supervision of a pharmacist. It is the pharmacist's role to help women assess whether desogestrel 75 microgram film-coated tablets is a suitable contraception option for them. Pharmacists are required to check that there are no contraindications to supply and to know when to refer women to their doctor for further advice.

9.2.1. Method of Pharmacist Recruitment for Participation

The study objectives will be accomplished by means of a cross-sectional survey of all targeted pharmacists that received and read the aRMM materials supplied for Hana and Lovima in the UK. Invitations will be sent by email to pharmacists from CIG Research's opt-in panel of 12,500 UK community pharmacists. Response rates of 2-3% are typical in studies of this type and length.

Information on this panel is held on CIG's cloud-based servers and updated continuously to ensure all unsubscribes are removed and new participants wishing to join the panel are classified according

to their job title, location and outlet type. When invitations are sent to participate in this survey, the panel stratification classification may be used to boost responses from under-represented segments in collected responses, by encouraging pharmacists in those segments to take part.

The respondents' understanding of the appropriate use and risks of desogestrel 75 microgram film-coated tablets will be evaluated using an online survey. Each invitation will include information on how to access the survey online.

CIG Research will compensate pharmacists for their time spent completing the survey in the form of reward points, which can be redeemed for vouchers. This remuneration programme is independent of Maxwellia Ltd and Laboratoire HRA Pharma, and is governed by UK laws and regulations.

9.2.2. Inclusion Criteria

All respondents invited to participate will be qualified pharmacists working in community pharmacies in the UK, will have read at least one of the aRMM materials and held at least one consultation with a female customer regarding the supply of desogestrel 75 microgram film-coated tablets in the previous six months. The sample will aim to be representative of community pharmacists by age, gender, outlet size, and by region within the UK, including Northern Ireland.

Respondents will be invited to participate on the basis that they meet and confirm their acceptance of the inclusion criteria:

- Their information will only be used for research purposes and will not be passed to any other organisation without their permission;
- They have the right to refuse to answer questions or withdraw at any time. They consent to CIG Research collecting and using the information that they voluntarily provide for the purposes of research;
- They understand that if they become aware of any AEs during the course of the study, they will report these to CIG Research, who will pass their comments to the client about whose products they relate. They may choose to have these passed on anonymously or with their contact details, which will be collected at the end of the survey.

9.2.3. Exclusion Criteria

Pharmacists will not be included in the study if they:

- Have not received and read the aRMM materials supplied for the products in the UK, or do not recall having received or read them;
- Have participated in the user testing of the draft questions for the survey (described in Section 9.4.4: User and pilot testing of the survey questions);
- Are employed in full-time research, GP practices or hospitals (i.e. not community-based pharmacists);
- Work only as online pharmacists and do not provide consultations;
- Are in the employment of or are contracted to the MHRA, Maxwellia Ltd, Laboratoire HRA Pharma, Communications International Group or Consensio LLP.

9.3 Variables

The variables for analyses will be derived from the study data to address the objectives outlined in Section 8: Research Questions and Objectives, as follows:

- Assessment of pharmacists' knowledge/understanding of how to supply desogestrel 75 microgram film-coated tablets to patients
- Utilisation of the aRMM materials during consultations
- Accessibility of each of the aRMMs to the pharmacist
- Confidence about advising customers on the use of desogestrel 75 microgram film-coated tablets
- Usefulness of the aRMMs.

9.4 Data Sources

A structured, self-administered questionnaire comprised of closed and open ended questions or statements with multiple response choices (i.e. questions or statements asking the pharmacists to choose from a defined list of responses) will be used to collect the survey data. Questions will be asked in an order which provides a 'funnel' from general introductory topics towards the scenario-based questions, which constitute risk knowledge responses, on which KPIs have been set. Open ended questions will be included to collect qualitative responses showing reasoning for previously provided answers.

The questionnaire will collect data on pharmacist characteristics (i.e. job title, outlet type, region), and their responses to the scenario-based risk knowledge questions. The data collected from the survey will be used to inform the evaluation of the effectiveness of the aRMMs.

The questionnaire will begin with screening questions to confirm eligibility. Depending on the answers to the screening questions, survey participation will either be terminated or continued. If ineligible, the respondent will be immediately notified with a 'thank you' message that survey participation has ended. If eligible, the respondent will be allowed to continue survey participation.

The full questionnaire can be found in **Annex 3**.

9.4.1 Screening questions for pharmacists

The following question types will be used to screen out respondents:

- Consent to participate
- Consent to report AEs
- Job title – to include pharmacists and exclude other roles within community pharmacy
- Whether the pharmacist has had at least one consultation with a female customer about the supply of desogestrel 75 microgram film-coated tablets as oral contraception during the six month period preceding the study
- Whether the pharmacist recalls reading one or both sets of aRMMs in the six months prior to the survey
- Whether they are employed by or contracted to the MHRA, Laboratoire HRA Pharma, Maxwellia Ltd, Communications International Group or Consensio LLP.

Pharmacists who have taken part in testing the aRMMs or in user testing of the survey questionnaire will be screened out of the invitation to participate.

9.4.2 Data on pharmacist demographic characteristics

The following question types will be used to collect demographic characteristics data:

- Outlet type
- Brand of multiple outlet
- Location of pharmacy
- Job title within the pharmacist cohort – supervisor/manager/proprietor/locum/pharmacist
- Length of time practising as a community pharmacist
- Age of respondent
- Gender of respondent.

9.4.3 Data pertaining to evaluation of the effectiveness of the aRMMs

The questionnaire includes eight case study scenarios in the form of short representations of typical situations in which a patient requests desogestrel 75 microgram film-coated tablets and is either supplied or not supplied, based on their presentation. In each case, the option to “supply” or “do not supply” will be chosen by the respondents and will be correct or incorrect. The number of correct responses to each scenario will assess the knowledge of the pharmacists. The knowledge level analysed using descriptive statistics and confidence intervals will be used to determine the effectiveness of the aRMMs. In the case of incorrect responses to the case study questions, respondents will be provided with the correct response for their information. In the case of correct responses, they will be informed that their response was correct.

Additional evaluation measures will include:

- Reading and utilising of each of the aRMMs among participants
- Ease of access to the aRMMs in the pharmacy during consultations
- Use of consulting facilities in the pharmacy
- Level of confidence in advising patients on the use of desogestrel 75 microgram film-coated tablets and correct supplying
- Self-rated knowledge/comprehension of the use of desogestrel 75 microgram film-coated tablets and correct supplying.

9.4.4 User and pilot testing of the survey questions

Ahead of the pilot and main study launch, in September 2021, the proposed questions for the survey were user tested with 5 pharmacists in the UK to establish that questions were clearly understood and what the average completion time of the survey was. These respondents will be excluded from the main survey. This user testing included an open ended question about the flow and ease of use of the questionnaire, and specifically the case study scenarios. This user testing ran successfully and didn’t identify any major issues. Following the user testing, one change was recommended to the wording of question: "Which, if any, of these organisations have you worked for or been contracted to in the last year", to be altered to: "Which, if any, of these organisations have you been employed by or contracted to in the last year" to clarify that “worked for” was intended to mean “employed by”, as opposed to having had dealings with. The amendment was made and the questionnaire was then assessed in a full pilot study.

The pilot study was conducted with 30 pharmacists who completed the survey, in order to evaluate the quality of data produced by respondents and to ensure that the study leads to meaningful results. This included evaluating each of the case study scenarios in terms of the answers given and whether they differentiate clearly between correct and incorrect answers. Given the pilot sample size of 30 responses, the statistical validity of correct answer rates on the scenarios were limited, and only indicated approximate levels of success or failure in each case. The pilot also assessed whether the process runs successfully and that all biases in question wording, scale responses and order effect were mitigated - i.e. all questions were answered and not skipped, open ended

questions were filled in correctly, and the survey flow, routing and question logic ensured efficient and considered responses.
Participants in this this pilot study were recruited from a random sample of approximately 1000 pharmacists invited from the CIG Research panel in order to establish response rates based on the inclusion criteria above. The sample of 30 responses was based on the expected response rate of 3% on 1000 targets, assuming a large proportion of pharmacists have read the aRMMs and were eligible to participate. The pilot was used to predict response rates for the full survey. 30 responses allowed effective assessment of the value and meaningfulness of responses to the survey. Within a sample of 30 responses, a variety of job titles, genders, ages, and multiple and independent outlet pharmacists would be expected.

The quality of the data collected in the pilot was analysed and any issues or shortcomings in the questionnaire design were reported. Fieldwork and data analysis of the pilot took four weeks from the pilot study launch. A report with results of the pilot study was provided to Maxwellia and HRA and changes were suggested for the questionnaire and in the protocol. If the quality of pilot data met the criteria described above and meaningful results were achieved, no changes to the protocol or questionnaire would be required, and the pilot sample data would be combined with the main study data to produce the final report. It would be acceptable to do this as the pilot study was conducted using the same software, questionnaire and recruitment methods as the main study, with the same high quality data being collected. The only difference was that the pilot was conducted 3 months before the main study, but this is not deemed to be a major limitation. However, the quality of the completed pilot data did not meet the criteria described above, an updated protocol and pilot study report were provided to the MHRA within four weeks. The pilot sample of 30 respondents will not be counted in the main study.

9.4.5 Data collection process

CIG Research will send invitations by email to its opt-in members of its pharmacist panel with a unique URL link to the online survey for each panel member, which will be hosted in the electronic surveying system QuestionPro. Responses may be completed on desktop, tablet or mobile devices, with the survey limited to one response per participant.

The email invitation (example in **Annex 1**) will include an overview of the rationale for the study and a URL link to the survey. Survey data collection will be open for a maximum of 30 days. The survey study date will begin six months after the first product launch.

All questions will be validated (compulsory to complete) within the surveying system. This means that respondents will not be able to complete the survey unless they have answered all questions. The survey will have to be completed in one sitting. However, the survey timer will be set for 60 minutes to allow respondents to take a break. The vast majority of surveys are completed ‘at one sitting’, but given that this questionnaire will be approximately 15 minutes long, it is possible that the break will be required. In this case, the survey will have to remain open as it will not be possible to close the survey and return to it later. All invitees will be notified about the length of the survey in the invitation.

Questions will be programmed to ensure that they are asked in the appropriate sequence. Skip patterns will be clearly indicated. Respondents cannot go back to a question once the question has been answered and they cannot skip ahead. Response options will be presented in randomised lists to minimise positional bias. Programming was reviewed by Quality Control and simulated users (user testers) prior to implementation.

The first invitation will be sent to all panel members whose job title is within the pharmacist cohort. During the fieldwork, it is anticipated that the majority of responses will come in within the first

week, and reminders will be sent to pharmacists who have not started the survey after 3-7 days (see section 9.4.6).

Responses will be collated automatically within the survey software and will be monitored throughout the fieldwork process. The CIG Research team will check the flow of responses, any aberrant responses, and the number of minutes each respondent takes to complete the questionnaire. Once the sample has been achieved, with 200 respondents having completed the survey, it will be closed to further respondents.

In the case of potential AE reporting during fieldwork, a survey email address will be provided for respondents wishing to contact CIG Research. This will be checked at least twice daily for AE comments, which will be reported to the client(s) within 24 hours.

9.4.6 Follow-up reminder process

It is expected that two reminders will be required to achieve the sample defined above (2-3% response rate), with those who have already responded having been removed from the reminder process. The intervals between reminders will be approximately 3-7 days.

Further reminders to boost sampling will be issued should there be a shortfall in numbers within any segments, where specific sub-samples are under-represented in the collected responses (e.g. certain age groups, regions or outlet types). CIG Research will monitor the responses, and should any segment not achieve a sufficient number of responses, reminder invitations will be sent to specifically targeted panel members who have not yet started the survey. Filters will be used to target only profiles that match under-represented criteria (e.g. those who are 'female' or 'age 50+'). In order to attract these non-respondents to start and complete the survey, the incentive will be increased by 50%. This is expected to achieve the full sample successfully. If any sample group is still under-represented, CIG Research will explore the remaining of its panel further, in order to get desired results.

9.4.7 Respondent remuneration

CIG Research's panel of opt-in pharmacists are compensated for their time participating in surveys throughout the year. CIG Research funds this programme from its commercial research, and there is no link to individual clients in the process. CIG Research's pharmacist panel receive points for surveys completed. When they have accumulated 500 points, they may redeem these against Amazon vouchers. The number of points issued for a survey is usually proportionate to the length of the questionnaire and difficulty in obtaining the sample.

9.5 Study size

This section presents sample size and precision of the estimate calculations for various survey sample sizes. The precision of the estimate calculations are based on the following assumptions:

- The confidence intervals (CIs) around the estimate are two-sided
- The probability of type-I error (alpha) is 5%
- The table below provides precision of the estimate (width of 95% CI around the estimate) for a range of sample sizes at or around the 50% mark, which is the least accurate point in the standard deviation curve.

Table 2. Sample size obtained for various precisions

Sample size	Statistical precision (%)
100	± 9.8

150	± 8.0
200	± 6.9
250	± 6.2
300	±5.7
1600 (total case studies)	± 2.5

The sample size chosen for this study is dependent on statistical and feasibility considerations. On the basis of the maximum feasible sample size achievable within the scope of this study, and the relative precision of this dataset, a sample of 200 pharmacists has been chosen. It may be necessary to over-sample up to 250 in order to achieve the 200, based on 80% having read aRMMs and conducted at least one consultation with a patient on desogestrel 75 microgram film-coated tablets in the six months prior to the survey. This represents a response rate of approximately 2% of the CIG Research panel and is typical of the response rates achieved for questionnaires of 12-20 minutes' length.
Each respondent will be shown eight case study examples of consultations, and will answer corresponding questions. The 200 responses will generate a combined response to 1600 case studies, which will be taken together to measure the proposed success criteria, with a variance of ± 2.5% on 1600 responses.

9.6 Data management

All data collected during the study will be held confidentially by CIG Research using an electronic data collection system called QuestionPro. This system encrypts all identifiable information, and respondent identifiers are stored separately from survey responses.

To minimise data entry errors, skip logic for certain questions as well as the ability to mark only one response or multiple responses, as appropriate, form part of the survey programming. There will be no follow-up queries to respondents for this project. Detailed management of data is described in section 9.8 Quality control.

9.7 Data analysis

The threshold of 80% correct answers to supply or not supply desogestrel 75 microgram film-coated tablets in the eight case studies has been set as a KPI on the basis that previous analysis of comparable PASS studies has shown that receipt and use rates for RM tools among HCPs rarely exceed 80%[3], whereas percentages of correct knowledge of key safety messages mostly lie between 70% and 90%. On this basis, a threshold of 80% has been set as an average across the eight case studies, rather than on each case study.

On completion of the fieldwork, all data will be checked and validated to ensure that any erroneous or duplicated responses are excluded. Data extraction for the total sample and for each segment within the sample will be carried out and CIG Research will compile a series of tables and charts for the final report, combining and comparing segments as appropriate. Detailed commentary will be provided for each table and each chart, explaining the data, interpreting it and drawing appropriate conclusions.

Data segmentation will also be generated for key variables, each of which have a minimum sample size of 30 responses (e.g. splitting the sample by gender and age, outlet type and job title). In addition, key segments can be generated against specific answers.

Detailed methodology for summary and statistical analyses of data collected in this study will be included in the report on the survey.

Data collected from the survey will be reported as descriptive statistics. Frequency distributions with 95% CIs will be calculated for pharmacist responses to all questions that address the survey objectives.

CIG Research will apply all appropriate statistical validation to the recommended sampling approach, to the quota setting and recruitment processes. 100% of responses will be validated to ensure quality of completion, non-replication (i.e. ballot-stuffing) and response to all questions by all respondents.

Open ended questions will be analysed using the standard market research process of generating code frames. In this case, each open ended answer will be broken down into the individual statements it makes, and each statement will be given a code, such that all respondents making the same or very similar comments will be allocated that code. One respondent may make many statements within their answer and may therefore generate several codes, so the total number of coded answers usually exceeds 100% of the sample size. Once all respondents' answers are coded, there will be a residue of disparate 'other answers', which usually constitutes less than 5% of the total. In excess of 95% of the total will have been coded with (typically) between 10 and 20 codes in the code frame. The full study analysis will include the following statistics, including metrics for survey administration:

- The number and percentage of target respondents within the CIG Research opt-in panel who are invited to participate; number of invitations sent in total;
- The number and percentage of invitees who open the invitation but do not proceed to participate in the survey; open and click through rates;
- Reasons for ineligibility – i.e. the number opening the survey and commencing responses but who are ruled ineligible on the grounds of not recalling receiving and reading the aRMMs, job title, outlet type or agreement to have their data included;
- The number and percentage commencing the survey but failing to complete other than through eligibility – drop-outs;
- Final number of survey completions;
- The number and percentage of pharmacists by job title and outlet type who completed the survey;
- The comparative profile of pharmacists who gave correct or incorrect responses to the eight case study scenarios in terms of their demography;
- The demographic characteristics of those participating – e.g. age, gender, years since qualifying;
- Pharmacist responses to questions pertaining to the survey objectives:

    - Pharmacists' knowledge/understanding of the risks associated with the supply of desogestrel 75 microgram film-coated tablets
    - The number and percentage of pharmacists who correctly responded to each scenario about the risks of supplying desogestrel 75 microgram film-coated tablets
    - Recall of reading and utilising the aRMMs
    - Utilisation of the aRMMs during consultations
    - Number of consultations in the last six months
    - Location of consultations within the pharmacy.

Detailed analysis will be carried out for each scenario. Where the percentage of pharmacists answering a scenario question correctly is below the level defined to represent success, the training materials relating to that scenario will be reviewed and improved as appropriate. **Annex 4** includes risks and contraindications that are covered in the scenarios and four corresponding answer options.

All scenario answers will be analysed and the percentage proportion of correct versus incorrect answers will be shown. If less than 80% correct answers are provided, the aRMMs have not passed the success criteria and the relevant training materials will be amended. There are three possible incorrect answers for each scenario question. If one incorrect answer is overperforming, related section in training materials will be updated, but if all three incorrect answers over-index to a statistically significant level at the 95% confidence limit applied to all analysis of this data (see table 2), changes will be made in all of them.

Given that the aRMMs from both brands are closely aligned, and that pharmacists may forget or be mistaken as to which set they have used, both sets of materials will be amended as appropriate if an issue is identified.

The report will include a detailed executive summary, together with conclusions and recommendations in line with the information required for the EMA PASS template for the final study report.

9.8 Quality control

The study will be conducted in accordance with all applicable regulatory requirements. The testing will also be conducted in accordance with all applicable subject privacy requirements (including European GDPR), and the guiding principles of the current version of the Declaration of Helsinki.

Documentation of all data management activities will allow step-by-step retrospective assessment of data quality and performance. Management of data will be performed in accordance with applicable standards (including MHRA *'GXP' Data Integrity Guidance and Definitions*[4]) and data cleaning procedures to ensure the integrity of the data (e.g. removing errors and inconsistencies in the data).

The survey data will be collected using a secure online data entry system. The proposed system has been validated and is secure for receiving and storing survey data. A cloud-based data repository will be used to warehouse survey data and other relevant programme information. This platform ensures compliance with Annex 11 *EudraLex The Rules Governing Medicinal Products in the European Union*[5] for the entry, storage, manipulation, analysis and transmission of electronic information.

The system is integrated with dashboard reporting services to enable real time access to data collected online. All data entered will be single data entered by the respondent. Data will be checked in real time against the programmed edit specifications as they are entered to ensure that data are being entered according to acceptable parameters and requirements. Data exported into Excel for the purposes of generating presentation charts for reporting will be aggregated and not manipulated in any way that alters the results of the survey, and will match the data held within the secure online data entry system. All versions generated will be dated, kept with accompanying documentation and archived. This archived data will be available for independent audit throughout the study and retrospectively.

9.9 Limitations of the research methods

It is a limitation that the participating pharmacists will be self-selected since respondents will voluntarily respond to the invitation to participate. However, the survey recruitment strategies are intended to recruit a representative sample. All data from the survey are self-reported and therefore

susceptible to possible reporting bias. There could be discrepancies between what pharmacists report about their practices and their actual behaviours. In this case, it would be difficult to validate whether pharmacists' responses to practice-related questions completely concur with their actual behaviours since this is a self-reported survey.

A secondary limitation inherent in survey research is the reliance on the respondent's recall of whether or not the aRMM materials were read and utilised. If respondents say they did not read and utilise the aRMMs, they will be screened out. It is possible that pharmacists may simply not recall the tools that were received and read. It is possible that removing those who do not recall reading the aRMMs will reduce the overall sample size, depending on the proportion of all pharmacists eligible to participate in the survey.

Given that this study is being conducted jointly on behalf of two companies whose products and support information are provided to pharmacies in the UK, it is likely that a small proportion of respondents may be confused as to which company's product is which and which company has supplied which support materials. In this case, it is not envisaged that the two companies will receive different analyses based on their brands, although the survey questionnaire does include awareness questions for both brands, which will allow for segmentation by brand. An option for 'brand unknown' is included in the survey questions, so respondents can select that if they are not sure which brand's materials they have used.

The objective of this PASS is to measure the effectiveness of the pharmacy training materials. This study will look at two process indicators: a) reaching the target population and b) assessing clinical knowledge. These process indicators are intended to provide insight into to what extent the dissemination of pharmacy materials has been executed as planned and whether the intended measures impact on behaviour.

For the switch of desogestrel from POM to P, where it is not feasible for the two applicants to obtain data on outcome indicators for reductions in adverse events, effectiveness evaluation of this PASS is exclusively based on the careful interpretation of data on process indicators. Situations like these are acknowledged in the *Guideline on good pharmacovigilance practices Module XVI*[6], where measurement of effectiveness may need to rely on process indicators instead of outcome indicators.

10. Protection of human subjects

All parties will ensure protection of pharmacists' personal data and will not include names on any client forms, reports, publications, or in any other disclosures, except where required by laws. In the case of data transfer, parties will maintain high standards of confidentiality and protection of pharmacist data. In the specific case of AE reporting, respondents are required to give their permission for information to be passed to the appropriate company (see Section 11, below).

Due to the nature of the study, informed consent is not required. Participants need to go to the survey website in order to complete the survey. Consent is implied by these actions. Additionally, at the beginning of the survey, the respondent will be asked if they agree to take part in the survey. If yes, the respondent continues with the survey questions. If no, the survey is terminated.

11. Management and reporting of adverse events/adverse reactions

This study does not involve data collection on clinical endpoints on individual patients. However, safety information may be identified during the course of data collection (e.g. through an email note

to CIG Research). Any safety information for an individual patient that is volunteered by a study participant during the course of this research will be reported as described below.

The following safety events must be reported on the NIS AE monitoring report form: serious and non-serious adverse events associated with the use of the Maxwellia or Laboratoire HRA Pharma products, and scenarios involving exposure during pregnancy, exposure during breast feeding, medication error, overdose, abuse, misuse, lack of efficacy and occupational exposure (all reportable, regardless of whether associated with an AE), when associated with the use of a Maxwellia or Laboratoire HRA Pharma product. These AEs will be reported to the appropriate client as outlined above (Section 9.4.5).

In the case of AE reporting, it is envisaged that wherever possible, each company will receive information pertaining to their own brand and will not receive information pertaining to their competitor's brand. Where it is not possible to identify which brand an AE refers to, both companies will receive the AE information.

12. Plans for disseminating and communicating study results

A final report describing the survey objectives, detailed methods, results, discussion and conclusions will be developed at the end of the survey for submission to the MHRA within the timeframe specified in 'Section 6: Milestones.' In addition, the study results will be posted on the EU PAS register.

13. References

5. Hana Summary of Product Characteristics (SmPC) https://www.medicines.org.uk/emc/product/12735/smpc
6. Lovima Summary of Product Characteristics (SmPC) https://www.medicines.org.uk/emc/product/12736/smpc
7. EMA/DIA Information Day, 2017: Preliminary results of a cumulative systematic review and meta-analysis of risk minimisation survey studies Minutes of the PRAC meeting 6-9 March 2017 (europa.eu)
8. MHRA *'GXP' Data Integrity Guidance and Definitions* letter (publishing.service.gov.uk)
9. EudraLex: The Rules Governing Medicinal Products in the European Union, Volume 4 *Good Manufacturing Practice Medicinal Products for Human and Veterinary Use*, Annex 11: Computerised Systems Annex 11 Final 0910 (europa.eu)
10. Guideline on good pharmacovigilance practices (GVP) – Module XVI – Risk minimisation measures: selection of tools and effectiveness indicators (Rev 2) (europa.eu)

Appendix 1.1 - Annex 1. Example invitation to participate in the survey

Dear Pharmacist,
This survey has been requested by the MHRA as part of a post-authorisation safety study (or PASS) among pharmacists in relation to the recent switch of desogestrel 75 microgram film-coated tablets from POM to Pharmacy (P). As this is a new category of medicine available as a P medicine, the MHRA has requested a PASS study to be conducted.

The study reviews the information and training you may have received about the product to enable you to correctly advise patients and mitigate risk, using a series of scenarios for you to consider. The scenarios have been developed to ensure a clear understanding of the product and ability to supply appropriately in different situations. It is important that you take your time answering the questions.

This survey should take approximately 15 minutes to complete and it will have to be completed in one sitting within 60 minutes. Please do not close the survey until you have completed it as you will not be allowed to re-open it. It is possible to complete the survey on a desktop, laptop, tablet or mobile device, but we recommend completing it on your desktop for the best experience.
When the survey fieldwork ends, you will receive **Reward Points** in appreciation of your time and cooperation, which can be redeemed against Amazon vouchers.

Start survey

Many thanks for your ongoing support. We will have one or two more surveys launching in the next month, and you can add to your points total by participating. Please look out for your invitations to these.

Please make sure to complete the survey, fill in your details and opt in to receive your Reward Points. To check your accumulated Reward Points, please email rewardpoints@1530.com

Your help is greatly appreciated.

Yours faithfully,

Adrian Wistreich
Research Director

Appendix 1.1 - Annex 2. ENCePP checklist for study protocols

Study title:
Assessment of the effectiveness of additional Risk Minimisation Measures (aRMMs) among pharmacists for provision of desogestrel 75 microgram film-coated tablets in a community pharmacy setting

EU PAS Register® number:
Study reference number (if applicable):

Section 1: Milestones	**Yes**	**No**	**N/A**	**Section Number**
1.1 Does the protocol specify timelines for				6
1.1.1 Start of data collection[1]	☒	☐	☐	
1.1.2 End of data collection[2]	☒	☐	☐	
1.1.3 Progress report(s)	☐	☐	☒	
1.1.4 Interim report(s)	☐	☐	☒	
1.1.5 Registration in the EU PAS Register®	☒	☐	☐	
1.1.6 Final report of study results	☒	☐	☐	

Comments:

Section 2: Research questions	**Yes**	**No**	**N/A**	**Section Number**
2.1 Does the formulation of the research questions and objectives clearly explain:	☒	☐	☐	
2.1.1 Why the study is being conducted? (e.g. to address an important public health concern, a risk identified in the risk management plan, an emerging safety issue)	☒	☐	☐	7
2.1.2 The objective(s) of the study?	☒	☐	☐	8
2.1.3 The target population? (i.e. population or subgroup about whom the study results are intended to be generalised)	☒	☐	☐	9
2.1.4 Which hypothesis(es) is(are) to be tested?	☐	☐	☒	
2.1.5 If applicable, that there is no *a priori* hypothesis?	☐	☐	☒	

[1] Date from which information is first recorded in the study dataset or, in the case of secondary use of data, the date from which data extraction starts.
[2] Date from which the analytical dataset is completely available.

Comments:

Section 3: Study design		**Yes**	**No**	**N/A**	**Section Number**
3.1	Is the study design described? (e.g. cohort, case-control, cross-sectional, other design)	☒	☐	☐	9
3.2	Does the protocol specify whether the study is based on primary, secondary or combined data collection?	☒	☐	☐	
3.3	Does the protocol specify measures of occurrence? (e.g. rate, risk, prevalence)	☐	☐	☒	
3.4	Does the protocol specify measure(s) of association? (e.g. risk, odds ratio, excess risk, rate ratio, hazard ratio, risk/rate difference, number needed to harm (NNH))	☐	☐	☒	
3.5	Does the protocol describe the approach for the collection and reporting of adverse events/ adverse reactions? (e.g. adverse events that will not be collected in the case of primary data collection)	☒	☐	☐	11

Comments:

Section 4: Source and study populations		**Yes**	**No**	**N/A**	**Section Number**
4.1	Is the source population described?	☒	☐	☐	9
4.2	Is the planned study population defined in terms of:				9
	4.2.1 Study time period	☒	☐	☐	
	4.2.2 Age and sex	☐	☐	☒	
	4.2.3 Country of origin	☒	☐	☐	
	4.2.4 Disease/indication	☐	☐	☒	
	4.2.5 Duration of follow-up	☒	☐	☐	
4.3	Does the protocol define how the study population will be sampled from the source population? (e.g. event or inclusion/exclusion criteria)	☒	☐	☐	9

Comments:

Section 5: Exposure definition and measurement		**Yes**	**No**	**N/A**	**Section Number**
5.1	Does the protocol describe how the study exposure is defined and measured? (e.g. operational details for defining and categorising exposure, measurement of dose and duration of drug exposure)	☐	☐	☒	

Section 5: Exposure definition and measurement		**Yes**	**No**	**N/A**	**Section Number**
5.2	Does the protocol address the validity of the exposure measurement? (e.g. precision, accuracy, use of validation sub-study)	☐	☐	☒	
5.3	Is exposure categorised according to time windows?	☐	☐	☒	
5.4	Is intensity of exposure addressed? (e.g. dose, duration)	☐	☐	☒	
5.5	Is exposure categorised based on biological mechanism of action and taking into account the pharmacokinetics and pharmacodynamics of the drug?	☐	☐	☒	
5.6	Is (are) (an) appropriate comparator(s) identified?	☐	☐	☒	

Comments:

Section 6: Outcome definition and measurement		**Yes**	**No**	**N/A**	**Section Number**
6.1	Does the protocol specify the primary and secondary (if applicable) outcome(s) to be investigated?	☒	☐	☐	8
6.2	Does the protocol describe how the outcomes are defined and measured?	☒	☐	☐	9.7
6.3	Does the protocol address the validity of outcome measurement? (e.g. precision, accuracy, sensitivity, specificity, positive predictive value, use of validation sub-study)	☒	☐	☐	9
6.4	Does the protocol describe specific outcomes relevant for Health Technology Assessment? (e.g. HRQoL, QALYs, DALYs, healthcare services utilisation, burden of disease or treatment, compliance, disease management)	☐	☐	☒	

Comments:

Section 7: Bias		**Yes**	**No**	**N/A**	**Section Number**
7.1	Does the protocol address ways to measure confounding? (e.g. confounding by indication)	☐	☐	☒	
7.2	Does the protocol address selection bias? (e.g. healthy user/adherer bias)	☒	☐	☐	9.9
7.3	Does the protocol address information bias? (e.g. misclassification of exposure and outcomes, time-related bias)	☐	☐	☒	

Comments:

Section 8: Effect measure modification	**Yes**	**No**	**N/A**	**Section Number**
8.1 Does the protocol address effect modifiers? (e.g. collection of data on known effect modifiers, sub-group analyses, anticipated direction of effect)	☐	☐	☒	

Comments:

Section 9: Data sources	**Yes**	**No**	**N/A**	**Section Number**
9.1 Does the protocol describe the data source(s) used in the study for the ascertainment of:				
9.1.1 Exposure? (e.g. pharmacy dispensing, general practice prescribing, claims data, self-report, face-to-face interview)	☒	☐	☐	9
9.1.2 Outcomes? (e.g. clinical records, laboratory markers or values, claims data, self-report, patient interview, including scales and questionnaires, vital statistics)	☒	☐	☐	9
9.1.3 Covariates and other characteristics?	☐	☐	☒	
9.2 Does the protocol describe the information available from the data source(s) on:				
9.2.1 Exposure? (e.g. date of dispensing, drug quantity, dose, number of days of supply prescription, daily dosage, prescriber)	☐	☐	☒	
9.2.2 Outcomes? (e.g. date of occurrence, multiple event, severity measures related to event)	☐	☐	☒	
9.2.3 Covariates and other characteristics? (e.g. age, sex, clinical and drug use history, co-morbidity, co-medications, lifestyle)	☐	☐	☒	
9.3 Is a coding system described for:				
9.3.1 Exposure? (e.g. WHO Drug Dictionary, Anatomical Therapeutic Chemical (ATC) Classification System)	☐	☐	☒	
9.3.2 Outcomes? (e.g. International Classification of Diseases (ICD), Medical Dictionary for Regulatory Activities (MedDRA))	☐	☐	☒	
9.3.3 Covariates and other characteristics?	☐	☐	☒	

Section 9: Data sources	**Yes**	**No**	**N/A**	**Section Number**
9.4 Is a linkage method between data sources described? (e.g. based on a unique identifier or other)	☐	☐	☒	

Comments:

Section 10: Analysis plan	**Yes**	**No**	**N/A**	**Section Number**
10.1 Are the statistical methods and the reason for their choice described?	☒	☐	☐	9.5
10.2 Is study size and/or statistical precision estimated?	☒	☐	☐	9.5
10.3 Are descriptive analyses included?	☒	☐	☐	8.3
10.4 Are stratified analyses included?	☐	☐	☒	
10.5 Does the plan describe methods for analytic control of confounding?	☐	☐	☒	
10.6 Does the plan describe methods for analytic control of outcome misclassification?	☐	☐	☒	
10.7 Does the plan describe methods for handling missing data?	☒	☐	☐	9.8
10.8 Are relevant sensitivity analyses described?	☒	☐	☐	9.8

Comments:

Section 11: Data management and quality control	**Yes**	**No**	**N/A**	**Section Number**
11.1 Does the protocol provide information on data storage? (e.g. software and IT environment, database maintenance and anti-fraud protection, archiving)	☒	☐	☐	9.6
11.2 Are methods of quality assurance described?	☒	☐	☐	9.8
11.3 Is there a system in place for independent review of study results?	☒	☐	☐	9.8

Comments:

Section 12: Limitations	**Yes**	**No**	**N/A**	**Section Number**
12.1 Does the protocol discuss the impact on the study results of:				
12.1.1 Selection bias?	☒	☐	☐	9.9
12.1.2 Information bias?	☒	☐	☐	9.9
12.1.3 Residual/unmeasured confounding? (e.g. anticipated direction and magnitude of such biases, validation sub-study, use of validation and external data, analytical methods)	☐	☐	☒	
12.2 Does the protocol discuss study feasibility? (e.g. study size, anticipated exposure uptake, duration of follow-up in a cohort study, patient recruitment, precision of the estimates)	☒	☐	☐	9

Comments:

Section 13: Ethical/data protection issues	**Yes**	**No**	**N/A**	**Section Number**
13.1 Have the requirements of the Ethics Committee/ Institutional Review Board been described?	☐	☒	☐	
13.2 Has any outcome of an ethical review procedure been addressed?	☐	☒	☐	
13.3 Have data protection requirements been described?	☒	☐	☐	10

Comments:

Section 14: Amendments and deviations	**Yes**	**No**	**N/A**	**Section Number**
14.1 Does the protocol include a section to document amendments and deviations?	☒	☐	☐	5

Comments:

Section 15: Plans for communication of study results	**Yes**	**No**	**N/A**	**Section Number**
15.1 Are plans described for communicating study results? (e.g. to regulatory authorities)	☒	☐	☐	12
15.2 Are plans described for disseminating study results externally, including publication?	☐	☐	☒	

Comments:

Name of the main author of the protocol: _____

Date: dd/Month/year

Signature: _____

Appendix 1.1 - Annex 3. Questionnaire design

SURVEY LEGEND

Instructions to the programmer who is tasked with scripting the survey into the survey software.
MULTI CODE is inserted for questions in which respondents may choose more than one option from the pre-defined list of answers.
SINGLE CODE is inserted for questions where only one answer is permitted from the pre-defined list of answers.
Close on codes (x-y) requires that those who choose any of the specified answers denoted by those codes will be redirected to terminate the survey because they are not eligible to continue. These respondents will receive a notification that they are not eligible to continue with the questionnaire.
OPEN ENDED An open ended question is a comment box in which respondents may write as much as they wish in answer to the question. Analysis of open ended questions follows the standard market research guidelines of generating code frames.

IF QA code (x or y) denotes that the following question will be filtered (i.e. visible) only to those who answered QA with a pre-defined answer which is attributed with the code (i.e. x or y).
SLIDER less than one to x describes the format for answering a question using a scale with x points, where a score of 0 is entitled 'less than one' and a score of x or more is entitled 'x plus'. A slider is a graphic response option within the survey software allowing respondents to drag their cursor to a specific point on this scale.
RANDOMISE Randomising is an option within survey software to ensure that each respondent sees the list of answers or names in a different (random) order, thus removing Order Effect from the survey. The software automatically re-combines the responses for each answer prior to presenting them for analysis.
QB PIPE FROM QA refers to the process of branching, whereby those who select options in QA are shown options pertaining to QA in QB.
REPEAT FOR X SCENARIOS repeat the same instruction for each of the x scenarios which appear in the survey.
SLIDER SUM 100% This is a feature within the survey software whereby respondents may attribute percentages to each of two or more answers, and the software will require their answers to add up to 100%. This feature uses the same slider visual described above.
SINGLE CODE GRID A single code grid is a matrix of scale questions where a respondent may answer only once per row in the matrix, and is required to do so.

INTRODUCTION

Dear Pharmacist,

This survey has been requested by the MHRA as part of a post-authorisation safety study (or PASS) among pharmacists in relation to the recent switch of desogestrel 75 microgram film-coated tablets from POM to Pharmacy (P), as this is a new category of medicine available as a P medicine.

The study reviews the information and training you may have received about the products to enable you to correctly advise patients and mitigate risk, using a series of scenarios for you to consider. The scenarios have been developed to ensure a clear understanding of the product and ability to supply appropriately in different situations. **It is important that you take your time answering the questions.**

This survey should take **approximately 15 minutes** to complete and it will have to be completed in one sitting within 60 minutes. Please do not close the survey until you have completed it as you will not be allowed to re-open it. It is possible to complete the survey on a desktop, laptop, tablet or mobile device, but we recommend completing it on your desktop for the best experience.

Upon completion of the questionnaire, you will receive Reward Points in appreciation of your time and cooperation.

Any information you provide will be treated as confidential. It will be combined with feedback from others like yourself. You will remain anonymous unless you give permission to be identified. Your information will only be used for research purposes, with the requirement that reports on aggregated results will be shared with health authorities, and will not be passed to any other organisation without your permission.

You have the right to refuse to answer questions or withdraw at any time. For more information about your rights, please see our privacy notice, available here: Privacy Policy

By proceeding to the next screen:

· I consent to CIG Research collecting and using the information about me that I voluntarily provide for the purposes of research.
· I have read, understand and agree to the terms described above.

a. YES, I am happy to proceed with the research survey on this basis
b. NO, I am not happy to proceed with the research survey on this basis and I do not wish to continue

This survey has been commissioned by healthcare manufacturers upon request from the MHRA. When working on their projects, we are required to report if any participant mentions an adverse event in relation to one of their products.
Should this happen, it would be necessary for us to complete a report and pass your comments to our clients so that they can investigate. We can submit a report anonymously or with your personal details. Please confirm whether you are happy to proceed:

a. Yes, I am happy to proceed, but please submit my report anonymously as I do not want the company to contact me

b. Yes, I am happy to proceed. Please submit the report with my personal details (name and e-mail address). I understand that the company may contact me for further information about the adverse event
c. No, I am not happy to proceed. I understand that this means I will not be able to continue with this survey – CLOSE

Which, if any, of these organisations have you been employed by or contracted to in the last year?

MULTI CODE Close on codes a-e

a. Maxwellia Ltd
b. Laboratoire HRA Pharma
c. Communications International Group
d. Consensio LLP
e. MHRA
f. None of these

DEMOGRAPHIC QUESTIONS

QA What is your job title?
SINGLE CODE Close on codes e-m

a. Pharmacist Proprietor
b. Pharmacist Manager / Supervisor
c. Pharmacist
d. Locum Pharmacist
e. Non-pharmacist Manager/Supervisor
f. Non-pharmacist Proprietor
g. Accuracy Checking Technician
h. Pharmacy Technician
i. Dispensing Assistant
j. Medicines Counter Assistant / Pharmacy Assistant / Beauty Counter Assistant
k. Healthy Living Advisor / Champion
l. Healthcare Advisor / Consultant
m. Other

QB. What type of outlet do you work in?
SINGLE CODE Close on codes g-j

a. One shop independent
b. Group branch shop (2 to 5 outlets)
c. Group branch shop (6 to 9 outlets)
d. Group branch shop (10 to 49 outlets)
e. Group branch shop (50 plus outlets)
f. Multiple head office
g. Hospital
h. GP practice pharmacy
i. Exclusively online pharmacy (no consultations)
j. Other

QC. IF QB code e or f Which multiple do you work in?
SINGLE CODE

a. Boots
b. LloydsPharmacy

c. Superdrug
d. Rowlands Pharmacy
e. Well Pharmacy
f. Day Lewis
g. Supermarket pharmacy
h. Other

QD. In what type of location is your pharmacy based?
SINGLE CODE

a. City centre
b. Town centre
c. Suburb
d. Village
e. Rural

QE. Where is your pharmacy?
SINGLE CODE

a. Scotland
b. Northern Ireland
c. Wales
d. North East
e. North West
f. Yorkshire and the Humber
g. West Midlands
h. East Midlands
i. South East
j. South West
k. East of England
l. Greater London

QF. What is your gender?
SINGLE CODE

a. Male
b. Female
c. Other
d. Prefer not to say

QG. What is your age?
SINGLE CODE

a. Under 25
b. 25-29
c. 30-34
d. 35-39
e. 40-44
f. 45-49
g. 50-54
h. 55-59
i. 60-64
j. 65 plus
k. Prefer not to say

QH. For how many years have you been qualified as a pharmacist?
SLIDER less than one to 30 plus

STUDY QUESTIONS

Q1. In the last six months, have you held any consultations regarding the supply of desogestrel 75 microgram film-coated tablets (DSG) in the pharmacy without a prescription?
SINGLE CODE Close on code b

a. Yes
b. No

Q2. In the last six months have you received and read training materials or consultation checklists regarding the supply of desogestrel 75 microgram film-coated tablets without a prescription to help minimise risk when having consultations?
SINGLE CODE Close on b and c

a. Yes, received and read
b. Yes, received but not read
c. No

Q3. Which, if any, of these materials have you read to help minimise risk when having consultations regarding the supply of desogestrel 75 microgram film-coated tablets without a prescription? **MULTI CODE Close if Pharmacy training guide or Checklist not selected**

RANDOMISE MULTI CODE	Hana	Lovima	Brand unknown
Pharmacy training guide	o	o	o
Consultation/ supply aid checklist	o	o	o
SmPC	o	o	o
Pack copy	o	o	o

Q4. How many consultations do you estimate that you have had with patients about non-prescription desogestrel 75 microgram film-coated tablets in the pharmacy in the last six months?
SLIDER from 1 to 200 plus (increments of 1)

Q5. When these consultations did not result in the supply of desogestrel 75 microgram film-coated tablets, what were the main reasons for this? *Please write in short descriptions and try to be very specific* **OPEN ENDED**

Q6. Where in the pharmacy are these consultations conducted?
SLIDER SUM 100%

a. In a private consultation area
b. At the pharmacy counter
c. Elsewhere

Q7. How confident do you feel about advising patients on the use of desogestrel 75 microgram tablets?
SINGLE CODE

a. Completely
b. Very

c. Fairly
d. Not very
e. Not at all

Q8. And how confident are you about correctly supplying desogestrel 75 microgram film-coated tablets without a prescription?
SINGLE CODE

a. Completely
b. Very
c. Fairly
d. Not very
e. Not at all

Q9. How would you rate your own level of knowledge about desogestrel 75 microgram film-coated tablets?
SINGLE CODE GRID

RANDOMISE	Excellent	Good	Fair	Poor	Very Poor	None at all
Its mode of action	o	o	o	o	o	o
Its side effects	o	o	o	o	o	o
Recommended dosage, frequency	o	o	o	o	o	o
Its use with concomitant medication	o	o	o	o	o	o
Exclusion of pregnancy	o	o	o	o	o	o

Q10. **PIPE FROM Q3**Which, if any, of these materials have you used in conjunction with consultations regarding the supply of desogestrel 75 microgram film-coated tablets without a prescription?

RANDOMISE MULTI CODE	Hana	Lovima	Brand unknown
Pharmacy training guide	o	o	o
Consultation/ supply aid checklist	o	o	o
SmPC	o	o	o
Pack copy	o	o	o
Other	o	o	o

Q11a. After using the materials for consultations regarding the supply of desogestrel 75 microgram film-coated tablets without a prescription, how useful did you find them?
SINGLE CODE

a. Extremely useful
b. Very useful
c. Somewhat useful
d. Not useful
e. No opinion

Q11b **IF Q11a is d**: Why were the materials not useful to you? *Please write a short description and try to be very specific* **OPEN ENDED**

Q12. **PIPE FROM Q3** Were the materials easily accessible to you when giving consultations?
SINGLE CODE

RANDOMISE MULTI CODE	Yes	No
a. Pharmacy training guide – Hana	o	o
b. Consultation/ supply aid checklist – Hana	o	o
c. SmPC – Hana	o	o
d. Pack copy – Hana	o	o
e. Pharmacy training guide – Lovima	o	o
f. Consultation/ supply aid checklist – Lovima	o	o
g. SmPC – Lovima	o	o
h. Pack copy - Lovima	o	o
i. Other	o	o

Q13. **DESOGESTREL 75 microgram film-coated tablets SCENARIOS**
We would like you to take time reading the following scenarios of typical situations in which a patient requests desogestrel 75 microgram film-coated tablets. Please select one of the two "supply" / "do not supply" options that you believe is a correct course of action, and then choose one of the four answers supporting your decision for supplying or not supplying desogestrel that is the most accurate in your view.
While considering your answers, you can access any of the support materials you would typically use during this type of consultation, including the training materials for Lovima and Hana.

Scenario 1

A woman in her early 20s asks if she can buy the contraceptive pill without having to see a GP. She has recently moved to the area to start a new job after having a gap year travelling and hasn't yet registered with a GP practice in the area. She has a regular boyfriend and they always use condoms and haven't had sex since her last period, which started about 10 days ago. She doesn't have any medical conditions and is not taking any other medicines. Her periods are regular. However, she says that she has started to experience occasional bleeding after sex. She contracted hepatitis A couple of months ago while traveling and felt quite poorly for a couple of weeks.

Select the correct course of action from the following for supplying desogestrel:

SINGLE CODE

A. Supply desogestrel
B. Do not supply desogestrel

Now please consider the reason for your decision about supplying/not supplying desogestrel in the above scenario. Which **one** of these actions is correct to your knowledge?

a. Supply desogestrel and advise her to start taking it on day 1 of her next menstrual period
b. Supply desogestrel and advise her to contact her GP if she continues to experience occasional bleeding after sex
c. Do not supply desogestrel as she is experiencing unexplained vaginal bleeding
d. Do not supply desogestrel as she is experiencing unexplained vaginal bleeding and has a recent history of liver disease

Correct course of action: d. Do not supply desogestrel as she is experiencing unexplained vaginal bleeding and has a recent history of liver disease

Desogestrel should not be supplied for 2 reasons: the customer has been experiencing unexplained vaginal bleeding, and she has a history of liver disease; you may not know if her liver function has returned to normal. She should be advised to register with a GP for further investigation.

Scenario 2

A woman in her 30s asks to speak to you as she has heard she can buy a contraceptive pill from the pharmacy. She has previously had a combined contraceptive pill prescribed by her GP, but stopped taking it about a year ago as she had split up with her partner. Her periods are regular and her last period was about 2 weeks ago; she has not had sex since her last period. She is taking sertraline for depression and has no other medical conditions.

Select the correct course of action from the following:

SINGLE CODE

A. Supply desogestrel
B. Do not supply desogestrel

Now please consider the reason for your decision about supplying/not supplying desogestrel in the above scenario. Which **one** of these actions is correct to your knowledge?

a. Supply desogestrel (3 month supply maximum) and advise her to start taking it on day 1 of her next period
b. Supply desogestrel (12 month supply maximum) and advise her to start taking it on day 1 of her next period
c. Do not supply desogestrel as it interacts with sertraline
d. Do not supply desogestrel as depression is a contraindication

Correct course of action: a. Supply desogestrel (3 month supply maximum) and advise her to start taking it on day 1 of her next period

Desogestrel can be supplied as depression and sertraline are not contraindications for its use, although some women using hormonal contraceptives including desogestrel have reported experiencing depression. The woman should be advised to read the patient information leaflet and speak to her GP if she notices changes in her mood or depressive symptoms. She should be advised to start taking desogestrel on day 1 of her next period and should be supplied up to three month supply as she is changing her method of contraception (first supply of desogestrel).

Scenario 3

A woman in her 20s comes into the pharmacy and asks if she can buy the contraceptive pill. She has just started a new relationship; she and her boyfriend have not yet had sex, but have discussed it and she would like to start taking a reliable form of contraception before they do. She says that she split up with her previous boyfriend about 6 months ago and has not had sex with anyone since. She has regular periods with no bleeding in between, and has not experienced bleeding after sex in the past. On further questioning, she says that she is taking carbamazepine for epilepsy and says that her epilepsy is well controlled.

Select the correct course of action from the following:

SINGLE CODE

A. Supply desogestrel
B. Do not supply desogestrel

Now please consider the reason for your decision about supplying/not supplying desogestrel in the above scenario. Which **one** of these actions is correct to your knowledge?

a. Supply desogestrel as it is reasonable to assume she isn't pregnant as she hasn't had sex for 6 months
b. Supply desogestrel as there are no contraindications
c. Do not supply desogestrel as it may affect her epilepsy and increase her risk of seizures
d. Do not supply desogestrel as carbamazepine is a hepatic enzyme-inducing drug which may reduce the efficacy of desogestrel

Correct course of action: d. Do not supply desogestrel as carbamazepine is a hepatic enzyme-inducing drug which may reduce the efficacy of desogestrel

Women taking carbamazepine long-term should be referred to their GP for further advice on contraception options.

Scenario 4

A woman in her 30s comes into the pharmacy with a young baby. She asks if she can have a word in private as she would like to start taking desogestrel and has heard that she can buy it from the pharmacy. She gave birth just over 4 months ago and since then she and her husband have been using condoms and spermicide when having sex, but she would prefer to take a contraceptive pill as that is what she has used in the past. She confirms that she is fully breastfeeding, hasn't had a period since giving birth and confirms that she is not pregnant. She is taking enalapril to manage hypertension, which is well controlled, and has no other medical conditions.

Select the correct course of action from the following:

SINGLE CODE

A. Supply desogestrel
B. Do not supply desogestrel

Now please consider the reason for your decision about supplying/not supplying desogestrel in the above scenario. Which **one** of these actions is correct to your knowledge?

a. Supply desogestrel and advise her that she can start taking it straight away
b. Supply desogestrel and advise her that she can start taking it straight away but should use additional contraceptive measures (abstinence or barrier) for the first 7 days
c. Do not supply desogestrel as she has hypertension
d. Do not supply desogestrel as she is breastfeeding

Correct course of action: b. Supply desogestrel and advise her that she can start taking it straight away but should use additional contraceptive measures (abstinence or barrier methods) for the first 7 days

Desogestrel can be supplied as high blood pressure which is well controlled is not a contraindication and pregnancy can be ruled out with reasonable certainty as this woman meets one or more of the criteria for exclusion of pregnancy. It is reasonable to exclude pregnancy if a woman has used a reliable method of contraception correctly and consistently, is fully breastfeeding, not having periods and is less than 6 months after giving birth. Since she has had her baby more than 21 days ago, she should use additional contraceptive measures (abstinence or barrier methods) for the first 7 days.

Scenario 5

A woman in her 30s asks to have a chat to find out if desogestrel would be a suitable contraceptive for her; she has not taken desogestrel previously. She has been with her partner for over 10 years and previously had a contraceptive implant, but had it removed a couple of months ago. She and her partner have been using condoms since she had her implant removed. She says her periods are regular and she has no bleeding between her periods or after sex. She has type 2 diabetes, which is well controlled; she is taking metformin. She had a deep vein thrombosis about 5 years ago, but has not had a recurrence. She has a BMI of >30.

Select the correct course of action from the following:

SINGLE CODE

A. Supply desogestrel
B. Do not supply desogestrel

Now please consider the reason for your decision about supplying/not supplying desogestrel in the above scenario. Which **one** of these actions is correct to your knowledge?

a. Supply desogestrel as a history of thrombosis is not a contraindication
b. Supply desogestrel as her diabetes is well controlled
c. Do not supply desogestrel and refer her to her doctor as she has a history of thrombosis
d. Do not supply desogestrel and refer her to her doctor as she has type 2 diabetes

Correct course of action: d. Do not supply desogestrel and refer her to her doctor as she has type 2 diabetes

Although this customer's diabetes is well controlled, women with diabetes should be carefully observed during the first few months of taking desogestrel and should be referred to their GP or nurse before taking it. Obesity and past history of venous thromboembolism (VTE) are not contraindications for desogestrel. Only active VTE represents a contraindication, but women who have had a previous VTE should be made aware of the possibility of recurrence.

Scenario 6

A 16 year old young woman asks for a repeat supply of desogestrel. She has been taking desogestrel for 3 months. She says that she has been experiencing some spotting and her periods haven't been as regular as they used to be, but this isn't bothering her. She has been taking desogestrel as directed every day and hasn't missed a dose. She has no medical conditions and is not taking any other medicines. She asks if she can have more than a three month supply.

Select the correct course of action from the following:

SINGLE CODE

A. Supply desogestrel
B. Do not supply desogestrel

Now please consider the reason for your decision about supplying/not supplying desogestrel in the above scenario. Which **one** of these actions is correct to your knowledge?

a. Supply desogestrel (3 month supply maximum) and advise her to consult her GP if the spotting is after sex or the irregular periods become bothersome
b. Supply desogestrel (12 month supply maximum) and advise her to consult her GP if the spotting is after sex or the irregular periods become bothersome
c. Do not supply desogestrel as she is experiencing spotting and irregular periods
d. Do not supply as she may be pregnant

Correct course of action: a. Supply desogestrel (3 month supply maximum) and advise her to consult her GP if the spotting is after sex or the irregular periods become bothersome

Women can continue to take desogestrel if they experience changes to their bleeding pattern, but should consult their GP if their bleeding is after sex or becomes bothersome. Desogestrel is indicated for women of childbearing age. Pharmacists should refer to relevant guidance on safeguarding and consent in women under the age of 16. As she is under 18, a maximum of three months should be supplied.

Scenario 7

A woman in her 40s asks if she can buy desogestrel. She and her husband have been using condoms and spermicide for contraception since she had breast cancer, but he doesn't really like using condoms. She asks if desogestrel would be suitable for her as she had breast cancer nearly 10 years ago and gets occasional migraines. Apart from this, she has no other medical conditions and isn't taking any prescription medicines. Her periods are regular and she hasn't experienced any bleeding between her periods or after sex.

Select the correct course of action from the following:

SINGLE CODE

A. Supply desogestrel
B. Do not supply desogestrel

Now please consider the reason for your decision about supplying/not supplying desogestrel in the above scenario. Which **one** of these actions is correct to your knowledge?

a. Supply desogestrel as she has no contraindications and advise her to see her GP if her migraines get worse or become more frequent
b. Supply desogestrel as she had breast cancer more than 5 years ago and advise her to see her doctor if her migraines get worse or become more frequent
c. Do not supply desogestrel as she has a history of breast cancer
d. Do not supply desogestrel as she gets occasional migraines

Correct course of action: c. Do not supply desogestrel as she has a history of breast cancer

Women who have or have had a history of sex steroid-sensitive malignancies such as breast, uterine or ovarian cancer should be referred to their GP to discuss the use of hormonal contraceptives before starting treatment.

Scenario 8

A woman in her 30s asks to speak to you in private. She explains that she had unprotected sex a couple of days ago and would like to buy emergency contraception. She has taken ulipristal acetate in the past and would like to take the same tablet again as she didn't experience any side-effects. You determine that she is suitable for ulipristal acetate and provide her with a pack. She says that she has just started a new relationship and would also like to start taking regular contraception. You discuss contraceptive options with her, including long-acting reversible contraceptives (LARCs), and explain that only barrier methods such as condoms will protect her from STIs. She decides she would like to start taking desogestrel. She isn't taking any other medication, has no medical conditions and her periods are regular. She mentions that she smokes.

Select the correct course of action from the following:

SINGLE CODE

A. Supply desogestrel
B. Do not supply desogestrel

Now please consider the reason for your decision about supplying/not supplying desogestrel in the above scenario. Which **one** of these actions is correct to your knowledge?

a. Supply desogestrel and advise her to start taking it straight away
b. Supply desogestrel and advise her to start taking it on day 1 of her next menstrual period and to use additional contraceptive measures (abstinence or barrier methods) until then
c. Do not supply desogestrel as she is not certain she is not pregnant
d. Do not supply desogestrel as she is a smoker

Correct course of action: b. Supply desogestrel and advise her to start taking it on day 1 of her next menstrual period and to use additional contraceptive measures (abstinence or barrier methods) until then

If a woman wishes to start taking desogestrel after using emergency contraception, it is advisable to start taking it on day 1 of her next menstrual period. If the first day of her next menstrual period is within 5 days of taking ulipristal acetate for emergency contraception, she should wait 5 days after taking ulipristal acetate before starting desogestrel. She should use additional contraceptive measures (abstinence or barrier methods) during these 5 days and for an additional 7 days after starting desogestrel. Ulipristal acetate and desogestrel both bind to the progesterone receptor. Concomitant use may result in reduced efficacy of both and is therefore not recommended. Smoking is not a contraindication for desogestrel.
The woman should be reminded that if her period does not come, she will need to take a pregnancy test and/or speak to her GP. This is because emergency contraception is not always effective and there is still a risk of pregnancy.

Appendix 1.1 - Annex 4: Risks assessed in case study scenarios

Number	Answer	Risk/contraindication
Scenario 1	e. Incorrect	Contraindicated if there is a recent history of liver disease and unexplained vaginal bleeding
	f. Incorrect	Contraindicated if there is unexplained vaginal bleeding and a recent history of liver disease
	g. Incorrect	Contraindicated if there is unexplained vaginal bleeding and a recent history of liver disease
	h. Correct	Correct understanding of recent history of liver disease and unexplained vaginal bleeding
Scenario 2	e. Correct	Correct understanding of using desogestrel in depression and taking an SSRI
	f. Incorrect	A maximum of 3 months treatment should be supplied for an initial supply
	g. Incorrect	Not contraindicated when taking an SSRI
	h. Incorrect	Depression is not a contraindication
Scenario 3	e. Incorrect	Contraindicated if taking a hepatic enzyme-inducing drug
	f. Incorrect	Contraindicated if taking a hepatic enzyme-inducing drug
	g. Incorrect	Contraindicated if taking a hepatic enzyme-inducing drug
	h. Correct	Correct understanding of the effect hepatic enzyme-inducing drugs on desogestrel
Scenario 4	e. Incorrect	Additional contraceptive measures should be used for the first 7 days
	f. Correct	Correct understanding of the use of desogestrel in hypertension, while breastfeeding and starting to use desogestrel after giving birth
	g. Incorrect	Hypertension is not a contraindication
	h. Incorrect	Breastfeeding is not a contraindication
Scenario 5	e. Incorrect	Diabetes is a contraindication History of thrombosis is not a contraindication
	f. Incorrect	Diabetes is a contraindication
	g. Incorrect	Diabetes is a contraindication History of thrombosis is not a contraindication

	h. Correct	Correct understanding of using desogestrel in diabetes and a history of thrombosis
Scenario 6	e. Correct	Correct understanding of periods, side-effects, pregnancy and maximum quantity that can be supplied
	f. Incorrect	A maximum of 3 months treatment can be supplied to a female under the age of 18
	g. Incorrect	Not contraindicated unless bleeding is after sex or becomes bothersome
	h. Incorrect	Not contraindicated if pregnancy can be excluded
Scenario 7	e. Incorrect	A history of sex steroid-sensitive malignancies is a contraindication
	f. Incorrect	A history of sex steroid-sensitive malignancies is a contraindication
	g. Correct	Correct understanding of using desogestrel in breast cancer (sex steroid-sensitive malignancies) and migraine
	h. Incorrect	A history of sex steroid-sensitive malignancies is a contraindication Migraine is not a contraindication
Scenario 8	e. Incorrect	Desogestrel should not be started immediately after taking ulipristal acetate
	f. Correct	Correct understanding of emergency contraception and excluding pregnancy
	g. Incorrect	Not contraindicated if pregnancy can be excluded
	h. Incorrect	Smoking is not a contraindication

Appendix 1.2: User Testing and pilot Topline Reports

User testing
CIG Research delivered invitations to a random selection of pharmacists from the panel, based on job titles – proprietor, pharmacist, pharmacist supervisor and .locum pharmacist.

5 pharmacists completed the planned questionnaire between 5pm on 23rd and 4pm on 24th September 2021, from a total of 11 who began the survey.

Those who completed the survey did so in an average of 12 minutes – this excluded any time spent looking at images of training materials. The majority completed the survey in under 12 minutes and one took 27 minutes.

Those who commenced but failed to complete the questionnaire were terminated:

- One at filter question A: *Which, if any, of these organisations have you worked for or been contracted to in the last year* because he ticked all five companies. This respondent may have assumed that 'worked for…' meant having dealt with these companies. Consideration could be given to amending the wording of the question to read *Which, if any, of these organisations have you been employed by or contracted to in the last year*
- Four answered 'No' to Q1: *In the last six months, have you held any consultations regarding the supply of desogestrel 75 microgram film-coated tablets (DSG) in the pharmacy without a prescription?* Given that there will be another three months before the main survey runs, that level of non-involvement in consultations is expected to drop considerably
- One dropped out at Q2.

Responses to all questions by those completing the survey were well made and correctly completed.

All scenarios were answered and of the 40 answers, 29 were correct (73%) – although this is NOT a statistically viable sample.

None of the respondents expressed any concerns or issues with their completion of the survey when offered to do so at the end of the completion process.

<u>Conclusion</u>
With the one exception of the possible re-wording of filter question A (see above) we do not recommend any changes to the questionnaire design as a result of this materials testing. Given the length of interview and the response rate, we envisage no problems with achieving the 200 sample as specified.

Pilot

1. BACKGROUND

Desogestrel 75 microgram film-coated tablets has been reclassified as a pharmacy only (P) medicine in the UK by Maxwellia Ltd and HRA Pharma. A post-authorisation safety study (PASS) was requested by the MHRA as part of the reclassification procedure. The PASS will assess the effectiveness of the agreed aRMMs for desogestrel 75 microgram film-coated tablets.

The current approved protocol version is dated 2 August 2021 (version 3). It was approved following two requests for further information (previous assessment report dated 15 Sep 2021, appendix 1).

The MAHs submitted the results of a pilot study and proposed updates to the protocol on 2 Dec 2021 (version 3). The full pilot study report and tracked proposed study can be found in appendices 2 & 3.

2. ASSESSMENT OF PILOT STUDY

The pilot study report is dated 27 Oct 2021 (appendix 2). The aim of the pilot study is "whether the Assessment of the effectiveness of additional Risk Minimisation Measures (aRMMs) study process runs successfully and that all biases in question wording, scale responses and order effect are mitigated…". The most relevant sections of the report are copied below.

Sampling
This survey was distributed to 949 panel members, of whom 177 opened the invitation to take part. 30 respondents completed the survey what took them on average 12 minutes.

- Of the 177, 97 (55%) began the questionnaire, and 93 were happy to participate. 71 wanted to report anonymously any adverse events and 21 were happy to be identified
- Of the 97, six respondents (6%) claimed to have been employed by one of the organisations rendering them ineligible for the study – five had worked for the MHRA in this group
- 15 respondents (15%) were ineligible on the basis of their job title
- Eight respondents (8%) were ineligible on the basis of their outlet type
- 30 respondents (31%) had not conducted any consultations since the launch in July 2021. This represents 46% of those otherwise eligible to participate
- Three more had received but not read the training materials and one had not received them (11% of those who were otherwise eligible)
- One eligible respondent dropped out before completing the survey
- The response time average was 12 minutes (between 6 and 38 minutes) for completing the survey, with a wide range of individual responses times, including some which may have been extended by time away from the computer.

Sample profile
The 30 completed surveys comprised of:

- 53% independents (1-49 outlets) and 47% multiples (50 plus outlets)
- 50% were in city/town centre locations and 37% in suburban areas. The remained were in villages
- 30% were from Greater London
- 53% were men
- The sample mean age was 35.5 years
- The average number of years qualified as a pharmacist was 12.1.

Materials read

Material read	Pharmacy training guide	Consultation/supply aid checklist	SmPC	Pack copy	Other
Hana	83% (25)	83% (25)	73% (22)	57% (17)	13% (4)
Lovima	53% (16)	63% (19)	53% (16)	50% (15)	10% (3)
Brand unknown	17% (5)	10% (3)	7% (2)	13% (4)	7% (2)

*Report included percentages - absolute numbers added by assessor

Consultations

In the last six months, the average number of total consultations held per respondent was 41. As the sliding scale for this question was in increments of 20, this may be a significant over-estimate of consultations, and the question format should be adjusted to increments of one in the full survey.

27 of the 30 respondents provided reasons why the consultation did not result in supply – the most prevalent one being that patients did not want to pay for the product if they could get it free on the NHS. Of the others, the woman being possibly pregnant was most often the reason, and in a few cases, contra-indications prevented the sale.

80% of the consultations were held in a private consultation area and 19% at the counter (1% were held elsewhere). In cases where the consultation did not result in the supply of desogestrel, open answers were given as to the reason. These included:

- Patients not wanting to pay for what they thought would be a free service
- Concern about possible pregnancy
- Possible hypertension
- Waiting for stock
- Patient referred to GP

Confidence and knowledge

The majority of respondents were at least fairly confident on both advising and supplying desogestrel, but only 17% and 13% were completely confident. None were either not very or not at all confident. The majority of respondents rating their knowledge as excellent or good on the following aspects: 1) Mode of action; 2) Side effects; 3) Recommended dosage, frequency; 4) Use with concomitant medication; 4) Exclusion of pregnancy.

Materials used in conjunction with consultations

every respondent made use of a training guide, 29 used a checklist and 25 the SmPC. The majority reported that the materials were easily accessible.

Scenarios

Across the eight scenarios, there were 240 responses from the 30 respondents. The total correct answers were 163 (68%) and incorrect 77 (32%). The responses to the individual scenarios are outlined below in percentages, with number of responses in brackets. The correct answers are marked in green. Please note that the variance on a sample of 30 people is +/-18%, equivalent to a KPI threshold on 240 responses of 6.5%. On this basis, the 80% overall KPI would not have been met by this sample. The scenarios with the lowest level of correct responses were 2 and 5.

Scenario:	1	2	3	4	5	6	7	8
a	3% (1)	20% (6)	3% (1)	0% (0)	17% (5)	17% (5)	57% (17)	0% (0)
b	23% (7)	7% (2)	7% (2)	10% (3)	0% (0)	7% (2)	7% (2)	17% (5)
c	3% (1)	57% (17)	10% (3)	77% (23)	30% (9)	70% (21)	33% (10)	80% (24)
d	70% (21)	17% (5)	80% (24)	13% (4)	53% (16)	7% (2)	3% (1)	3% (1)

The 77 incorrect responses were generated by 22 people. Those incorrect on any of the eight scenarios did not differ markedly from the sample as a whole in terms of demographics. Eight people (27%) got all eight scenario answers correct. In addition, some respondents gave the correct 'supply/do not supply' answer, but for the wrong reasons. Inclusion of these responses changes the results, with 79% of scenario outcomes being correct, even though 11% of these

were for the wrong reasons. In a simple 'supply/don't supply' scenario, the 80% +/- 6.5% KPI would have been met.

Key findings of the pilot report

This report included the following conclusions:

a) Only one in three of those commencing the survey were both eligible and prepared to complete it. Almost half of those eligible on criteria of job description and outlet type dropped out because they had not held any consultations since the launch of the two brands in July
b) Among all of the respondents who had read aRMM materials, 83% had read the training guide and 83% the checklist from Hana, followed by 53% who had read the training guide and 63% the checklist from Lovima. 17% were not sure which brand's training guide they had read, 10% could not remember the brand of the checklist.
c) During consultations in the pharmacy, 67% used Hana's training guide and 79% its checklist. 30% used Lovima's training guide, while 45% used its checklist. Almost all
d) respondents reported that the training materials were easily accessible in the pharmacy
e) While the majority of respondents felt very or completely confident in advising on and supplying desogestrel, four in 10 felt fairly confident
f) The vast majority of respondents rated themselves as having excellent or good levels of knowledge of the product and how it should be used
g) The eight scenarios were correctly answered 68% of the time. The decision to supply or not supply was correct in 79% of cases, although in 11% of cases this was for the wrong reasons.

In this pilot sample, the 80% KPI set for correct scenario response was not reached. Based on the insights after analysis of the results, a number of amendments to the questionnaire are recommended prior to running the full survey. These revisions will form part of a Protocol re-submission to the MHRA.

Appendix 1.3: Final Tables and Listings

Table 1.1: Survey Administration Statistics

Table 1.1.1 Data collection

Between January 20th and February 1st, the pattern of responses was as follows:

Date	Started survey	Completed survey	Cumulative completes
20.01.2022	186	63	63
21.01.2022	73	21	84
22.01.2022	24	2	86
23.01.2022	12	2	88
24.01.2022	22	6	94
25.01.2022	7	1	95
26.01.2022	152	14	109
27.01.2022	32	3	112
28.01.2022	153	40	152
29.01.2022	47	21	173
30.01.2022	20	5	178
31.01.2022	39	6	184
01.02.2022	124	15	201
02.02.2022	41	9	210

Response rate

- 8,343 (23.7%) viewed the invitation during the fieldwork period
- 932 (11.2% of those viewing) commenced the survey
- 862 (92.4% of those starting) were happy to take part
- 829 (88.9% of those starting) agreed to report any adverse events
- 809 (86.8% of those starting) had not worked for any of the organisations which would preclude participation
- 572 (61.4% of those starting) were eligible based on their job title
- 518 (55.6% of those starting) were eligible based on their outlet type
- 280 (30.0% of those starting) had held at least one consultation regarding the supply of desogestrel 75 microgram film-coated tablets (DSG) in the last 6 months
- 247 (26.5% of those starting) had received and read training materials or consultation checklists regarding the supply of desogestrel 75 microgram film-coated tablets without a prescription to help minimise risk when having consultations
- 37 dropped out during the survey
- 210 completed the survey (22.5% of those starting)

Table 1.2 Survey Participant Eligibility Results – All Respondents

Total number of respondents starting the survey	N=922	%
By proceeding to the next screen:I consent to CIG collecting and using the information about me that I voluntarily provide for the purposes of market research.· I have read, understand and agree to the terms described above.		
YES, I am happy to proceed with the market research survey on this basis	852	98.16
NO, I am not happy to proceed with the market research survey on this basis and I do not wish to continue	16	1.84
This survey has been commissioned by healthcare manufacturers upon request from the MHRA. When working on their projects, we are required to report if any participant mentions an adverse event in relation to one of their products.Should this happen, it would be necessary for us to complete a report and pass your comments to our clients so that they can investigate. We can submit a report anonymously or with your personal details. Please confirm whether you are happy to proceed:		
Yes, I am happy to proceed, but please submit my report anonymously as I do not want the company to contact me	642	78.20
Yes, I am happy to proceed. Please submit the report with my personal details (name and e-mail address). I understand that the company may contact me for further information about the adverse event	177	21.56
No, I am not happy to proceed. I understand that this means I will not be able to continue with this survey	2	0.24
Which, if any, of these organisations have you been employed by or contracted to in the last year?		
Maxwellia Ltd (discontinued)	7	0.88
Laboratoire HRA Pharma (discontinued)	7	0.88
Communications International Group (discontinued)	13	1.63
Consensio LLP (discontinued)	7	0.88
MHRA (discontinued)	29	3.63
None of these	849	92.10
What is your job title?		
Pharmacist Proprietor	28	3.74
Pharmacist Manager / Supervisor	158	21.12
Pharmacist	258	34.49
Locum Pharmacist	118	15.78
Other (discontinued)	186	24.87
What type of outlet do you work in?		
One shop independent	85	15.15
Group branch shop (2 to 5 outlets)	93	16.58
Group branch shop (6 to 9 outlets)	28	4.99
Group branch shop (10 to 49 outlets)	48	8.56
Group branch shop (50 plus outlets)	228	40.64
Multiple head office	24	4.28
Other (discontinued)	55	9.80
In the last six months, have you held any consultations regarding the supply of desogestrel 75 microgram film-coated tablets (DSG) in the pharmacy without a prescription?		
Yes	270	57.82
No (discontinued)	197	42.18
In the last six months have you received and read training materials or consultation checklists regarding the supply of desogestrel 75 microgram film-coated tablets without a prescription to help minimise risk when having consultations?		
Yes, received and read	237	88.10

Yes, received but not read (discontinued)	15	5.58
No (discontinued)	17	6.32

Table 1.3 Survey Participant Eligibility Results – By outlet type

	Independents	Multiples
Total number of respondents starting the survey	N=254	N=252
What is your job title?		
Pharmacist Proprietor	9.5%	0.8%
Pharmacist Manager / Supervisor	30.7%	30.6%
Pharmacist	35.4%	48.8%
Locum Pharmacist	24.4%	19.8%
What type of outlet do you work in?		
One shop independent	33.5%	NA
Group branch shop (2 to 5 outlets)	36.6%	NA
Group branch shop (6 to 9 outlets)	11.0%	NA
Group branch shop (10 to 49 outlets)	18.9%	NA
Group branch shop (50 plus outlets)	NA	90.5%
Multiple head office	NA	9.5%
In the last six months, have you held any consultations regarding the supply of desogestrel 75 microgram film-coated tablets (DSG) in the pharmacy without a prescription?		
Yes	55.3%	60.4%
No (discontinued)	44.7%	39.6%
In the last six months have you received and read training materials or consultation checklists regarding the supply of desogestrel 75 microgram film-coated tablets without a prescription to help minimise risk when having consultations?		
Yes, received and read	90.1%	86.2%
Yes, received but not read (discontinued)	4.6%	6.5%
No (discontinued)	5.3%	7.3%

Table 2: Demographic Description of Eligible Pharmacists – Completed Surveys by segment: outlet type

Question	N=200	%	Independents N=97 (%)	Multiples N=103 (%)
What is your job title?				
Pharmacist Proprietor	15	5.0	10.3%	0.0%
Pharmacist Manager / Supervisor	63	31.5	34.0%	29.1%
Pharmacist	88	44.0	33.0%	54.4%
Locum Pharmacist	39	19.5	22.7%	16.5%
What type of outlet do you work in?				
One shop independent	23	11.5	23.7%	NA
Group branch shop (2 to 5 outlets)	41	20.5	42.2%	NA
Group branch shop (6 to 9 outlets)	9	4.5	9.3%	NA
Group branch shop (10 to 49 outlets)	24	12.0	24.7%	NA
Group branch shop (50 plus outlets)	98	49.0	NA	95.2%
Multiple head office	4	2.5	NA	4.9%
Which multiple do you work in?				
Boots	34	17.0	NA	33.0%
LloydsPharmacy	18	9.0	NA	17.5%
Superdrug	5	2.5	NA	4.9%
Rowlands Pharmacy	2	1.0	NA	1.9%
Well Pharmacy	11	5.5	NA	10.7%
Day Lewis	1	0.5	NA	1.0%
Supermarket Pharmacy	18	9.0	NA	17.5%
Other	14	7.0	NA	13.6%
In what type of location is your pharmacy based?				
City centre	39	19.5	23.7%	15.5%
Town centre	67	33.5	29.0%	36.9%
Suburb	66	33.0	33.0%	33.0%
Village	21	10.5	11.3%	9.7%
Rural	7	3.5	2.1%	4.9%
Where is your pharmacy?				
Scotland	9	4.5	6.3%	2.9%
Northern Ireland	5	2.5	3.1%	1.9%
Wales	11	5.5	4.1%	6.8%
North East	13	6.5	7.2%	5.8%
North West	16	8.0	10.3%	5.8%
Yorkshire and the Humber	11	5.5	3.1%	7.8%
West Midlands	24	12.0	8.3%	15.5%
East Midlands	19	9.5	8.3%	10.7%
South East	28	14.0	12.4%	15.5%
South West	16	8.0	3.1%	12.6%
East of England	6	3.0	4.1%	1.9%
Greater London	42	21.0	29.9%	12.6%
What is your gender?				
Male	249	53.1	63.9%	40.8%
Female	207	44.1	30.9%	58.3%
Other	2	0.4	0.0%	0.0%
Prefer not to say	11	2.3	5.2%	1.0%

What is your age?				
Under 25	9	4.5	2.1%	5.8%
25-29	5	2.5	8.3%	17.5%
30-34	11	5.5	14.4%	19.7%
35-39	13	6.5	19.9%	12.6%
40-44	16	8.0	14.4%	19.4%
45-49	11	5.5	7.2%	14.6%
50-54	24	12.0	10.3%	4.9%
55-59	19	9.5	4.1%	5.8%
60-64	28	14.0	11.3%	5.8%
65 plus	16	8.0	3.1%	2.9%
Mean age		40.6	40.8	40.3
For how many years have you been qualified as a pharmacist?				
Mean number of years	200	15.88	16.51	15.29

Table 3: Responses to all Questions Related to the Reading and Utilising of the aRMMs – Completed Surveys by segment: outlet type

Question	N=200	%	Precision or Margin of Error (±%)	Independents N=97 (%)	Multiples N=103 (%)
Which, if any, of these materials have you read to help minimise risk when having consultations regarding the supply of desogestrel 75 microgram film-coated tablets without a prescription?					
Pharmacy training guide					
Hana	170	85.0	5.0	81.4%	88.4%
Lovima	120	60.0	6.8	62.9%	57.3%
Brand unknown	18	9.0	4.0	9.3%	8.7%
Consultation/ supply aid checklist					
Hana	164	82.0	5.3	80.4%	83.5%
Lovima	111	55.5	6.9	60.8%	50.5%
Brand unknown	20	10.0	4.2	9.3%	10.7%
SmPC					
Hana	126	63.0	6.7	56.7%	68.9%
Lovima	81	40.5	6.8	42.3%	38.8%
Brand unknown	23	11.5	4.4	10.3%	12.6%
Pack copy					
Hana	120	60.0	6.8	59.8%	60.2%
Lovima	81	40.5	6.8	45.4%	35.9%
Brand unknown	14	7.0	3.5	6.2%	7.8%
Other					
Hana	29	14.5	4.9	14.4%	14.6%
Lovima	17	8.5	3.9	7.2%	9.7%
Brand unknown	16	8.0	3.8	9.3%	6.8%

How many consultations do you estimate that you have had with patients about non-prescription desogestrel 75 microgram film-coated tablets in the pharmacy in the last six months?					
Mean number of consultations	15.27	Range 1-200	Std dev. 14.31	18.8	11.1

Table 3.1: Responses to all Questions Related to the Reading and Utilising of the aRMMs – Completed Surveys by segment: gender, age

Question	Men N=104	Women N=90	Under 40 N=90	40 plus N=110
Which, if any, of these materials have you read to help minimise risk when having consultations regarding the supply of desogestrel 75 microgram film-coated tablets without a prescription?				
Pharmacy training guide				
Hana	87.5%	82.2%	87.8%	82.7%
Lovima	69.2%	51.1%	55.6%	63.6%
Brand unknown	7.7%	10.0%	7.8%	10.0%
Consultation/ supply aid checklist				
Hana	82.7%	81.1%	84.4%	80.0%
Lovima	64.4%	46.7%	47.8%	61.8%
Brand unknown	8.7%	11.1%	10.0%	10.0%
SmPC				
Hana	58.7%	67.8%	76.7%	51.8%
Lovima	46.2%	35.6%	47.8%	34.5%
Brand unknown	10.6%	12.2%	8.9%	13.6%
Pack copy				
Hana	59.6%	62.2%	66.7%	54.5%
Lovima	49.0%	33.3%	41.1%	40.0%
Brand unknown	5.8%	7.8%	5.6%	8.2%
Other				
Hana	16.3%	12.2%	17.8%	11.8%
Lovima	11.5%	5.6%	12.2%	5.5%
Brand unknown	7.7%	8.9%	10.0%	6.4%

Table 3.2: Distribution of number of consultations held

Number of consultations held in the last 6 months	N=200	(%)
1	43	21.5
2	18	9.0
3-4	36	18.0
5-9	38	19.0
10-19	26	13.0
20-30	19	9.5
31-60	6	3.0
61-100	7	3.5
101-200	7	3.5

Table 3.4: Average numbers of consultations by segment

Segment	Base	Mean number of consultations in the last six months
Independents	97	18.8
Multiples	103	11.1
Pharmacists	161	17.5
Locums	39	6.2
Urban	106	14.2
Suburban/rural	94	16.5
Men	104	19.5
Women	90	10.7
Aged under 40	90	16.6
Aged 40 plus	110	14.2

Table 4: Responses to all Questions Related to the use of the aRMMs in conjunction with consultation – Completed Surveys

Question	Base (read materials)	N	%	Precision or Margin of Error (±%)
Which, if any, of these materials have you used in conjunction with consultations regarding the supply of desogestrel 75 microgram film-coated tablets without a prescription?				
Pharmacy training guide				
Hana	198	130	65.7	6.6
Lovima	198	80	40.4	6.8
Brand unknown	198	18	9.1	4.0
Consultation/ supply aid checklist				
Hana	195	148	75.9	6.0
Lovima	195	86	44.1	7.0
Brand unknown	195	19	9.7	4.2
SmPC				
Hana	155	80	51.6	7.9
Lovima	155	54	34.8	7.5
Brand unknown	155	22	14.2	5.5
Pack copy				
Hana	142	81	56.3	8.2
Lovima	142	53	36.8	7.9
Brand unknown	142	17	11.8	5.3
Other				
Hana	47	26	55.3	14.2
Lovima	47	15	31.9	13.3
Brand unknown	47	11	23.4	12.1
After using the materials for consultations regarding the supply of desogestrel 75 microgram film-coated tablets without a prescription, how useful did you find them?				
Extremely useful	200	81	40.5	6.8
Very useful	200	93	46.5	6.9
Somewhat useful	200	23	11.5	4.4
Not useful	200	0	0.0	0.0

No opinion	200	3	1.5	1.7
Mean score (+5 to +1)	200		4.2	Std.dev. 0.77

Table 4.1: Responses to all Questions Related to the use of the aRMMs in conjunction with consultation – Completed Surveys by segment: gender, age

Question	Men N=104	Women N=90	Under 40 N=90	40 plus N=110
Which, if any, of these materials have you used in conjunction with consultations regarding the supply of desogestrel 75 microgram film-coated tablets without a prescription?				
Pharmacy training guide				
Hana	67%	64.0%	64.0%	67.0%
Lovima	53%	27.0%	36.0%	44.0%
Brand unknown	8%	10.1%	9.0%	9.2%
Consultation/ supply aid checklist				
Hana	80%	71.1%	77.0%	75.0%
Lovima	57%	32.2%	35.6%	50.9%
Brand unknown	7%	12.2%	10.3%	9.3%
SmPC				
Hana	52%	52.1%	57.5%	45.3%
Lovima	49%	21.9%	36.3%	33.3%
Brand unknown	14%	13.7%	15.0%	13.3%
Pack copy				
Hana	56%	56.1%	62.9%	50.0%
Lovima	48%	25.8%	38.6%	35.1%
Brand unknown	12%	10.6%	12.9%	10.8%
Other				
Hana	56%	52.6%	52.0%	59.1%
Lovima	33%	31.6%	32.0%	31.8%
Brand unknown	22%	26.3%	28.0%	18.2%
After using the materials for consultations regarding the supply of desogestrel 75 microgram film-coated tablets without a prescription, how useful did you find them?				
Extremely useful	41.3%	38.9%	31.1%	48.2%
Very useful	45.2%	47.8%	50.0%	43.6%
Somewhat useful	11.5%	12.2%	16.7%	7.3%
Not useful	0.0%	0.0%	0.0%	0.0%
No opinion	1.9%	1.1%	2.2%	0.9%
Mean score (+5 to +1)	4.2	4.2	4.1	4.4

Table 5: Self-rated Confidence and Knowledge – completed surveys, by segment: age, gender

Question	Total sample N=200	%	Precision or Margin of Error (±%)	Under 40 years old N=90	Aged 40 plus N=100	Men N=104	Women N=90
How confident do you feel about advising patients on the use of desogestrel 75 microgram film-coated tablets?							
Completely (5)	38	19.0	5.4	13.3%	23.64	21%	16.7%
Very (4)	83	41.5	6.8	37.8%	44.6%	39%	42.2%
Fairly (3)	75	37.5	6.7	46.7%	30.0%	38%	38.9%
Not very (2)	4	2.0	2.0	2.2%	1.8%	2%	2.2%
Not at all (1)	0	0.0	0.0	0.0%	0.0%	0%	0.0%
Mean score (+5 to +1)	200	3.8	Std.dev. 0.77	3.6	3.9	3.8	3.7
And how confident are you about correctly supplying desogestrel 75 microgram film-coated tablets without a prescription?							
Completely (5)	35	17.5	5.3	12.2%	26.4%	20%	13.3%
Very (4)	88	44.0	6.9	42.2%	50.0%	42%	44.4%
Fairly (3)	72	36.0	6.6	42.2%	21.8%	36%	38.9%
Not very (2)	5	2.5	2.2	3.3%	1.8%	2%	3.3%
Not at all (1)	0	0.0	0	0.0%	0.0%	0%	0.0%
Mean score (+5 to +1)	200	3.8	Std. dev. 0.76	3.6	4.0	3.8	3.7
How would you rate your own level of knowledge about desogestrel 75 microgram film-coated tablets: Its mode of action							
Excellent	45	22.5	5.8	14.4%	29.1%	26%	18.9%
Good	101	50.5	6.9	52.2%	49.1%	48%	51.1%
Fair	46	23.0	5.8	27.8%	19.1%	22%	25.6%
Poor	7	3.5	2.5	4.4%	2.7%	4%	3.3%
Very Poor	1	0.5	1.0	1.1%	0.0%	0%	1.1%
Mean score (+5 to +1)	200	3.9	Std. dev. 0.80	3.7	4.0	4.0	3.8
How would you rate your own level of knowledge about desogestrel 75 microgram film-coated tablets: Its side effects							
Excellent	39	19.5	5.5	11.1%	26.4%	20%	20.0%
Good	109	54.5	6.9	60.0%	50.0%	52%	54.4%
Fair	47	23.5	5.9	25.6%	21.8%	26%	22.2%
Poor	3	1.5	1.7	1.1%	1.8%	2%	1.1%
Very Poor	2	1.0	1.4	2.2%	0.0%	0%	2.2%
Mean score (+5 to +1)	200	3.9	Std. dev. 0.76	3.8	4.0	3.9	3.9
How would you rate your own level of knowledge about desogestrel 75 microgram film-coated tablets: Recommended dosage, frequency							
Excellent	86	43.0	6.9	36.7%	48.2%	42%	44.4%
Good	92	46.0	6.9	53.3%	40.0%	43%	47.8%

Fair	21	10.5	4.2	8.9%	11.8%	14%	6.7%
Poor	0	0.0	0.0	0.0%	0.0%	0%	0.0%
Very Poor	1	0.5	1.0	1.1%	0.0%	0%	1.1%
Mean score (+5 to +1)	200	4.3	Std. dev. 0.70	4.2	4.4	4.3	4.3
How would you rate your own level of knowledge about desogestrel 75 microgram film-coated tablets: Its use with concomitant medication							
Excellent	37	18.5	5.4	13.3%	22.7%	21%	16.7%
Good	105	52.5	6.9	47.8%	56.4%	50%	52.2%
Fair	54	27.0	6.2	34.4%	20.9%	27%	28.9%
Poor	4	2.0	2.0	4.4%	0.0%	2%	2.2%
Very Poor	0	0.0	0.0	0.0%	0.0%	0%	0.0%
Mean score (+5 to +1)	200	3.9	Std. dev. 0.72	3.7	4.0	3.9	3.8
How would you rate your own level of knowledge about desogestrel 75 microgram film-coated tablets: Exclusion of pregnancy							
Excellent	55	27.5	6.2	23.3%	30.9%	31%	24.4%
Good	100	50.0	6.9	50.0%	50.0%	43%	55.6%
Fair	42	21.0	5.6	25.6%	17.3%	23%	20.0%
Poor	3	1.5	1.7	1.1%	1.8%	3%	0.0%
Very Poor	0	0.0	0.0	0.0%	0.0%	0%	0.0%
Mean score (+5 to +1)	200	4.0	Std. dev. 0.74	4.0	4.1	4.0	4.4

Table 6: Self-rated Knowledge – completed surveys, by segment: role, urban/suburban, number of consultations

Question	Pharmacists N=161 (%)	Locums N=39 (%)	Urban N=106 (%)	Suburban/ rural N=94 (%)	1-2 consults N=61 (%)	3-9 consults N=74 (%)	10+ consults N=65 (%)
How would you rate your own level of knowledge about desogestrel 75 microgram film-coated tablets: Its mode of action							
Excellent	23.0%	20.5%	21.7%	23.4%	21%	17.6%	29.2%
Good	48.4%	59.0%	51.9%	48.9%	44%	55.4%	50.8%
Fair	23.6%	20.5%	22.6%	23.4%	26%	23.0%	20.0%
Poor	4.3%	0.0%	2.8%	4.3%	8%	2.7%	0.0%
Very Poor	0.6%	0.0%	0.9%	0.0%	0%	1.4%	0.0%
Mean score (+5 to +1)	3.9	4.0	3.9	3.9	3.8	3.9	4.1
How would you rate your own level of knowledge about desogestrel 75 microgram film-coated tablets: Its side effects							
Excellent	18.6%	23.1%	20.8%	18.1%	15%	20.3%	23.1%
Good	57.8%	41.0%	55.7%	53.2%	48%	56.8%	58.5%
Fair	20.5%	35.9%	20.8%	26.6%	33%	21.6%	16.9%
Poor	1.9%	0.0%	0.9%	2.1%	3%	1.4%	0.0%
Very Poor	1.2%	0.0%	1.9%	0.0%	2%	0.0%	1.5%
Mean score (+5 to +1)	3.9	3.9	3.9	3.9	3.7	4.0	4.0
How would you rate your own level of knowledge about desogestrel 75 microgram film-coated tablets: Recommended dosage, frequency							
Excellent	42.2%	46.2%	46.2%	39.4%	51%	37.8%	41.5%
Good	46.0%	46.2%	43.4%	48.9%	38%	52.7%	46.2%
Fair	11.2%	7.7%	9.4%	11.7%	10%	9.5%	12.3%
Poor	0.0%	0.0%	0.0%	0.0%	0%	0.0%	0.0%
Very Poor	0.6%	0.0%	0.9%	0.0%	2%	0.0%	0.0%
Mean score (+5 to +1)	4.3	4.4	4.3	4.3	4.4	4.3	4.3
How would you rate your own level of knowledge about desogestrel 75 microgram film-coated tablets: Its use with concomitant medication							
Excellent	19.3%	15.4%	15.1%	22.3%	16%	21.6%	16.9%
Good	52.2%	53.8%	53.8%	51.1%	54%	51.4%	52.3%
Fair	26.1%	30.8%	29.2%	24.5%	26%	25.7%	29.2%
Poor	2.5%	0.0%	1.9%	2.1%	3%	1.4%	1.5%
Very Poor	0.0%	0.0%	0.0%	0.0%	0%	0.0%	0.0%
Mean score (+5 to +1)	3.9	3.8	3.8	3.9	3.8	3.9	3.8
How would you rate your own level of knowledge about desogestrel 75 microgram film-coated tablets: Exclusion of pregnancy							
Excellent	27.3%	28.2%	27.4%	27.7%	31%	25.7%	26.2%
Good	49.7%	51.3%	49.1%	51.1%	43%	50.0%	56.9%
Fair	21.7%	17.9%	20.8%	21.3%	21%	24.3%	16.9%
Poor	1.2%	2.6%	2.8%	0.0%	5%	0.0%	0.0%
Very Poor	0.0%	0.0%	0.0%	0.0%	0%	0.0%	0.0%

Mean score (+5 to +1)	4.0	4.1	4.0	4.1	4.0	4.0	4.1

Table 7: Responses to all Questions Related to use of Consulting Facilities and Ease of Access to aRMMs in Pharmacy During Consultation – completed surveys, by segment: outlet type

Question	N=200	%	Precision or Margin of Error (±%)	Independents N=97 (%)	Multiples N=103 (%)
Where in the pharmacy are these consultations conducted? (total = 100%)					
In a private consultation area	84.365	84.4	5.0	86.7%	82.2%
At the pharmacy counter	14.21	14.2	4.9	12.1%	16.2%
Elsewhere	1.425	1.4	1.6	1.3%	1.6%
After using the materials for consultations regarding the supply of desogestrel 75 microgram film-coated tablets without a prescription, how useful did you find them?					
Extremely useful	81	40.5	6.8	37.1%	43.7%
Very useful	93	46.5	6.9	48.5%	44.7%
Somewhat useful	23	11.5	4.4	13.4%	9.7%
Not useful	0	0.0	0.0	0.0%	0.0%
No opinion	3	1.5	1.7	1.0%	1.9%
Mean score (+5 to +1)		4.2	Std.dev. 0.77	4.2	4.3
Were the materials easily accessible to you when giving consultations: yes.					
Pharmacy training guide					
Hana	153	85.3	4.9	68 (79.1%)	89 (90.8%)
Lovima	123	66.8	6.5	62 (70.5%)	61 (63.5%)
Consultation/ supply aid checklist					
Hana	152	86.4	4.8	73 (83.0%)	79 (89.8%)
Lovima	117	65.0	6.6	59 (67.0%)	58 (63.0%)
SmPC					
Hana	136	80.0	5.5	62 (72.9%	74 (87.1%)
Lovima	109	62.3	6.7	51 (62.2%)	58 (62.4%)
Pack copy					
Hana	140	79.1	5.6	66 (77.6%)	74 (80.4%)
Lovima	99	56.6	6.9	51 (60.0%)	48 (53.3%)
Other					
Other	50	27.9	6.2	19 (21.3%)	31 (34.4%

Table 8: Responses to all Questions Related to use of Consulting Facilities and Ease of Access to aRMMs in Pharmacy During Consultation – completed surveys, by segment: gender, urban/suburban

Question	Men N=104	Women N=90	Urban N=106 (%)	Suburban/ rural N=94 (%)
Where in the pharmacy are these consultations conducted? (total = 100%)				
In a private consultation area	86.1%	82.4%	83.3%	85.6%
At the pharmacy counter	12.5%	16.3%	15.3%	13.0%
Elsewhere	1.4%	1.3%	1.4%	1.5%
After using the materials for consultations regarding the supply of desogestrel 75 microgram film-coated tablets without a prescription, how useful did you find them?				
Extremely useful	41.3%	38.9%	40.6%	40.4%
Very useful	45.2%	47.8%	42.5%	51.1%
Somewhat useful	11.5%	12.2%	15.1%	7.4%
Not useful	0.0%	0.0%	0.0%	0.0%
No opinion	1.9%	1.1%	1.9%	1.1%
Mean score (+5 to +1)	4.3	4.2	4.2	4.3
Were the materials easily accessible to you when giving consultations: yes.				
Pharmacy training guide				
Hana	85.4%	85.5%	83.7%	87.2%
Lovima	75.8%	56.3%	67.0%	66.7%
Consultation/ supply aid checklist				
Hana	85.1%	86.8%	88.2%	84.3%
Lovima	70.8%	58.2%	68.1%	61.6%
SmPC				
Hana	77.8%	84.2%	86.9%	73.3%
Lovima	65.2%	60.3%	62.8%	61.7%
Pack copy				
Hana	82.0%	75.6%	79.4%	78.8%
Lovima	64.2%	48%	62.0%	50.6%
Other				
Other	30.3%	26.2%	30.3%	25.0%

Table 9: Reasons why some consultations didn't result in supply

Question	N=200	%	Precision or Margin of Error (±%)
When these consultations did not result in the supply of desogestrel 75 microgram film-coated tablets, what were the main reasons for this?			
Cost/patient not willing to pay	39	19.5	5.5
Specific symptoms indicated unsuitability	12	6.0	3.3
Not suitable'	5	2.5	2.2
Patient wanted more/larger supply	2	1.0	1.4
Contra-indications with medical history/age/co-morbidity	33	16.5	5.1
Possibility of pregnancy	7	3.5	2.5
Patient unsure of medical details	1	0.5	1.0
Patient already on contraception	3	1.5	1.7
Patient changed their mind/unsure/wanted time to think about it	15	7.5	3.7
Required referral to GP	8	4.0	2.7
Patient outside appropriate time period	3	1.5	1.7
Pharmacy too busy to fully consult patient	3	1.5	1.7
Patient wanted a combined oral contraceptive	4	2.0	2.0
Out of stock/lack of availability	6	3.0	2.4
Not applicable/all resulted in supply	61	30.5	6.4
Other answers	7	3.5	2.5
Don't remember	1	0.5	1.0

Table 10: Responses to all Questions Related to Confidence – completed surveys, by segment: age, gender

Question	Total sample N=200	%	Precision or Margin of Error (±%)	Under 40 years old N=90	Aged 40 plus N=100	Men N=104	Women N=90
How confident do you feel about advising patients on the use of desogestrel 75 microgram film-coated tablets?							
Completely (5)	38	19.0	5.4	13.3%	23.6%	21%	16.7%
Very (4)	83	41.5	6.8	37.8%	44.6%	39%	42.2%
Fairly (3)	75	37.5	6.7	46.7%	30.0%	38%	38.9%
Not very (2)	4	2.0	2.0	2.2%	1.8%	2%	2.2%
Not at all (1)	0	0.0	0.0	0.0%	0.0%	0%	0.0%
Mean score (+5 to +1)	200	3.8	Std.dev. 0.77	3.6	3.9	3.8	3.7
And how confident are you about correctly supplying desogestrel 75 microgram film-coated tablets without a prescription?							
Completely (5)	35	17.5	5.3	12.2%	26.4%	20%	13.3%
Very (4)	88	44.0	6.9	42.2%	50.0%	42%	44.4%
Fairly (3)	72	36.0	6.6	42.2%	21.8%	36%	38.9%
Not very (2)	5	2.5	2.2	3.3%	1.8%	2%	3.3%
Not at all (1)	0	0.0	0	0.0%	0.0%	0%	0.0%
Mean score (+5 to +1)	200	3.8	Std. dev. 0.76	3.6	4.0	3.8	3.7

Table 10.1: Responses to all Questions Related to Confidence – completed surveys, by segment: role, urban/suburban, number of consultations

Question	Pharmacists N=161 (%)	Locums N=39 (%)	Urban N=106 (%)	Suburban/ rural N=94 (%)	1-2 consults N=61 (%)	3-9 consults N=74 (%)	10+ consults N=65 (%)
How confident do you feel about advising patients on the use of desogestrel 75 microgram film-coated tablets?							
Completely (5)	18.6%	20.5%	21.7%	16.0%	15%	18.9%	23.1%
Very (4)	44.1%	30.8%	43.4%	39.4%	39%	37.8%	47.7%
Fairly (3)	34.8%	48.7%	31.1%	44.7%	41%	41.9%	29.2%
Not very (2)	2.5%	0.0%	3.8%	0.0%	5%	1.4%	0.0%
Not at all (1)	0.0%	0.0%	0.0%	0.0%	0%	0.0%	0.0%
Mean score (+5 to +1)	3.8	3.7	3.8	3.7	3.6	3.8	3.9
And how confident are you about correctly supplying desogestrel 75 microgram film-coated tablets without a prescription?							
Completely (5)	16.8%	20.5%	19.8%	14.9%	13%	17.6%	21.5%
Very (4)	46.6%	33.3%	41.5%	46.8%	39%	41.9%	50.8%
Fairly (3)	34.2%	43.6%	34.9%	37.2%	41%	39.2%	27.7%
Not very (2)	2.5%	2.6%	3.8%	1.1%	7%	1.4%	0.0%
Not at all (1)	0.0%	0.0%	0.0%	0.0%	0%	0.0%	0.0%
Mean score (+5 to +1)	3.8	3.7	3.8	3.8	3.6	3.8	3.9

Table 11: Supply/don't supply responses to Scenarios Relating to Understanding of aRMMs – completed surveys

Scenario	Correct Supply/ Don't supply	Supply N=200 (%)	Don't supply N=200 (%)	Correct (%)	Margin of error (+/-%)
1	Don't supply	14 (7.0%)	186 (93.0%)	93.0%	3.5
2	Supply	177 (88.5%)	23 (11.5%)	88.5%	4.3
3	Don't supply	21 (10.5%)	179 (89.5%)	89.5%	4.2
4	Supply	165 (82.5%)	35 (17.5%)	82.5%	5.2
5	Don't supply	29 (14.5%)	171 (85.5%)	85.5%	4.8
6	Supply	132 (66.0%)	68 (34.0%)	66.0%	6.6
7	Don't supply	49 (24.5%)	151 (75.5%)	75.5%	5.9
8	Supply	158 (79.0%)	42 (21.0%)	79.0%	5.6
	MEAN			82.6% (N=1600)	1.8

Table 11: Reason responses to Scenarios Relating to Understanding of aRMMs – completed surveys

Scenario	Correct A-D	A N=20 (%)	B N=200 (%)	C N=200 (%)	D N=200 (%)	% Correct	Margin of error (+/-%)
1	D	3 (1.5%)	9 (4.5%)	38 (19.0%)	150 (75.0%)	75.0%	6.0
2	A	170 (85.0%)	9 (4.5%)	14 (7.0%)	7 (3.5%)	85.0%	4.9
3	D	7 (3.5%)	5 (2.5%)	8 (4.0%)	180 (90.0%)	90.0%	4.2
4	B	20 (10.0%)	148 (74.0%)	9 (4.5%)	23 (11.5%)	74.0%	6.1
5	D	24 (12.0%)	6 (3.0%)	95 (47.5%)	75 (37.5%)	37.5%	6.7
6	A	103 (51.5%)	30 (15.0%)	57 (28.5%)	10 (5.0%)	51.5%	6.9
7	C	26 (13.0%)	25 (12.5%)	141 (70.5%)	8 (4.0%)	70.5%	6.3
8	B	13 (6.5%)	143 (71.5%)	40 (20.0%)	4 (2.0%)	71.5%	6.2
						69.6%	2.2

Table 11.1: Reason responses to Scenarios Relating to Understanding of aRMMs – completed surveys, by segment: outlet type, gender, role

Scenario	Correct A-D	Independents N=97 % Correct	Multiples N=103 % Correct	Men N=104 % Correct	Women N=90 % Correct	Pharmacists N=161 % Correct	Locums N=39 % Correct

1	D	72.2%	77.7%	69.2%	83.3%	73.9%	79.5%
2	A	82.5%	87.4%	81.7%	88.9%	85.1%	84.6%
3	D	90.7%	89.3%	86.5%	93.3%	88.2%	97.4%
4	B	76.3%	71.8%	71.2%	75.6%	73.3%	76.9%
5	D	34.0%	40.8%	34.6%	40.0%	36.7%	41.0%
6	A	48.5%	54.4%	52.9%	51.1%	55.1%	51.3%
7	C	70.1%	70.9%	66.4%	63.3%	70.2%	71.8%
8	B	70.1%	72.8%	73.1%	68.9%	72.7%	66.7%
	Mean	68.1%	71.4%	67.0%	70.6%	69.40%	71.15%

Table 11.2: Reason responses to Scenarios Relating to Understanding of aRMMs – completed surveys, by segment: urban/suburban, age

Scenario	Correct A-D	Urban N=106 (%)	Suburban/ rural N=94 (%)	Under 40 years old N=90	Aged 40 plus N=100
1	D	78.3%	71.3%	77.8%	72.7%
2	A	82.1%	88.3%	78.9%	90.0%
3	D	86.8%	93.6%	90.0%	90.0%
4	B	72.6%	75.5%	74.4%	73.6%
5	D	32.1%	43.6%	35.6%	39.1%
6	A	47.2%	56.4%	58.9%	45.5%
7	C	65.1%	76.6%	73.3%	68.2%
8	B	68.9%	77.5%	74.4%	69.1%
	Mean	66.6%	72.9%	70.4%	68.5%

Table 11.3: Reason responses to Scenarios Relating to Understanding of aRMMs – completed surveys, by segment: number of consultations

Scenario	Correct A-D	Conducted 1-2 consults N=61 % Correct	Conducted 3-9 consults N=74 % Correct	Conducted 10 plus consults N=65 % Correct
1	D	83.6%	71.6%	70.8%
2	A	93.4%	83.8%	78.5%
3	D	91.8%	91.9%	86.2%
4	B	70.5%	78.4%	72.3%
5	D	42.6%	33.8%	36.9%
6	A	45.9%	54.0%	53.9%
7	C	68.9%	71.6%	70.8%
8	B	72.1%	75.7%	66.2%
	Mean	71.1%	70.3%	66.9%

Table 12: Responses to scenarios which didn't meet the KPI

Table 12.1: Responses to Scenario 5 – completed surveys, by all segments

A woman in her 30s asks to have a chat to find out if desogestrel would be a suitable contraceptive for her. She has been with her partner for over 10 years and previously had a contraceptive implant, but had it removed a couple of months ago. She and her partner have been using condoms since she had her implant removed. She says her periods are regular and she has no bleeding between her periods or after sex. She has type 2 diabetes, which is well controlled; she is taking metformin. She had a deep vein thrombosis about 5 years ago, but has not had a recurrence. She has a BMI of >30.

A. Incorrect	Supply desogestrel as a history of thrombosis is not a contraindication
B. Incorrect	Supply desogestrel as her diabetes is well controlled
C. Incorrect	Do not supply desogestrel and refer her to her doctor as she has a history of thrombosis
D. Correct	Do not supply desogestrel and refer her to her doctor as she has type 2 diabetes

D Correct	Base	N	%	Precision or Margin of Error (±%)
Total	200	75	37.5	6.7
Independents	97	33	34.0	9.4
Multiples	103	41	40.8	9.5
Men	104	36	34.6	9.1
Women	90	36	40.0	10.1
Pharmacists	161	59	36.7	7.4
Locums	39	16	41.0	15.4
Urban	106	34	32.1	8.9
Rural	94	41	43.6	10.0
Aged under 40	90	32	35.6	9.9
Aged 40 plus	100	43	39.1	9.6

Table 12.2: Responses to Scenario 6 – completed surveys, by all segments

A 16 year old young woman asks for a further supply of desogestrel. She has been taking desogestrel for 3 months. She says that she has been experiencing some spotting and her periods haven't been as regular as they used to be, but this isn't bothering her. She has been taking desogestrel as directed every day and hasn't missed a dose. She has no medical conditions and is not taking any other medicines. She asks if she can have more than a three month supply.

Correct	Supply desogestrel (3 month supply) and advise her to consult her GP if the spotting is after sex or the irregular periods become bothersome
Incorrect	Supply desogestrel (6 month supply) and advise her to consult her GP if the spotting is after sex or the irregular periods become bothersome
Incorrect	Do not supply desogestrel as she is experiencing spotting and irregular periods
Incorrect	Do not supply as she may be pregnant

A correct	Base	N	%	Precision or Margin of Error (±%)
Total	200	103	51.5	6.6
Independents	97	47	48.5	9.9
Multiples	103	48	54.4	9.6
Men	104	55	52.9	9.6
Women	90	46	51.1	10.3
Pharmacists	161	83	55.1	7.7
Locums	39	20	51.3	15.7
Urban	106	50	47.2	9.5
Rural	94	53	56.4	10.4
Aged under 40	90	53	58.9	10.2
Aged 40 plus	100	50	45.5	9.8

Table 12.3: Responses to Scenario 7 – completed surveys, by all segments

A woman in her 40s asks if she can buy desogestrel. She and her husband have been using condoms and spermicide for contraception since she had breast cancer, but he doesn't really like using condoms. She asks if desogestrel would be suitable for her as she had breast cancer nearly 10 years ago and gets occasional migraines. Apart from this, she has no other medical conditions and isn't taking any prescription medicines. Her periods are regular and she hasn't experienced any bleeding between her periods or after sex.

A. Incorrect	Supply desogestrel as she has no contraindications and advise her to see her GP if her migraines get worse or become more frequent
B. Incorrect	Supply desogestrel as she had breast cancer more than 5 years ago and advise her to see her doctor if her migraines get worse or become more frequent
C. Correct	Do not supply desogestrel as she has a history of breast cancer
D. Incorrect	Do not supply desogestrel as she gets occasional migraines

C correct	Base	N	%	Precision or Margin of Error (±%)
Total	200	141	70.5	5.9
Independents	97	68	70.1	9.1
Multiples	103	56	70.9	8.8
Men	104	69	66.4	9.1
Women	90	66	73.3	9.1
Pharmacists	161	113	70.2	7.1
Locums	39	28	71.8	14.1
Urban	106	69	65.1	9.1
Rural	94	72	76.6	8.6
Aged under 40	90	66	73.3	9.1
Aged 40 plus	100	75	68.2	9.1

Table 12.4: Responses to Scenario 8 – completed surveys, by all segments

A woman in her 30s asks to speak to you in private. She explains that she had unprotected sex a couple of days ago and would like to buy emergency contraception. She has taken ulipristal acetate in the past and would like to take the same tablet again as she didn't experience any side-effects. You determine that she is suitable for ulipristal acetate and provide her with a pack. She says that she has just started a new relationship and would also like to start taking regular contraception. You discuss contraceptive options with her, including long-acting reversible contraceptives (LARCs), and explain that only barrier methods such as condoms will protect her from STIs. She decides she would like to start taking desogestrel. She isn't taking any other medication, has no medical conditions and her periods are regular. She mentions that she smokes.

A. Incorrect	Supply desogestrel and advise her to start taking it straight away
B. Correct	Supply desogestrel and advise her to start taking it on day 1 of her next menstrual period and to use additional contraceptive measures (abstinence or barrier methods) until then
C. Incorrect	Do not supply desogestrel as she may be pregnant
D. Incorrect	Do not supply desogestrel as she is a smoker

B correct	Base	N	%	Precision or Margin of Error (±%)
Total	200	143	71.5	5.6
Independents	97	68	70.1	9.1
Multiples	103	73	72.8	8.6
Men	104	76	73.1	8.5
Women	90	62	68.9	9.6
Pharmacists	161	117	72.7	6.9
Locums	39	26	66.7	14.8
Urban	106	73	68.9	8.8
Rural	94	70	77.5	8.4
Aged under 40	90	67	74.4	9.0
Aged 40 plus	100	76	69.1	9.1

Appendix 1.4: Verbatim responses to Q5

- Unwanted side effects
- 20% due to age
- Age
- Age exclusions and out of licence
- Age related issues out with licence
- Age, weight
- All consultations resulted in a supply
- All had desogestrel
- All qualified for sale
- All resulted in supply
- All resulted in the supply
- Any contraindications or allergies to the active ingredients or excipients. Also if any red flags have been raised
- Available free elsewhere
- Because the patient was already on a regular contraceptive, which was the combined pill. She forgot to request another supply from the doctor so she wanted a supply of Hana.
- Both patients were supplied with desogesterol
- Both supplied
- BP high. Patient not sure if safe
- Busy pharmacy
- Clinical eg epileptic or pregnant
- Contra indications
- Contra-indicated medical history
- Contra-indication e.g. past breast cancer
- CONTRAINDICATION WITH HANA
- Contraindication with current medication
- Contraindications
- Contraindications to supply highlighted after completing the checklist, 2 diabetic, age restriction
- Cost
- Cost too much
- Cost when normally free
- Could not exclude pregnancy
- Did not meet the guidance for supply due to being outside the PoP guidance
- Did not meet the PGD requirements or patient did not want to pay!
- Do not fall into inclusion criteria of having one.
- Drug interactions
- Exclusions list
- Greater than 72hrs post intercourse
- Haven't encountered any
- Haven't encountered yet
- High B.P.
- High Blood Pressure
- I don’t remember
- I have not had any consultation that would not result in the supply.

- I haven't had this situation yet
- I made supply after the consultation
- Inappropriate
- Inappropriate and or referred to GP
- Inappropriate for the patient due to enzyme inducers
- Is believable
- It resulted in the supply
- Lack of stock.
- Lack of understanding on the use of Lovima/Hana and why it is different from other contraceptives.
- Looking for contraceptive but might already be pregnant. Most consultations resulted on sale of medicine
- Made first supply
- Medical history contraindication eg clotting disorder,ischaemic heart disease
- Migraines (c/i), blood pressure not ever checked but history of heart disease exists in family, a few were under 16 (mainly 15 years old)
- My one and only consultation resulted in the supply
- N/A - All consultations were suitable
- N/A Only one consultation and this did result in a supply
- Need a GP review
- Need for switch to something simpler
- Needed protection
- No consultations resulted in non-supply of desogestrel 75microgram due to any medical reasons but I would say approximately 2 were due to price issues. The patients did not want to pay and would rather wait and try and get it from their GP (as it is free on the NHS).
- None - all resulted in the supply of the medication
- None, I had only one consultation and supplied
- None in stock
- None resulted in non-supply.
- Not applicable. The consultation ended in a sale
- Not had a consultation that did not result in supply
- Not had a refusal to supply case
- Not had before, other health conditions, pt not clear on wht contraceptive they are currently taking
- Not had menstrual period on time. Possibility of being pregnant.
- Not had such a scenario
- Not had this happen yet
- Not in stock
- Not suitable
- Not suitable due to co-morbidities
- Not suitable due to other medical history
- Not suitable e.g. diabetes, on carbamazepine
- Not willing to pay
- Obtain from GP
- On customer's request

- One had rather odd history and GP had refused to give further supply. Referred back to GP or sexual health clinics
- One case of thrombosis in the past (patient wasn't aware this was a contraindication), another case with liver disease and history of breast cancer, these patients were referred to GP for review and suitable contraception advice
- One consultation resulted in supply
- One consultation resulted in supply
- One patient changed their mind after hearing about side effects
- Only done one and I supplied
- Only one consultation and I did make a supply
- Only one incident when the client was mentioning irregular bleeding after sexual intercourse was the request rejected and referred to family doctor
- Only one. Patient was already on the 21 day pill and had run out so wanted to buy
- Other co-morbidities e.g. diabetes,
- other medical contraindications such as medical conidtions or unable to supply as beyond 72 hour window
- Outside time period, unsuitable due to intolerance
- Pateient that are allergic to peanut ,soya,Thrombosis ,Jaundice ,cancer or vaginal bleeding
- Patient already on this pill-supply made as Emergency-POM.
- Patient came close to closing time. I did not have enough time to conduct a consultation
- Patient changed her mind, patient was taking interacting medication
- Patient could prefer to have the combined pill
- Patient couldn’t get to doctor in time to start next pack
- Patient decided not to purchase due to cost and stated she would wait to get on prescription
- Patient did not realise they had to pay
- Patient did not want to pay the pack price
- Patient did not want to pay when they could get it for free
- Patient didn't want to pay for something available free on NHS
- Patient didn’t want to buy
- Patient had bleeding in between her periods so I advised her to consult her doctor
- Patient had not had their blood pressure checked prior to consultation.
- Patient may have had a contraindication to the use of it
- Patient not suitable
- Patient not sure of medication
- Patient not willing to pay
- Patient on carbamazepine
- Patient recently had mirena coil removed and hadn't yet decided on her next contraceptive
- Patient refused to pay for supply
- Patient unaware that they had to pay
- Patient unsure
- Patient unsure, prefers to get free from sexual health clinic
- Patient unwilling to take desogestrel due to personal bad experience in the past or knowledge of someone else with some bad experience
- Patient wanted Combined Oral Contraceptive
- Patient wanted larger supply

- Patient wanted time to think about it
- Patient was not aware there was a local sexual health clinic within 5 minutes walk that offered free contraceptive services as a walk in
- Patient was not ready to pay
- Patient was pregnant
- Patient was unsure of medical details or not clearly answering questions
- Patient with history of high blood pressure that wasn't well controlled. Referred to GP.
- Patient worried about not getting periods at all
- Patient wrongly assumed it would be free
- Patients did not want to pay for the pill
- Patients on meds for hepatitis. Unusual bleeding
- patients preferred to remain on the brand they were familiar with.
- Patients wanted Combined oral Contraceptive oill
- Patients wanted to think about it more and did not want to make a decision in a rush.
- Patients were not happy to pay for Hana and planned to make an appointment with their GP
- People on holiday in Wales
- Possible pregnancy
- Pregnancy risk
- Presenting patients were too young
- Price
- Price and prescription availability
- Price patients deem it to be too expensive and prefer to speak to the GP to obtain it free of charge
- Pt finding the cost prohibitive
- PT had unexplained vaginal bleeding
- Purchase cost
- Refer to GP
- Referral to GP required
- Refusal to pay
- Run out
- Side effects
- Some patients did not realise that the service was a sale of the product, not a free supply.
- Some people did not feel safe to use the medicine, others had been using it for a long time and believed that it was not convenient to continue doing it and the last people are afraid of the side effects of the medicine such as bleeding, so some avoided the use of the medicine, but they talked about all the benefits it has so that they reconsider it
- Supplied
- Supplied all
- Supplied each time
- Supplied in all
- Supplied on all 3 occasions
- Supplies on each occasion
- Supply given each time
- Supply made
- Supply was made in all cases
- Surprised by cost

- The only consultation I had resulted in a sale
- The patient chose not to proceed with the supply after our consultation, not on safety grounds but on the basis of getting FOC from GP/clinic
- The patient decided they were unhappy to pay for the medication and decided to access free contraception via their GP instead
- The price as customers knew that they can get desogetrel 75 microgram for free from GP
- There was only one consultation and she was supplied
- they already taking another contraceptive pill
- They both did
- They changed mind after learning of side effects
- They did
- They did result in supply
- They resulted in a supply
- They want the pill for free
- Timing too late
- Too expensive, and supplied on PGD
- Under 16
- unexplained vaginal bleeding, possible unprotected sex over 5 days
- unsafe or requires referral to GP
- Vaginal Bleed in between periods. Waiting for results of investigations
- Venous thromboembolic disorders
- Want it on rx
- We had no stock available
- When there was a possibility that women was already pregnant
- Window was too short
- Most consultation took place when requesting for morning after pill
- Never been on a contraception and needed a review with the GP first
- One person was excluded due to concerns around DVT (had an episode in the last month)
- Patient was put off by cost. Either too expensive or unhappy to pay anything for medicines