
 GlaxoSmithKline	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

Clinical Protocol

204675

	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

PROTOCOL AMENDMENT PAGE


Details of all amendments are recorded in the table below. Affected sections and pages are listed in the table; the actual amendment/ change have been made in the relevant section of the main protocol.


To highlight the change, the following features are used:


Added text: Use **of CAPITAL LETTERS, BOLD AND UNDERLINE**


Delete text: Use of Strikethrough e.g. ~~striktthrough~~

Amendment No. & New Protocol Version No.	Type of Amendment	Reason for Amendment	Other Documents Requiring Amendment	Section(s) Amended	PI Amendment Agreement Signature & Date
Amendment No.: 1	Non-Substantial/Minor <input checked="" type="checkbox"/>	Reduction in the number of countries involved from 4 to 3, with Italy being removed.	Informed Consent <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Safety Statement <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No CRF <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	1. Study synopsis	Signature:
Protocol Version No.: 3	Substantial/ Major <input type="checkbox"/>	There are multiple (>100) regional ethics committees in Italy, and the study protocol is required to be submitted to each one where recruitment will take place. This poses substantial operational difficulties, and could potentially lead to long delays in the study process. Pharmacy studies have been conducted for other products where participants were recruited from a limited number of countries, and results extrapolated to cover all other markets. As such, we feel that omitting Italy and conducting the study in the remaining 3 (out of 4) markets where alli [®] is sold will not affect the integrity of the results.		4.1. Data collection procedures 5.1 Inclusion criteria 8. Ethical and regulatory aspects	Date:
Amendment No.: 2	Non-Substantial/Minor <input checked="" type="checkbox"/>	Redistribution of study participants, from 120 in each of the 4 countries, to a targeted 33% (i.e. 160) of total participants from each of the	Informed Consent <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Safety Statement <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No CRF <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	1. Study synopsis	Signature:
Protocol Version No.: 3	Substantial/ Major <input type="checkbox"/>	remaining 3 countries (after removal of Italy), with a minimum of 25% (i.e. 120) and maximum of 50% (i.e. 240) from either of three countries. There are large differences in the number of community pharmacies between		5. Study Population	Date:

	Document Name	204675-Protocol			
	Type	countries, especially in the number of		Document Identifier	Effective Date
		Version			
	eldo clinical doc	those that are stocking alli [®] whom we	090032d580bf3a40	26-Jul-2016 10:42:05	
	Reason For Issue	4.0, Most Recent Effective, CURRENT will prioritise the recruitment towards.			
		<p>Confounding may occur in case if there is a large disparity in representativeness from individual countries along-with possibility of differential responses from the participants based on the country they belong to. To control possible distortion of overall response resulting due to skewed distribution of the participants, it becomes pertinent that there exists proportionate representativeness from each of the three participating countries. Thus decision has been made to restrict/stratify recruitment from individual countries.</p>			
Amendment No.: 3	Non-Substantial/Minor <input checked="" type="checkbox"/>	Duration of data collection has been amended from ‘approximately 8 weeks’ to ‘around 4 months’.	Informed Consent <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Safety Statement <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No CRF <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	1. Study synopsis	Signature:
Protocol Version No.: 3	Substantial/ Major <input type="checkbox"/>	The clinical study team reviewed the available pharmacy contacts and resources, and considered 4 months to be a more realistic projection of data collection duration.			Date:
Amendment No.: 4	Non-Substantial/Minor <input checked="" type="checkbox"/>	Pilot study has been amended, from 5 study participants in the UK, to 20 study participants across the UK, Spain and Finland. Detailed descriptions of the pilot study’s objectives have also been added.	Informed Consent <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Safety Statement <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No CRF <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	4.1 Data collection procedures	Signature:
Protocol Version No.: 3	Substantial/ Major <input type="checkbox"/>	<p>The clinical study team agreed that the pilot study will be crucial in determining a number of factors:</p> <ul style="list-style-type: none"> - comprehension of the questions and identify any ambiguous / misunderstood wording - completion / drop-out from the questionnaire and how this could be 			Date:

	Document Name	204675-00000001				
	Type	- Version		Document Identifier	Effective Date	
	eldo clinical doc	4.0: Most Recent Effective: CURRENT		090032d580bf3a40	26-Jul-2016 10:42:05	
	Reason For Issue	Auto Issue				
		<p>the questionnaire to determine whether they are filled in appropriately with relevant data</p> <ul style="list-style-type: none"> - completion time for pharmacists and pharmacy assistants to check that adequate time has been allowed for in the remuneration <p>In light of this, the number of pilot study participants have been expanded from 5 to 20 (covering both pharmacists and pharmacy assistants), and recruited from all 3 countries instead of just in the UK.</p>				
Amendment No.: 5	Non-Substantial/Minor <input checked="" type="checkbox"/>	Recruitment will be prioritised (instead of limited) to pharmacies who are marketing alli®.		Informed Consent <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Safety Statement <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No CRF <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	5. Study Population 5.1 Inclusion criteria	Signature:
Protocol Version No.: 3	Substantial/ Major <input type="checkbox"/>	We will focus our recruitment strategy on those pharmacies who are actively stocking alli®. However in order to maximize the recruitment pool and ensure that data collection takes place in a timely fashion, we have removed the inclusion criterion which limits the study to only those pharmacies that are selling alli®.				Date:
Amendment No.: 6	Non-Substantial/Minor <input checked="" type="checkbox"/>	We have removed the condition that recruitment will be stratified according to geographical areas within each country to reflect the distribution of the population (e.g. urban/rural areas), so that the recruitment process can be further streamlined.		Informed Consent <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Safety Statement <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No CRF <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	5. Study Population 5.4 Pharmacy staff recruitment	Signature:
Protocol Version No.: 3	Substantial/ Major <input type="checkbox"/>					Date:
Amendment No.: 7	Non-Substantial/Minor <input checked="" type="checkbox"/>	We have reworded the questionnaire from: <i>'Are there any other questions you would like to ask this customer? Please</i>		Informed Consent <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Safety Statement <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Appendix 2 - alli® Virtual Customers	Signature:
Protocol						Date:

Version 3	 GlaxoSmithKline	Document Name	204675 Protocol		CRF	(Vignettes)		
		Type	Version			<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Document Identifier	Effective Date
		<input type="checkbox"/> eido_clinical_doc Reason For Issue	4.0; Most-Recent; Effective; CURRENT To: Auto Issue				090032c580bf3a40	26-Jul-2016 10:42:05
		<p><i>‘If you have any further questions for this customer, please type them below:’</i></p> <p>This amendment is a response to the UK Ethics Committee’s query on whether a participant is limited to asking only 3 further questions.</p> <p>Participants are free to ask as many (or as few) questions as they wish, therefore we have amended the wording to be more open.</p>						

 GlaxoSmithKline	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

Confidential

Summary Information

Title: Evaluating the effectiveness of the revised alli® pack information in helping pharmacy staff within the EU supply alli® appropriately

Protocol Number: 204675

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* alli is a registered trademark of the GlaxoSmithKline group of companies.

 GlaxoSmithKline	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

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	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

Protocol Agreement

Evaluating the effectiveness of the revised alli® pack information in helping pharmacy staff within the EU supply alli® appropriately

The signature of the CRO's Representative below constitutes his/her approval of this protocol and provides the necessary assurances that this survey will be conducted according to all stipulations, administratively, as stated in the protocol, including all statements as to confidentiality. It is agreed that the conduct and results of this survey will be kept confidential and that the survey forms will become the property of GlaxoSmithKline Consumer Healthcare(GSKCH).

It is agreed that the protocol contains all necessary information required to conduct the survey and that the survey will not be initiated without the approval of an appropriate Institutional Review Board (IRB), Competent Authority (CA) or Independent Ethics Committee (IEC) if required.

It is agreed that all participants in this survey will have consented to take part in this survey. All participants will also be informed that their anonymised information will be kept confidential.

In some instances, a summary of the protocol and the survey results may be posted on one or more publicly accessible worldwide registers.

CRO's Representative

CRO Representative's Title and Position




	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

Table of Content

Table of Content.....	9
1. Study Synopsis.....	11
2. Background to the study.....	15
3. Study Objectives	18
4. Study Design.....	19
4.1 Data collection procedures	20
5. Study Population.....	21
5.1 Inclusion criteria	21
5.2 Exclusion criteria	21
5.3 Pharmacy staff withdrawal criteria	22
5.4 Pharmacy staff recruitment	22
5.5 Sample size	22
6. Data analysis methods	22
6.1 Criteria for evaluable data from pharmacy staff.....	22
6.2 Exclusion of data from analysis.....	23
6.3 Missing data	23
6.4 Endpoints.....	23
6.5 Analysis and statistical methods.....	24
7. Reporting of Adverse Events.....	27
8. Ethical and regulatory aspects	27
8.1 Local regulations/Declaration of Helsinki	28
8.2 Informed consent	28
9. Documentation	28
9.1 Completed questionnaires/retention of documents	28
9.2. Questionnaires.....	29
9.3 Data handling	30
9.4 Data queries.....	30


 GlaxoSmithKline	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

10. Process for amending the proposal	30
11. Conditions for terminating the study.....	30
12. Confidentiality of documents	30
13. Publication of data and protection of trade secrets	31
14. Quality Assurance	31
15. References.....	32
Appendix 1 - Abbreviations.....	33
Appendix 2 - alli® Virtual Customers (Vignettes).....	34


 GlaxoSmithKline	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

1. Study Synopsis


Title	Evaluating the effectiveness of the revised alli® pack information in helping pharmacy staff within the EU supply alli® appropriately
Objectives	<ol style="list-style-type: none"> 1. To evaluate whether revisions to the on-pack label for alli® are effective in enabling pharmacy staff to make an appropriate decision to supply alli® to consumers based upon the following criteria: <ul style="list-style-type: none"> • BMI (≥ 28 kg/m²) • Age (≥ 18 years old) • Contraindications to use of alli® (taking ciclosporin, chronic malabsorption syndrome, cholestasis, pregnancy or breast-feeding, taking warfarin or other oral anticoagulant) • Special warnings to use of alli® (kidney disease, taking medicinal products for diabetes, hypertension, hypercholesterolemia, taking antiepileptics, antiretrovirals, benzodiazepines, antidepressants, antipsychotics, levothyroxine or amiodarone). Consumer must have consulted their doctor prior to use 2. To identify whether there are specific criteria which pharmacy staff do not recognise as indications, contraindications or warnings for the use of alli®
Design and methodology	Updated on-pack information for alli® will be distributed to pharmacy staff approximately one month prior to their participation in the study to improve awareness of the information for supplying alli®. No other training relating to alli® will be provided to pharmacy

	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		


	<p>staff.</p> <p>A series of 33 virtual customers will be developed by clinical experts, based on clinical experience and the indications, contraindications, and warnings outlined in the Summary of Product Characteristics (SmPC) for alli®.</p> <p>The virtual customers will be designed to include both customers who are suitable and unsuitable for alli®, testing nearly the full range of the currently approved label as described below:</p> <p><u>Indications</u></p> <ul style="list-style-type: none"> • BMI $\geq 28 \text{ kg/m}^2$ • ≥ 18 years <p><u>Contraindications</u></p> <ul style="list-style-type: none"> • Taking ciclosporin • Chronic malabsorption syndrome • Cholestasis • Pregnant or breast-feeding • Taking warfarin or other oral anticoagulant <p><u>Warnings</u></p> <ul style="list-style-type: none"> • Kidney disease • Taking levothyroxine • Taking amiodarone • Taking medicinal products for diabetes • Taking medicinal products for hypertension • Taking medicinal products for hypercholesterolemia
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	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

	<ul style="list-style-type: none"> • Taking antiepileptics • Taking antiretrovirals • Taking benzodiazepines, antidepressants or antipsychotics <p><u>Purchasing on behalf of a third party prohibited</u></p> <p>Pharmacy staff will complete an online questionnaire containing a randomly ordered series of 33 virtual customers for whom they will make yes/no decisions as to whether to supply alli® and if no, they will be asked to provide the rationale for their decision.</p>
Planned number of pharmacy staff	<p>120 community pharmacy staff in 4 countries (UK, Spain, Italy and Finland) for a total of 480 pharmacy staff members (360 pharmacists, 120 pharmacy assistants).</p> <p><u>A TOTAL OF 480 COMMUNITY PHARMACY STAFF (INCLUDING PHARMACISTS AND PHARMACY ASSISTANTS) FROM UK, SPAIN AND FINLAND WITH A MINIMUM OF 25% OF TOTAL PARTICIPANTS (I.E. 120) AND A MAXIMUM OF 50% OF TOTAL PARTICIPANTS (I.E. 240) FROM EITHER OF THREE COUNTRIES.</u></p>
Main criteria for inclusion	<p>Qualified and practicing community pharmacist or pharmacy assistant referred to as pharmacy staff throughout the document.</p>
Main exclusion criteria	<ul style="list-style-type: none"> • Employed by The Research Company (Hamell) or The Sponsor • Currently or previously (within last 6 months) employed by: pharmaceutical company, healthcare company, market research company, healthcare advertising company, healthcare marketing company, regulatory or advisory authority

	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

Duration of data collection	Pharmacy staff will be recruited and data collected over approximately an eight week A period <u>OF AROUND 4 MONTHS.</u>
Data collection	Data will be collected on 15,840 decisions (33 decisions from each of 120 pharmacy staff in 4 <u>THE 480 COMPLETED QUESTIONNAIRES</u> <u>ACROSS 3</u> countries).
Criteria for evaluation	<p>Primary endpoint</p> <p>The primary endpoint will be the proportion of correct answers by the pharmacy staff to:</p> <ul style="list-style-type: none"> • Supply alli® when the virtual customer is suitable for the product • Not supply alli® when the virtual customer is not suitable for the product <p>80% correct answers will be considered to signify that the revised label is effective in enabling pharmacy staff to supply alli® appropriately^{1,2}.</p> <p>Secondary endpoints</p> <p>The secondary endpoints will include:</p> <ul style="list-style-type: none"> • The proportion of correct responses for each sub-score (indications, contraindications and warnings) analysed • The proportion of false positives* by the pharmacy staff • The proportion of false negatives# by the pharmacy staff

	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

	80% correct answers will be considered to signify that the revised label is effective with respect to each sub-score (indication, contraindication and warning) in enabling pharmacy staff to supply alli®.
Statistical methods	The proportions of correct and incorrect pharmacy staff responses overall and by criteria, and their 95% confidence intervals will be calculated and presented.

* A false positive is defined as an answer whereby the pharmacist responded that they would supply alli® to a Customer for whom it is **unsuitable**.

A false negative is defined as an answer whereby the pharmacist responded that they would not supply alli® to a customer for whom it is suitable.


2. Background to the study

Orlistat 60 mg capsules (hereafter called alli® capsules) and orlistat 27 mg chewable tablets have been approved for use without a prescription in the European Union (EU).

Orlistat has a well characterised safety profile that is based upon extensive clinical development and over 15 years of post-marketing experience with more than 40 million patient exposures. The intended indication for alli® is for weight loss in adults who are overweight (body mass index, BMI ≥ 28 kg/m²), taken in conjunction with a mildly hypocaloric, lower-fat diet.

Two surveys have previously been conducted to provide information about the demographic and clinical characteristics of consumers who purchase alli® capsules (WEUS RTP3350³ and WEUS RTP3841⁴). These surveys formed part of the EU Risk Management Plan (RMP) for alli®.

Following the results of the two RMP surveys, several amendments to the information included on the pack carton for alli® in the EU were recommended. The main finding from

 GlaxoSmithKline	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		


the surveys was that a large proportion of consumers using the product had a BMI <28 kg/m². In order to help address this, a prominent statement specifying that alli® is suitable: 'for adults with a BMI of 28 or above', was placed on the front of the pack. The wording of the statement on the back of the pack (above the height weight table) was also strengthened to clearly indicate that use of the product was intended for those with a BMI of 28 or above. The proportion of respondents overall who reported possible contraindications to alli® use was relatively low. To reinforce the contraindications further, these have been highlighted in bold text and the statement that alli® was not for use by those under 18 years of age, modified for clarity. A pharmacy reminder card was made available to retail pharmacy staff to improve awareness of the information for selling alli® to customers.

Community pharmacy staff play an important role in moderating access to non-prescription medicines. It is the pharmacist's (and in some countries, the pharmacy assistant's) role to assess customers for suitability to supply non-prescription medicines, ensuring they meet eligibility requirements in terms of indication and contraindications and warnings, in accordance with the SmPC. In order to be compliant, it is important that pharmacy staff are familiar with the latest package labelling.

The proposed survey, is designed to assess whether amendments to the pack text and format have been effective in ensuring appropriate recommendation of the product by pharmacy staff.

GSK submitted a protocol for a repeat survey in which data on suitability for alli® were to be collected from customers themselves (as per survey one and two). However, based on the lack of alli® sales due to the interruption in supply by the manufacturing site in 2012 and 2014 and the decision of a number of markets not to re-launch the product in 2015, this approach is considered to have a number of challenges, as follows:

- Due to the limited number of markets likely to re-launch alli®, a substantially larger number of pharmacies would need to be involved per market and pharmacy staff motivation to manage completion of questionnaires is likely to be low

	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

- Data may be of limited validity and quality, with potentially only 1-2 questionnaires completed per pharmacy, providing limited variability
- It may not be feasible to run the study in the 6-month time frame as previously agreed with the Committee for Medicinal Products for Human Use (CHMP); with the break in supply of over a number of years and no major promotion planned at the time of resupply, data collection could take up to a year or longer

The proposed protocol

The current protocol is an alternative approach to providing evidence of the effectiveness of the revised label. The protocol involves testing pharmacy staff knowledge and behaviour using virtual customers, without a requirement for testing pharmacy staff behaviour in a 'real life' scenario in the pharmacy and hence customer purchase. Virtual customers will be developed by clinical experts, who will take into account their clinical experience as well as the key on-pack information including product indication, contraindications and warnings.


Virtual customer methodology

The use of virtual patients, also known as case or clinical vignettes or 'paper patients', is an established, published methodology that is commonly used in medical education and research to test, for example, healthcare professionals' (HCPs') clinical judgement or adherence to prescribing guidelines.^{1,5,6,7,8} Studies have found that HCPs' responses to virtual cases are a good indication of what they will actually do in a clinical setting.⁷ A similar methodology has previously been applied in the pharmacy context by Hamell.^{2,9} These have produced data that have been accepted by regulatory agencies including the Medicines & Healthcare products Regulatory Agency (MHRA).

Virtual customer research will provide sufficient data, from a large enough sample of community pharmacy staff, to answer the question about the impact of on-pack label changes on pharmacy staff knowledge.

Advantages and disadvantages of virtual customer methodology

There are advantages to the virtual customer design.


 GlaxoSmithKline	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

- A large sample of pharmacy staff can be included, providing robustness around the generalisability of pharmacy staff behaviour.
- It can be conducted online.
- It can be conducted within a short timescale which means that assessment of the impact of the changes to the on-pack information can be completed in a timely way; significantly quicker than if data have to be collected direct from customers who purchase alli®.
- It offers the opportunity to provide robust answers around pharmacy staff behaviour in regards to specific issues (compared to only recruiting very small numbers of customers per pharmacy staff member). For example, the virtual customers can be constructed to include contraindications and warnings for the use of alli®, thereby demonstrating pharmacy staff knowledge of the contraindications and warnings. In a real life setting with low numbers of customers, it is possible that no customers with contraindications or warnings for the use of alli® will present to the participating pharmacy staff, which would mean that pharmacy staff knowledge could not be measured.

The disadvantage of the virtual customer design is that whilst the customer profiles will be designed to be realistic, this will not be a real world situation.

3. Study Objectives

1. To evaluate whether revisions to the on-pack label changes for alli® are effective in enabling pharmacy staff to make an appropriate decision to supply alli® to consumers based upon the following criteria:
 - BMI ($\geq 28 \text{ kg/m}^2$)
 - Age (≥ 18 years old)
 - Contraindications to use of alli® (taking ciclosporin, chronic malabsorption syndrome, cholestasis, pregnancy or breast-feeding, taking warfarin or other oral anticoagulant)

 GlaxoSmithKline	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		


- Special warnings to use of alli® (kidney disease, taking levothyroxine, amiodarone, antidiabetics, antiretrovirals, antidepressants, antipsychotics, benzodiazepines or cholesterol lowering drugs): Consumer must have consulted their doctor prior to use
2. To identify whether there are specific criteria which pharmacy staff do not recognise indications, contraindications or warnings for the use of alli®

4. Study Design

A series of 33 virtual customers will be developed in conjunction with clinical experts. The virtual customers will represent the spectrum of customers who could present in pharmacy requesting alli®, and will be based on the indications and contraindications and selected warnings specified in the pack text, as well as clinical experience of factors that drive customers to seek alli®. The virtual customer profiles will include a photograph of the customer to enable participants to make an estimation of BMI. Additional BMI values will be provided to pharmacy staff if requested (See Appendix 2 with Vignettes).

All participating pharmacy staff will be provided with updated on-pack information for alli® at least one month before completing the survey. This time interval between receiving the updated on-pack information and completion of the survey will ensure that pharmacy staff have had an opportunity to see the updated information but that it will not bias the results of the survey. The survey will therefore be more likely to reflect true levels of knowledge of the updated pack information. Pharmacy staff will not be restricted from accessing their on-shelf or supplied updated on-pack information to check details whilst completing the survey because this is what they would probably do in practice. Participants should not engage in any training or study other than from the materials provided. Conferring or seeking advice from others in order to complete the task is also prohibited as the study design is to simulate real life scenarios.

Following the one month time interval, participating pharmacy staff will complete an online questionnaire in which they will be presented with the series of 33 virtual customers

 GlaxoSmithKline	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

and asked to decide whether each customer is suitable for alli® and the reasons why not. Eliciting the rationale for not supplying alli® will enable further detailed assessment of pharmacy staff knowledge and understanding of the indication, contraindications and warnings for use of alli®.

4.1 Data collection procedures


Participants will complete an online questionnaire containing the 33 virtual customers, presented in a random order (translated into ~~32~~ languages: Spanish, ~~Italian~~ and Finnish). It is estimated that it will take around 40 minutes to review the 33 virtual customers.

~~Completion time will be tested in a pilot of the online questionnaire with 5 community pharmacy staff in the UK and will be expanded if necessary based on the results of the pilot test.~~ If they need to exit the questionnaire before completion, participants will be able to save their answers and then re-enter the questionnaire at a later time.

FUNCTIONALITY OF THE ONLINE QUESTIONNAIRE WILL BE TESTED IN A PILOT STUDY. THE OBJECTIVES OF THE PILOT STUDY ARE TO:

1. **TEST COMPREHENSION OF THE QUESTIONS AND IDENTIFY ANY AMBIGUOUS/MISUNDERSTOOD WORDING**
2. **TEST COMPLETION/DROP OUT FROM THE QUESTIONNAIRE AND HOW THIS COULD BE PREVENTED**
3. **TEST COMPLETION OF THE TEXT FREE AREAS OF THE QUESTIONNAIRE TO DETERMINE WHETHER THEY ARE FILLED IN APPROPRIATELY WITH RELEVANT DATA**
4. **TEST COMPLETION TIME FOR PHARMACISTS AND PHARMACY ASSISTANTS TO CHECK THAT ADEQUATE TIME HAS BEEN ALLOWED FOR IN THE REMUNERATION**

THE PILOT WILL BE RUN WITH 20 COMMUNITY PHARMACY STAFF (PHARMACISTS AND PHARMACY ASSISTANTS) ACROSS 3 COUNTRIES (UK, FINLAND AND SPAIN) AND MAY BE REPEATED IF SIGNIFICANT CHANGES TO THE QUESTIONNAIRE ARE REQUIRED.

 GlaxoSmithKline	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

5. Study Population

A sample of 120 community pharmacy staff in each of 4 countries (UK, Spain, Italy and Finland) will be recruited for a total of 480 pharmacy staff (360 pharmacists, 120 pharmacy assistants). In countries where alli® is being relaunched, participating pharmacy staff will be recruited from the pool of pharmacies that have restocked alli®. Recruitment will be stratified (where possible dependent on the distribution of pharmacies that have restocked) by geographic area within each country to reflect the distribution of the population in each country.

A TOTAL OF 480 COMMUNITY PHARMACY STAFF FROM 3 COUNTRIES (UK, FINLAND AND SPAIN) WILL BE RECRUITED. WHILST NOT ALL PHARMACIES IN THE PARTICIPATING HAVE YET RESTOCKED ALLI®, AND SOME OF THESE PHARMACISTS MAY BE INCLUDED IN THE STUDY, RECRUITMENT OF THOSE WHO HAVE RESTOCKED WILL BE PRIORITISED.


TO ACHIEVE PROPORTIONATE REPRESENTATION OF STUDY PARTICIPANTS FROM THE 3 CONUTRIES, RESTRICTION WILL BE PLACED ON NUMBER OF PARTICIPANTS RECRUITED FROM EACH OF THEM, WITH A TARGET DISTRIBUTION OF 33% OF TOTAL PARTICIPANTS FROM EACH OF THE THREE COUNTRIES, WITH A MINIMUM OF 25% AND A MAXIMUM OF 50% FROM EITHER OF THREE COUNTRIES.

5.1 Inclusion criteria

- Male or female
- Qualified and practising community pharmacist or pharmacy assistant in UK, Spain, Italy and Finland
- Marketing alli®

5.2 Exclusion criteria

- An employee of The Sponsor or The Research Company (Hamell)
- Currently or previously (within last 6 months) employed by:
 - A pharmaceutical company

	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

- A healthcare company
- A market research company
- A healthcare advertising company
- A healthcare marketing company
- A regulatory or advisory authority

5.3 Pharmacy staff withdrawal criteria

Pharmacy staffs have the right to withdraw from the study at any time for any reason.

5.4 Pharmacy staff recruitment

Pharmacy staff will be recruited from online communities and via direct contact.

Recruitment will be targeted to ensure representation, for example: geographically, a mixture of different types of pharmacy (large chains, small chains, independents), and different settings (urban/rural).

5.5 Sample size


The sample size was calculated based on the overall proportion of % correct responses to the correct responses included in the vignettes.

A sample size of 466 achieves 81% power to detect a difference of 0.0500 (80% - 85%) using a two-sided binomial test. The target significance level is 0.05. These results assume that the population proportion under the null hypothesis is 0.80.

6. Data analysis methods

6.1 Criteria for evaluable data from pharmacy staff

Analysis will be conducted on the evaluable population. To be considered evaluable, pharmacy staff must meet inclusion/exclusion criteria and complete all the questions of the 33 virtual customers.

 GlaxoSmithKline	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

Sensitivity analysis will be conducted on the all available data population. In this sensitivity analysis, any pharmacy staff with at least one response of the 33 virtual customers will be included in the analysis.

6.2 Exclusion of data from analysis

Pharmacy staff found not to have satisfied the proposal inclusion/exclusion criteria will be excluded from the analysis.

6.3 Missing data

Missing data will not be imputed.

6.4 Endpoints

6.4.1 Primary endpoint

The primary endpoint will be the proportion of correct answers by pharmacy staff to:

- Supply alli® when the virtual customer is suitable for the product
- Not supply alli® when the virtual customer is not suitable for the product

Suitability will be defined by the clinical expert and based on the SmPC. Proportions will be estimated with 95% confidence intervals. Correct answers in 80% of virtual customers will be considered good agreement, signifying that the revised label is effective in enabling pharmacy staff to supply alli® appropriately.


The primary endpoint is the % number of correct answer to the 33 vignettes.

80% correct answers will be considered to signify that the revised label is effective in enabling pharmacy staff to supply alli® appropriately^{1,2}.

6.4.2 Secondary endpoints

The secondary endpoints will include:

- The proportion of correct responses for each sub-score (indications, contraindications and warnings) analysed

 GlaxoSmithKline	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

- The proportion of false positives by the pharmacy staff
- The proportion of false negatives by the pharmacy staff

80% correct answers will be considered to signify that the revised label is effective with respect to each sub-score (indication, contraindication and warning) in enabling pharmacy staff to supply alli®.

If the success criteria are not met for any of the primary or secondary endpoints, then the false positive and false negative rates will be assessed for that specific endpoint. The need for further action will be based on the false positive or false negative rate being greater than 20%.


Any further actions will depend on the results of the survey. For example, if results of the survey show >20% false positive rate for any criterion listed in the objectives we will consider any (or a combination) of the following actions:

- Setting up a focus group of pharmacy staff to help identify any issues with the package information and areas that need to be rectified by improving the label
- Provide Pharmacy staff retraining e.g. based on outcome of survey, re-sending pharmacy reminder cards emphasizing low scoring areas

6.5 Analysis and statistical methods

6.5.1 Correct answers and blinding the responses to the set of correct answers to the virtual customer scenarios

- The set of correct answers is the set of all virtual customer scenarios i.e. 33 scenarios prepared by the clinicians and safety specialists based on the SmPC, to be evaluated by the pharmacy staff
- The correct responses to all the virtual customer scenarios will be prepared by the clinicians and safety specialists and will be permanently finalized and blinded/stored in a PDF file before the start of this survey. After the database lock, the data from this PDF file will be unblinded and used in agreement/reliability calculations. The staff conducting the study in the field (the study managers) will not know the correct


	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

response to each of the scenarios - in order not to be able to communicate results to pharmacy staff

Table 1 below shows the distribution of the indications/contraindications/warnings in the virtual customers to be evaluated by each participating member of pharmacy staff.

Table 1: Distribution of the contraindications/warning in the virtual customers

Indication/contraindication/warning to be tested	Number of different virtual customers
BMI	4
Age	2
Taking ciclosporin	2
Taking warfarin	2
Taking Levothyroxine	1
Cholestasis	2
Chronic malabsorption syndrome	2
Kidney disease	1
Pregnancy	1
Breast-feeding	2
Taking antiretrovirals	1
Purchasing for a third party	1
Taking antiepileptics	1
Taking antipsychotics	1
Taking antidepressants	1
Taking antihypertensives	1
Taking antidiabetic and cholesterol lowering medications	1
Taking amiodarone	1
Taking benzodiazepines	1
No contraindication or warning	5

	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

Total	33
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Primary endpoint

The primary end point will be the proportion (and its 95% confidence interval (CI)) of correct answers given by pharmacy staff.

The overall proportion of correct answers by the pharmacy staff will be calculated using 480 pharmacy staff in the denominator (if all pharmacy staff are included in the analysis).

A pharmacy staff member with a 100% correct responses to the reference responses will be scored 100% or 1.

The overall % of correct responses is calculated by averaging % correct responses across the 480 pharmacy staff.


The two-sided 95% CI of the overall % correct responses will be calculated based on the sample of 480 pharmacy staff using normal approximation.

To be considered evaluable, pharmacy staff must meet inclusion/exclusion criteria and complete the questions of the 33 virtual customers.

Sensitivity analysis will be conducted. In this sensitivity analysis, any pharmacy staff with at least one response of the 33 virtual customers will be included in the analysis.

Secondary endpoints

The proportion of virtual customers for whom alli® is not indicated but pharmacy staff would have supplied will be calculated separately for each indication (BMI <28kg/m², under 18 years) contraindication (taking ciclosporin, suffering from chronic malabsorption syndrome, suffering from cholestasis, pregnant or breastfeeding, or taking warfarin or other oral anticoagulant), and warning (kidney disease, taking levothyroxine, amiodarone, antidiabetics, antiretrovirals, antidepressants, antipsychotics, benzodiazepines or cholesterol lowering drugs). In addition, purchasing for a third party is prohibited. For the proportions, the corresponding two-sided 95% CI will be calculated and presented.

 GlaxoSmithKline	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

- False positive rate by pharmacy staff: will be calculated as the number of virtual customers classified by pharmacy staff as suitable for alli® who are actually unsuitable/total number of virtual customers considered suitable by pharmacy staff
- False negative rate by pharmacy staff: will be calculated as the number of virtual customers classified by pharmacy staff as unsuitable for alli® who are actually suitable/total number of customers considered unsuitable by pharmacy staff

The proportion of negative responses (decision not to supply alli®) that are correct but for the wrong reasons will be calculated to identify any additional educational needs of pharmacy staff.

All calculations will be conducted as outlined above for the primary endpoint.

The primary and secondary endpoints will be presented by country as well as overall across all countries.


7. Reporting of Adverse Events

Safety aspects do not apply to this study because it involves completion of an online questionnaire and no study products are being supplied/administered. However, pharmacy staff aware of adverse events occurring in consumers who have received alli® outside of this study should report these via the usual channels for adverse event reporting for marketed medicinal products in their country, and GSKCH will be notified.

8. Ethical and regulatory aspects

Appropriate ethical and competent authority approval will be sought from the EU countries in which this survey will be conducted: UK, Spain, ~~Italy~~ and Finland, should this be considered necessary.

No personal data, other than contact details for the purposes of co-ordination and sending reimbursement, will be collected. Personal details will be deleted on completion of the study.

 GlaxoSmithKline	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

8.1 Local regulations/Declaration of Helsinki

The study will be conducted in accordance with all applicable regulatory requirements, and with GSK policy.

The study will also be conducted in accordance with ICH Good Clinical Practice (GCP), all applicable subject privacy requirements, and the guiding principles of the current version of the Declaration of Helsinki.

8.2 Informed consent

Web or email informed consent will be obtained from each pharmacy staff member before participation in the study (and for amendments as applicable).

9. Documentation


9.1 Completed questionnaires/retention of documents

Data management and programming activities will be managed by a third party vendor, Clinical Accelerator. Hamell will be responsible for all other aspects of the day to day running of the study including questionnaire design, subject recruitment and project management, and delivery of data to GSK for analysis.

Following closure of the study, **The Research Companies** (Hamell and Clinical Accelerator) must maintain all study records (except for those required by local regulations to be maintained elsewhere), in a safe and secure location.

The records (study/master file) must be maintained to allow easy and timely retrieval, when needed (e.g., for a GSK audit or regulatory inspection) and must be available for review in conjunction with assessment of the facility, supporting systems, and relevant staff.

Where permitted by local laws/regulations or institutional policy, some or all of these records can be maintained in a format other than hard copy (e.g. microfiche, scanned, electronic); however, caution needs to be exercised before such action is taken.

 GlaxoSmithKline	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

The Research Companies must ensure that all reproductions are legible and are a true and accurate copy of the original and meet accessibility and retrieval standards, including re-generating a hard copy, if required (as appropriate). Furthermore, **The Research Companies** must ensure there is an acceptable back-up of these reproductions and that an acceptable quality control process exists for making these reproductions.

The Research Companies must assure that the pharmacy staff's anonymity will be maintained. GSKCH will inform **The Research Companies** of the time period for retaining these records to comply with all applicable regulatory requirements (GSKCH recommends that documents be kept for 10 years). The minimum retention time will meet the strictest standard applicable to that site for the study, as dictated by any institutional requirements or local laws or regulations, GSK standards/procedures, and/or institutional requirements.


No study document should be destroyed without a prior written agreement between GSKCH and **The Research Companies**. **The Research Companies** must notify GSKCH of any changes in the archival arrangements, including, but not limited to, archival at an off-site facility or transfer of ownership of the records in the event **The Research Companies** is no longer associated with the site.

9.2. Questionnaires

Data will be collected in a community setting via an online questionnaire where no source documents are available. The data collected from pharmacy staff on the electronic questionnaire will be:

- Pharmacy type
- Approximate date of last sale of alli®
- Role (pharmacist/pharmacy assistant)
- Yes/no response to the question of suitability for each virtual customer
- Rationale for any designation of unsuitability

All data will be entered directly onto the online questionnaire by the pharmacy staff member.

 GlaxoSmithKline	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

The questionnaires (including programmed checks and audit trails) will be sent electronically to **The Sponsor** at the conclusion of the study.

9.3 Data handling

Documentation of all data management activities should 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 the integrity of the data e.g. removing errors and inconsistencies in the data.

9.4 Data queries

As no source data will exist, no data queries will be generated for resolution. Programmed edit checks will be generated automatically as data are being entered to ensure data integrity. These will include completeness of data and patterns of responses as outlined in the Data Management Plan.

10. Process for amending the proposal


Proposal modifications which could potentially alter the scope of the investigation must be made only after consultation between an appropriate representative of **The Sponsor** and **The Research Company** (Hamell).

11. Conditions for terminating the study

The Sponsor reserves the right to terminate the data collection at any time. Should this be necessary, the procedures will be arranged after review and consultation by all parties. In terminating, **The Sponsor** will assure that adequate consideration is given to the protection of the interests of participating pharmacy staff.

12. Confidentiality of documents

Pharmacy staff will not be identified by their names or initials on study documents. All questionnaire databases will be anonymised. The personal data collected during

 GlaxoSmithKline	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

recruitment will be kept in a separate database and will be deleted on completion of the data collection and analysis.

13. Publication of data and protection of trade secrets


The protocol summary and a summary of the survey results may be posted on one or more publicly accessible worldwide registers. **The Research Company** will not seek to arrange for publication of any of the information or results in any scientific journal, or other publication or by way of lecture without **The Sponsor's** prior written consent.

14. Quality Assurance

To ensure compliance with GCP and all applicable regulatory requirements, GSK may conduct a quality assurance assessment and/or audit of the site records, and the regulatory agencies may conduct a regulatory inspection at any time during or after completion of the study.


In the event of an assessment, audit or inspection, the investigator (and institution) must agree to grant the advisor(s), auditor(s) and inspector(s) direct access to all relevant documents and to allocate their time and the time of their staff to discuss the conduct of the study, any findings/relevant issues and to implement any corrective and/or preventative actions to address any findings/issues identified.

The Sponsor will be available to help investigators prepare for an inspection.

 GlaxoSmithKline	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		


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 GlaxoSmithKline	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

Appendix 1 - Abbreviations

AE	Adverse Event
BMI	Body Mass Index
CHMP	Committee for Medicinal Products for Human Use
CI	Confidence Interval
CRF	Case Report Form
CRO	Contract Research Organisation
EU	European Union
GCP	Good Clinical Practice
GSKCH	GlaxoSmithKline Consumer Healthcare
HCP	Healthcare Professional
ICH	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
IEC	Independent Ethics Committee
IRB	Institutional Review Board
ITT	Intention to Treat
Kg/m ²	Kilograms/metre ²
MHRA	Medicines & Healthcare products Regulatory Agency
PP	Per Protocol
RMP	Risk Management Plan
SmPC	Summary of Product Characteristics
UK	United Kingdom

 GlaxoSmithKline	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

Appendix 2 - alli® Virtual Customers (Vignettes)

Thank you very much for consenting to participate in this survey to assess the suitability of different virtual customers for alli®. You will be presented with 33 very short customer vignettes. For each of these virtual customers, you will be asked whether or not you would supply alli® to each customer and, if your decision is not to supply alli®, you will be asked to give your reason.

Please provide a recommendation for all of the 33 virtual customers.


The exercise should take around 40 minutes to complete. You can stop, save your answers and come back and complete the exercise later if you need to.

ADVERSE EVENTS [this wording will be modified as required to meet individual country requirements]

This questionnaire should not be used for reporting adverse events (AEs). If you become aware of any adverse events, these should be reported via the usual channels for adverse event reporting in your country.


Before you start the survey, we need to tell you that we are now being asked to pass on to our client details of adverse events and/or product complaints that are mentioned during research. Although the answers you give will, of course, be treated in confidence, should you report while completing the questionnaire an adverse event and/or product complaint, we will need to report this even if it has already been reported by you directly to the company and the regulatory authorities. In such a situation are you willing to waive this confidentiality specifically in relation to that adverse event and/or product complaint? Everything else you report whilst completing the questionnaire will continue to remain confidential, and you will still have the option to remain anonymous if you so wish. Are you happy to participate with the research on this basis?

- ☐ I would like to proceed and protect my anonymity [continue]
- ☐ I would like to proceed and give permission for my contact details to be passed on to the Drug Safety department of the company if an adverse event is mentioned by me during the survey [continue]
- ☐ I don't want to proceed. I would like to end my participation here [end survey]

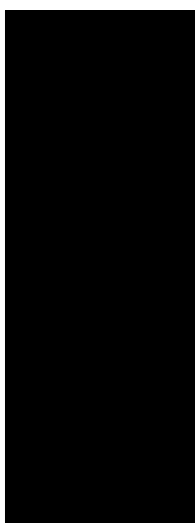
	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		

Before you start the exercise, please provide the following information:

Question 1: Which of the following best describes the type of pharmacy you work in?	<ol style="list-style-type: none"> 1. National chain (>10 pharmacies) 2. Moderate sized chain (5-10 pharmacies) 3. Small chain (2-4 pharmacies) 4. Independent
Question 2: When was the last time you sold a pack of alli® in your pharmacy?	<ol style="list-style-type: none"> 1. This week 2. Last week 3. Within the last month 4. Within the last 3 months 5. Within the last 6 months 6. More than 6 months ago 7. Have never sold
Question 3: Which of the following best describes your role in the pharmacy?	<ol style="list-style-type: none"> 1. Owner Pharmacist 2. Registered Pharmacist 3. Pharmacist Assistant 4. Counter Assistant 5. Other – Please specify

	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		


Customer 1



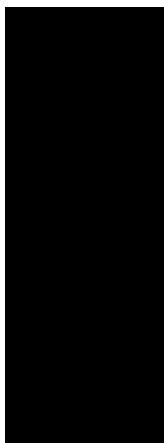
A young woman comes into the pharmacy, carrying a yoga mat, sports bag and shopping bags. She's on her way home from the gym. At the counter she tells you she's exhausted after doing an aerobics class as well as a yoga class – she's trying hard to get into shape. She explains that she wants to buy some weight loss pills because she is getting married in a few months, and despite all her effort she is struggling to reach her ideal weight.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?	No														
Do you have any medical conditions/illnesses?	No														
<p>Are there any other questions you would like to ask this customer?</p> <p>Please type question 1 here:.....</p> <p>Please type question 2 here:.....</p> <p>Please type question 3 here:.....</p> <p><u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u></p>	<p>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</p> <table border="1"> <tr> <td>Age</td> <td>21</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>no</td> </tr> <tr> <td>Pregnant</td> <td>no</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>	Age	21	BMI		Height		Weight		Breastfeeding	no	Pregnant	no	Spoken to doctor?	no
Age	21														
BMI															
Height															
Weight															
Breastfeeding	no														
Pregnant	no														
Spoken to doctor?	no														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		


Customer 2



A young female comes into the pharmacy. You recognise her from your daily commute on the train into work. She usually gets off at the same stop and heads towards the university. At the counter, she asks to speak with the pharmacist. She is carrying a bag from a health shop, but she tells you she's not convinced anything from there ever works. She enquires about weight loss pills because she thinks she has gained weight.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?	No														
Do you have any medical conditions/illnesses?	No														
<p>Are there any other questions you would like to ask this customer? Please type question 1 here:..... Please type question 2 here:..... Please type question 3 here:..... <u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u></p>	<p>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</p> <table border="1"> <tr> <td>Age</td> <td>19</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>no</td> </tr> <tr> <td>Pregnant</td> <td>no</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>	Age	19	BMI		Height		Weight		Breastfeeding	no	Pregnant	no	Spoken to doctor?	no
Age	19														
BMI															
Height															
Weight															
Breastfeeding	no														
Pregnant	no														
Spoken to doctor?	no														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		


Customer 3



A middle aged woman comes into the pharmacy on a Saturday afternoon. She has been out for lunch and shopping with a group of her oldest friends. She tells you she loves meeting up with the gang as it's a great opportunity for a glass of wine and a good gossip. Today, top of the agenda was her divorce and her new relationship with a younger man. After trying on some dresses for her next date with him she's realised she has crept up a dress size. She wants to look and feel her best and says she'd like to try alli® which one of her friends recommended.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?	No																					
Do you have any medical conditions/illnesses?	No																					
Are there any other questions you would like to ask this customer? Please type question 1 here:..... Please type question 2 here:..... Please type question 3 here:..... <u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u>	The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested: <table border="1"> <tr> <td>Age</td> <td></td> <td>40</td> </tr> <tr> <td>BMI</td> <td></td> <td></td> </tr> <tr> <td>Height</td> <td></td> <td></td> </tr> <tr> <td>Weight</td> <td></td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td></td> <td>no</td> </tr> <tr> <td>Pregnant</td> <td></td> <td>no</td> </tr> <tr> <td>Spoken to doctor?</td> <td></td> <td>no</td> </tr> </table>	Age		40	BMI			Height			Weight			Breastfeeding		no	Pregnant		no	Spoken to doctor?		no
Age		40																				
BMI																						
Height																						
Weight																						
Breastfeeding		no																				
Pregnant		no																				
Spoken to doctor?		no																				
Would you supply alli® to this customer?																						
Yes																						
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....																					

	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		


Customer 4



A young man in high-tech sports gear comes into the pharmacy, still sweating a little from his daily run and fiddling with his fitness tracker. He normally comes in to buy energy gels, sports drinks and blister pads, but today he asks to see the pharmacist. He asks you for advice on weight loss products as he is struggling to lose the last bit of weight to reach his target competition weight before running his next marathon, and he is keen to achieve a personal best.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?	No														
Do you have any medical conditions/illnesses?	No														
<p>Are there any other questions you would like to ask this customer?</p> <p>Please type question 1 here:.....</p> <p>Please type question 2 here:.....</p> <p>Please type question 3 here:.....</p> <p><u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u></p>	<p>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</p> <table border="1"> <tr> <td>Age</td> <td>25</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>N/A</td> </tr> <tr> <td>Pregnant</td> <td>N/A</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>	Age	25	BMI		Height		Weight		Breastfeeding	N/A	Pregnant	N/A	Spoken to doctor?	no
Age	25														
BMI															
Height															
Weight															
Breastfeeding	N/A														
Pregnant	N/A														
Spoken to doctor?	no														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

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	Type	Version	Document Identifier	Effective Date
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	Reason For Issue	Auto Issue		


Customer 5



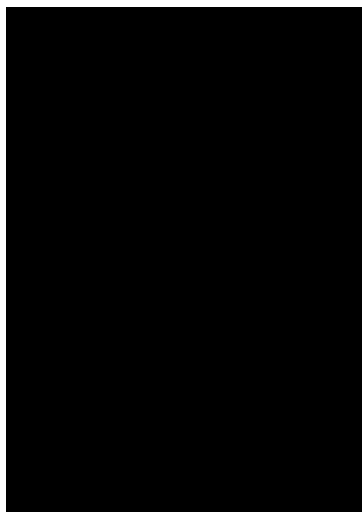
A young man comes into the pharmacy and asks to talk to you privately. He tells you he is worried about his weight. He works in computers and spends his free time playing computer games too. He feels lucky to have a great new girlfriend, but she has told him he is overweight and must do something about it – it is bad for his health. He asks you for recommendations to help him lose weight.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?	Ciclosporin Calsipotriol/betamethasone gel Doublebase emollient														
Do you have any medical conditions/illnesses?	Psoriasis														
<p>Are there any other questions you would like to ask this customer?</p> <p>Please type question 1 here:.....</p> <p>Please type question 2 here:.....</p> <p>Please type question 3 here:.....</p> <p><u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u></p>	<p>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</p> <table border="1"> <tr> <td>Age</td> <td>27</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>N/A</td> </tr> <tr> <td>Pregnant</td> <td>N/A</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>	Age	27	BMI		Height		Weight		Breastfeeding	N/A	Pregnant	N/A	Spoken to doctor?	no
Age	27														
BMI															
Height															
Weight															
Breastfeeding	N/A														
Pregnant	N/A														
Spoken to doctor?	no														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

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	Reason For Issue	Auto Issue		


Customer 6



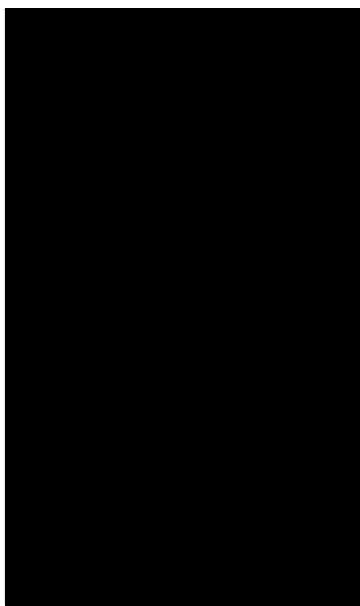
A woman comes into the pharmacy chatting animatedly on the phone. You notice she is wearing splints on her hands. Although young, she seems to have some difficulty putting her phone back into her handbag. She tells you she is very busy planning her wedding, which is in just three months, and she seems a little stressed about it. She had a bridal fitting yesterday and is worried that her dress is too tight. She wants to lose weight for her wedding day.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?	Ciclosporin Methotrexate Naproxen Paracetamol														
Do you have any medical conditions/illnesses?	Rheumatoid arthritis														
<p>Are there any other questions you would like to ask this customer?</p> <p>Please type question 1 here:.....</p> <p>Please type question 2 here:.....</p> <p>Please type question 3 here:.....</p> <p><u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u></p>	<p>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</p> <table border="1"> <tr> <td>Age</td> <td>32</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>no</td> </tr> <tr> <td>Pregnant</td> <td>no</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>	Age	32	BMI		Height		Weight		Breastfeeding	no	Pregnant	no	Spoken to doctor?	no
Age	32														
BMI															
Height															
Weight															
Breastfeeding	no														
Pregnant	no														
Spoken to doctor?	no														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

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Customer 7



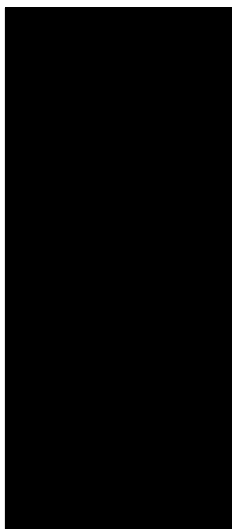
A middle-aged woman in an expensive suit comes into the pharmacy, in the middle of a work call on her mobile. When she hangs up, she explains that she is on a business trip and spotted the pharmacy whilst waiting for her taxi to the airport. She only has 20 minutes before her next business call and the taxi arriving, and complains about the hassle of frequent flying. She buys some multivitamins and asks for your expert opinion on weight loss products. She knows that exercise and healthy eating are best, but she travels one week out of every month and there is no time get into a routine.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?	Has been taking warfarin for the last 6 weeks Multivitamins														
Do you have any medical conditions/illnesses?	Deep vein thrombosis diagnosed 6 weeks ago following a long-haul flight														
<p>Are there any other questions you would like to ask this customer?</p> <p>Please type question 1 here:.....</p> <p>Please type question 2 here:.....</p> <p>Please type question 3 here:.....</p> <p><u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u></p>	<p>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</p> <table border="1"> <tr> <td>Age</td> <td>43</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>no</td> </tr> <tr> <td>Pregnant</td> <td>no</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>	Age	43	BMI		Height		Weight		Breastfeeding	no	Pregnant	no	Spoken to doctor?	no
Age	43														
BMI															
Height															
Weight															
Breastfeeding	no														
Pregnant	no														
Spoken to doctor?	no														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

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Customer 8



A stocky man in an ill-fitting suit comes in one afternoon. He tells you he's the manager of a bank branch up the road, where he has worked for 20 years. He has been happy enough there, but he is looking forward to retirement now – not too long to go. He says he has been warned that he needs to lose weight for his health, and wants to have a long and happy retirement. His wife is also desperate for him to lose weight; their first grandchild is on the way and she is worried about him. He needs something to help him get started and has heard there are diet pills.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?	Warfarin														
Do you have any medical conditions/illnesses?	Atrial fibrillation														
<p>Are there any other questions you would like to ask this customer?</p> <p>Please type question 1 here:.....</p> <p>Please type question 2 here:.....</p> <p>Please type question 3 here:.....</p> <p><u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u></p>	<p>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</p> <table border="1"> <tr> <td>Age</td> <td>62</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>N/A</td> </tr> <tr> <td>Pregnant</td> <td>N/A</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>	Age	62	BMI		Height		Weight		Breastfeeding	N/A	Pregnant	N/A	Spoken to doctor?	no
Age	62														
BMI															
Height															
Weight															
Breastfeeding	N/A														
Pregnant	N/A														
Spoken to doctor?	no														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

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Customer 9



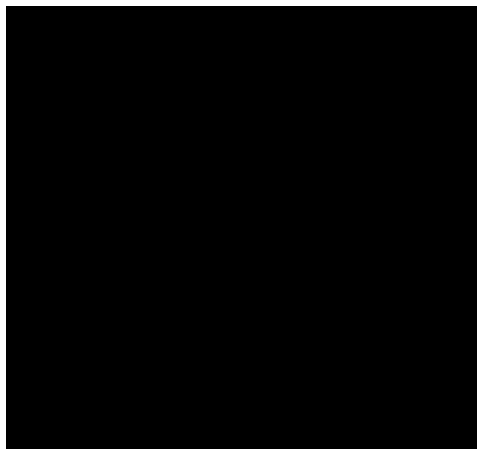
A pale-looking young woman comes into the pharmacy one Saturday lunchtime. She tells you she works part time in a charity shop. The shop was busy this morning and she wanted to get out for some fresh air during her break, even if it's just a short walk along to the pharmacy. She asks to talk privately. She tells you she is getting married in six months and wants to look her best on her big day.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?	Ciprofloxacin Pulmozyme Ipratropium Salbutamol Pancreatic enzymes														
Do you have any medical conditions/illnesses?	Cystic fibrosis Chronic malabsorption syndrome														
<p>Are there any other questions you would like to ask this customer?</p> <p>Please type question 1 here:.....</p> <p>Please type question 2 here:.....</p> <p>Please type question 3 here:.....</p> <p><u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u></p>	<p>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</p> <table border="1"> <tr> <td>Age</td> <td>22</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>no</td> </tr> <tr> <td>Pregnant</td> <td>no</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>	Age	22	BMI		Height		Weight		Breastfeeding	no	Pregnant	no	Spoken to doctor?	no
Age	22														
BMI															
Height															
Weight															
Breastfeeding	no														
Pregnant	no														
Spoken to doctor?	no														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

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Customer 10




A man wearing scruffy jeans and a paint-splattered checked shirt enters the pharmacy. He spends some time browsing your specialist foods section and picks out a gluten-free high-energy snack bar. He comments that he is halfway through painting a three-storey house and has to keep up his energy for climbing more ladders this afternoon. He mentions that he's trying to be good with his diet, but it can be hard when he is working; he often resorts to crisps and chocolate bars. Now he's gained weight, and whilst the guys on site don't mind, his new girlfriend is less keen on his

expanding waistline – can you recommend some diet pills?

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?	No														
Do you have any medical conditions/illnesses?	Coeliac disease Chronic malabsorption syndrome														
<p>Are there any other questions you would like to ask this customer?</p> <p>Please type question 1 here:.....</p> <p>Please type question 2 here:.....</p> <p>Please type question 3 here:.....</p> <p><u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u></p>	<p>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</p> <table border="1"> <tr> <td>Age</td> <td>30</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>N/A</td> </tr> <tr> <td>Pregnant</td> <td>N/A</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>	Age	30	BMI		Height		Weight		Breastfeeding	N/A	Pregnant	N/A	Spoken to doctor?	no
Age	30														
BMI															
Height															
Weight															
Breastfeeding	N/A														
Pregnant	N/A														
Spoken to doctor?	no														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

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Customer 11



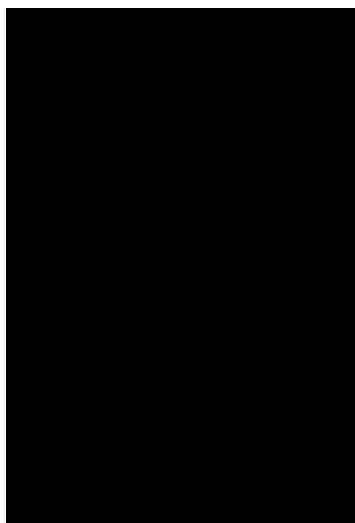
An older man in smart casual clothes comes into the pharmacy to fill out a prescription. In conversation, he tells you he is a solicitor and today is his day off. He would rather be playing golf than be here at the chemist, but he is under strict instructions. He was hoping that the regular golfing would be enough to keep his health under control, but he has been advised to take up something more strenuous to lose weight. He asks about diet pills, hoping that a short cut to weight loss will save him from having to put on a pair of running shoes.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?	Erythropoietin														
Do you have any medical conditions/illnesses?	Chronic kidney disease: GFR<60mmol/l														
<p>Are there any other questions you would like to ask this customer?</p> <p>Please type question 1 here:.....</p> <p>Please type question 2 here:.....</p> <p>Please type question 3 here:.....</p> <p><u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u></p>	<p>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</p> <table border="1"> <tr> <td>Age</td> <td>60</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>N/A</td> </tr> <tr> <td>Pregnant</td> <td>N/A</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>	Age	60	BMI		Height		Weight		Breastfeeding	N/A	Pregnant	N/A	Spoken to doctor?	no
Age	60														
BMI															
Height															
Weight															
Breastfeeding	N/A														
Pregnant	N/A														
Spoken to doctor?	no														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

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Customer 12



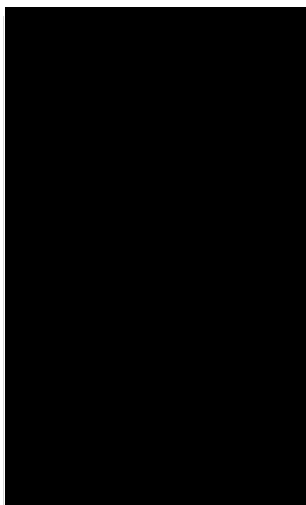
A middle-aged woman comes into the pharmacy carrying a sports bag. She tells you she is on her way to the swimming pool for the first time in years and is not looking forward to putting on her swimming costume, but she'd rather swim than sweat at the gym. She jokes that she had to buy a maximum support swimsuit to try and hold in the bulges. She wants to lose weight for her health, not just to look better in the pool – but getting into a prettier swimming costume before her summer holiday would be nice. She'd like to kick start her weight loss with diet pills.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?	Levothyroxine														
Do you have any medical conditions/illnesses?	Hypothyroidism														
<p>Are there any other questions you would like to ask this customer?</p> <p>Please type question 1 here:.....</p> <p>Please type question 2 here:.....</p> <p>Please type question 3 here:.....</p> <p><u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u></p>	<p>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</p> <table border="1"> <tr> <td>Age</td> <td>55</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>no</td> </tr> <tr> <td>Pregnant</td> <td>no</td> </tr> <tr> <td>Spoken to doctor?</td> <td>Yes: Doctor confirmed okay to take alli®</td> </tr> </table>	Age	55	BMI		Height		Weight		Breastfeeding	no	Pregnant	no	Spoken to doctor?	Yes: Doctor confirmed okay to take alli®
Age	55														
BMI															
Height															
Weight															
Breastfeeding	no														
Pregnant	no														
Spoken to doctor?	Yes: Doctor confirmed okay to take alli®														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

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Customer 13



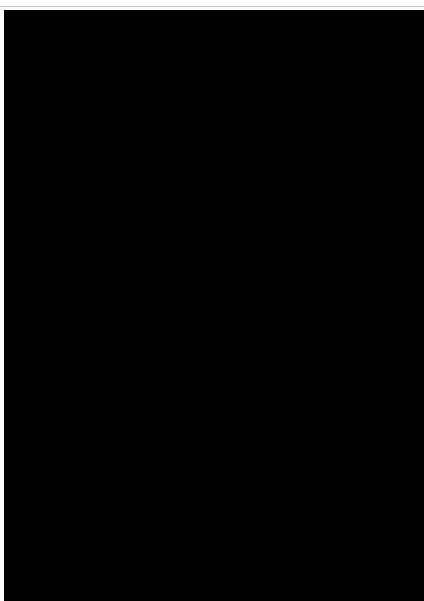
An older woman in loose clothing comes into the pharmacy, chatting away to a toddler she is pushing in a buggy. She seems delighted to be with her grandson, and tells you she takes care of him sometimes while her daughter works. She thinks that running around after a toddler must help to keep her fit, but even so her weight is creeping up. She has finally decided to do something about her weight because she wants to stay well to keep up with her grandson. She asks about weight loss tablets.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?	Colestyramine														
Do you have any medical conditions/illnesses?	Cholestasis secondary to gall stones														
<p>Are there any other questions you would like to ask this customer?</p> <p>Please type question 1 here:.....</p> <p>Please type question 2 here:.....</p> <p>Please type question 3 here:.....</p> <p><u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u></p>	<p>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</p> <table border="1"> <tr> <td>Age</td> <td>62</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>no</td> </tr> <tr> <td>Pregnant</td> <td>no</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>	Age	62	BMI		Height		Weight		Breastfeeding	no	Pregnant	no	Spoken to doctor?	no
Age	62														
BMI															
Height															
Weight															
Breastfeeding	no														
Pregnant	no														
Spoken to doctor?	no														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

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	Reason For Issue	Auto Issue		


Customer 14



An older man wearing expensive-looking but creased clothing, comes into the pharmacy. He tells you he has been on his own for 2 years since his wife died suddenly. He thought he would be the first to 'go' and her death was a shock. His doctor has recommended a weight loss programme but he has been lacking motivation to follow one or start any kind of exercise. He is worried that his weight will mean he'll never meet another woman and he worries about being alone for the rest of his life. He says it feels like it's time to smarten up, lose weight and get out to meet new people. He asks about weight loss tablets to speed up the process.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?		colestyramine															
Do you have any medical conditions/illnesses?		Cholestasis secondary to gall stones															
Are there any other questions you would like to ask this customer? Please type question 1 here:..... Please type question 2 here:..... Please type question 3 here:..... <u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u>		The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested: <table border="1"> <tr> <td>Age</td> <td>65</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>N/A</td> </tr> <tr> <td>Pregnant</td> <td>N/A</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>		Age	65	BMI		Height		Weight		Breastfeeding	N/A	Pregnant	N/A	Spoken to doctor?	no
Age	65																
BMI																	
Height																	
Weight																	
Breastfeeding	N/A																
Pregnant	N/A																
Spoken to doctor?	no																
Would you supply alli® to this customer?																	
Yes																	
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....																

	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		


Customer 15



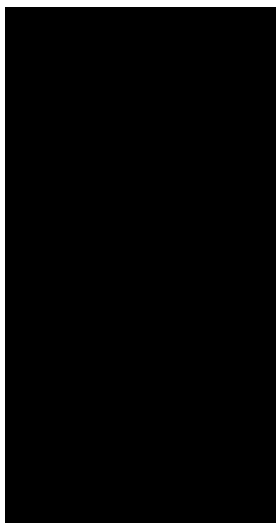
A man in brand new exercise kit comes into the pharmacy, limping slightly. He tells you he is heading to the gym, encouraged by his wife, because his doctor has told him that if he loses weight his knee will hurt less and he really wants to avoid having surgery if possible. He has never enjoyed going to the gym and wonders whether he could try the diet pills his wife used a couple of years ago.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?	Diclofenac Glucosamine plus chondroitin Omeprazole														
Do you have any medical conditions/illnesses?	Knee osteoarthritis														
<p>Are there any other questions you would like to ask this customer?</p> <p>Please type question 1 here:.....</p> <p>Please type question 2 here:.....</p> <p>Please type question 3 here:.....</p> <p><u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u></p>	<p>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</p> <table border="1"> <tr> <td>Age</td> <td>56</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>N/A</td> </tr> <tr> <td>Pregnant</td> <td>N/A</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>	Age	56	BMI		Height		Weight		Breastfeeding	N/A	Pregnant	N/A	Spoken to doctor?	no
Age	56														
BMI															
Height															
Weight															
Breastfeeding	N/A														
Pregnant	N/A														
Spoken to doctor?	no														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

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	Reason For Issue	Auto Issue		


Customer 16



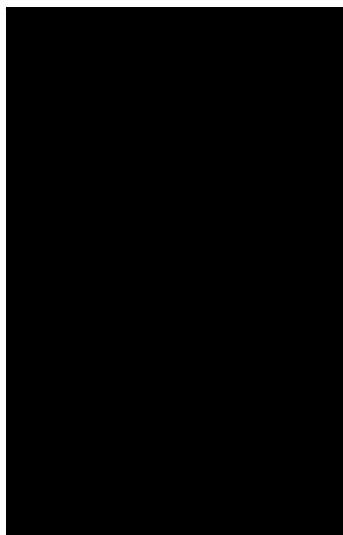
A well-groomed man comes into the pharmacy at lunchtime. He seems stressed and hurried. He is desperate for a promotion at work but at his recent executive health check he was advised to lose weight. He is worried that if he doesn't drop some weight, he won't make it into senior management. There is a gym at work but he rarely has time to exercise, so he wants to try some diet pills.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in a pharmacy?	Captopril Simvastatin														
Do you have any medical conditions/illnesses?	Hypertension														
<p>Are there any other questions you would like to ask this customer?</p> <p>Please type question 1 here:.....</p> <p>Please type question 2 here:.....</p> <p>Please type question 3 here:.....</p> <p><u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u></p>	<p>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</p> <table border="1"> <tr> <td>Age</td> <td>45</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>N/A</td> </tr> <tr> <td>Pregnant</td> <td>N/A</td> </tr> <tr> <td>Spoken to doctor?</td> <td>Yes: Doctor confirmed okay to take alli®</td> </tr> </table>	Age	45	BMI		Height		Weight		Breastfeeding	N/A	Pregnant	N/A	Spoken to doctor?	Yes: Doctor confirmed okay to take alli®
Age	45														
BMI															
Height															
Weight															
Breastfeeding	N/A														
Pregnant	N/A														
Spoken to doctor?	Yes: Doctor confirmed okay to take alli®														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

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	Reason For Issue	Auto Issue		


Customer 17



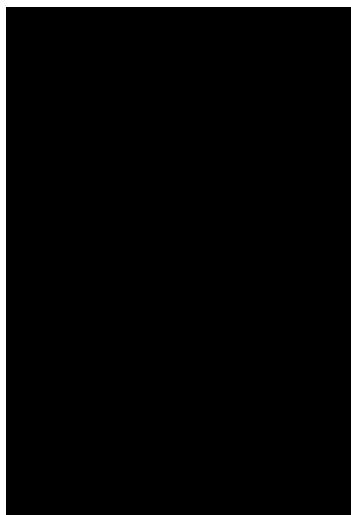
A young woman comes into the pharmacy. She is tired, saying she has been up half the night working on her PhD thesis. She has been so busy working in the lab and writing up her research to meet her deadline that she has neglected her health. She's been ordering pizza a lot. Although there is a park across the road from her flat, the closest she ever gets to it is a glimpse out of the window. She knows she has let things go this time and her weight is higher than it has ever been. She has always struggled with her weight and has tried all the popular diets, some of which have worked well for a while. She doesn't have time for a slimming group but needs to get her weight back under control. She asks about slimming pills.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?	No														
Do you have any medical conditions/illnesses?	No														
<p>Are there any other questions you would like to ask this customer?</p> <p>Please type question 1 here:.....</p> <p>Please type question 2 here:.....</p> <p>Please type question 3 here:.....</p> <p><u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u></p>	<p>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</p> <table border="1"> <tr> <td>Age</td> <td>25</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>no</td> </tr> <tr> <td>Pregnant</td> <td>no</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>	Age	25	BMI		Height		Weight		Breastfeeding	no	Pregnant	no	Spoken to doctor?	no
Age	25														
BMI															
Height															
Weight															
Breastfeeding	no														
Pregnant	no														
Spoken to doctor?	no														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

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Customer 18



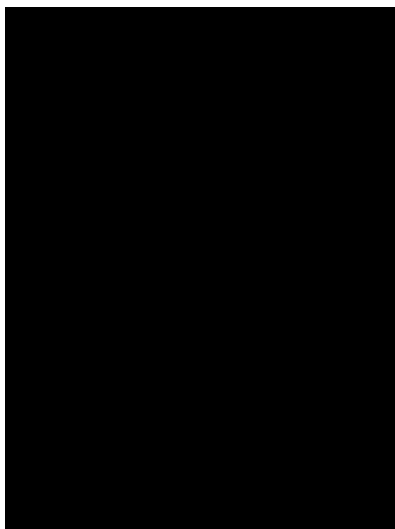
A tired looking woman comes into the pharmacy. She regularly comes in to pick up baby formula, nappies and pacifiers, but today she doesn't have her baby with her. She wants to speak with the pharmacist privately. She explains that before the baby was born, she was very fit and looked after herself. Now, she feels like she has no time to exercise, sleep or eat properly. She wants to shift her post pregnancy weight. She has tried a few diets but is worried that she will never return to her ideal weight again. She wants to know whether diet pills would help.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?	No														
Do you have any medical conditions/illnesses?	No														
<p>Are there any other questions you would like to ask this customer?</p> <p>Please type question 1 here:.....</p> <p>Please type question 2 here:.....</p> <p>Please type question 3 here:.....</p> <p><u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u></p>	<p>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</p> <table border="1"> <tr> <td>Age</td> <td>34</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>no</td> </tr> <tr> <td>Pregnant</td> <td>no</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>	Age	34	BMI		Height		Weight		Breastfeeding	no	Pregnant	no	Spoken to doctor?	no
Age	34														
BMI															
Height															
Weight															
Breastfeeding	no														
Pregnant	no														
Spoken to doctor?	no														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

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	Reason For Issue	Auto Issue		


Customer 19



A middle-aged woman dressed in office clothes comes into the pharmacy. She seems embarrassed but explains that since starting her new marketing manager job, she spends long days in front of the computer. She has regained the weight that she successfully lost over 2 years ago. She is keen to make a good impression at work, but her weight is affecting her confidence. She is unhappy and frustrated that she can no longer fit into her favourite suits. She feels that it is time to take control and wants to use alli® again; it worked last time.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy	No														
Do you have any medical conditions/illnesses?	No														
<p>Are there any other questions you would like to ask this customer?</p> <p>Please type question 1 here:.....</p> <p>Please type question 2 here:.....</p> <p>Please type question 3 here:.....</p> <p><u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u></p>	<p>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</p> <table border="1"> <tr> <td>Age</td> <td>46</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>no</td> </tr> <tr> <td>Pregnant</td> <td>no</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>	Age	46	BMI		Height		Weight		Breastfeeding	no	Pregnant	no	Spoken to doctor?	no
Age	46														
BMI															
Height															
Weight															
Breastfeeding	no														
Pregnant	no														
Spoken to doctor?	no														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

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Customer 20



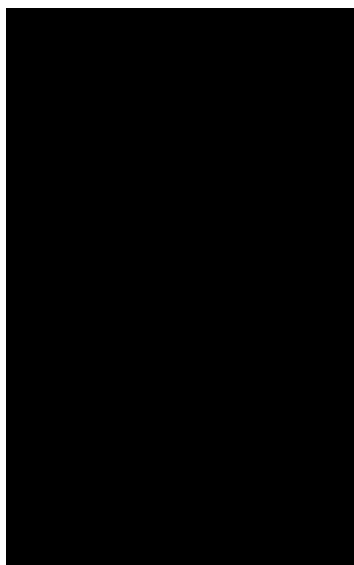
A young woman comes into the pharmacy pushing a buggy. She is smiley and chatty and keen to show off her baby to everyone in the shop. She's on her way to the hairdresser and is thinking about a new style to freshen up her look, but is worried that a shorter style will make her face look fat. She asks your opinion. She says she used to have short hair, but that was before she became pregnant and her shape is completely different now. She says she can't fit into any of her pre-pregnancy jeans. She loves being a mum, but sometimes she'd really like to feel a bit more like her old self. She wants to try diet pills to get her weight loss on track.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?	No														
Do you have any medical conditions/illnesses?	No														
<p>Are there any other questions you would like to ask this customer?</p> <p>Please type question 1 here:.....</p> <p>Please type question 2 here:.....</p> <p>Please type question 3 here:.....</p> <p><u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u></p>	<p>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</p> <table border="1"> <tr> <td>Age</td> <td>26</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>yes</td> </tr> <tr> <td>Pregnant</td> <td>no</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>	Age	26	BMI		Height		Weight		Breastfeeding	yes	Pregnant	no	Spoken to doctor?	no
Age	26														
BMI															
Height															
Weight															
Breastfeeding	yes														
Pregnant	no														
Spoken to doctor?	no														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

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Customer 21



A woman comes into the pharmacy with a baby in a buggy. She tells you she is planning to go back to work in a few months. She is a teacher in a primary school and has missed working with the children. She says she has enjoyed her maternity leave, but all the sitting in cafes, eating cakes and chatting to other mums has not been good for her waistline. She is very keen to lose some weight before she goes back to school. She has managed to lose the weight in the past, before her wedding two years ago, and she'd like to repeat her previous success – and this time keep it off! She asks for the weight loss pills she used last time - alli®.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?		No															
Do you have any medical conditions/illnesses?		No															
<p>Are there any other questions you would like to ask this customer?</p> <p>Please type question 1 here:.....</p> <p>Please type question 2 here:.....</p> <p>Please type question 3 here:.....</p> <p><u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u></p>		<p>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</p> <table border="1"> <tr> <td>Age</td> <td>36</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>yes</td> </tr> <tr> <td>Pregnant</td> <td>no</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>		Age	36	BMI		Height		Weight		Breastfeeding	yes	Pregnant	no	Spoken to doctor?	no
Age	36																
BMI																	
Height																	
Weight																	
Breastfeeding	yes																
Pregnant	no																
Spoken to doctor?	no																
Would you supply alli® to this customer?																	
Yes																	
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....																

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Customer 22



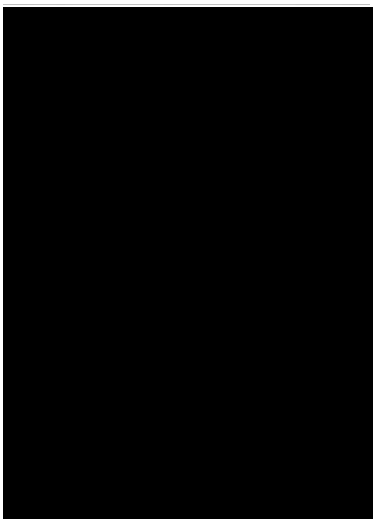
Two teenagers come into the pharmacy, chatting and laughing together. They spend a long time looking at make-up and trying lipsticks and foundations on their hands. Finally they come to the counter to purchase a lip gloss and matching nail colour. They tell you they are already starting to get ready for a big party they are going to in a few weeks. They describe their dresses to you and tell you how they plan to wear their hair. One of them asks rather uncertainly for a packet of weight loss pills, saying she wants to look amazing in her dress and adding that fat ankles will not look good with her shoes. She's worried that no guy will want to take her to the party.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?		No															
Do you have any medical conditions/illnesses?		No															
<p>Are there any other questions you would like to ask this customer?</p> <p>Please type question 1 here:.....</p> <p>Please type question 2 here:.....</p> <p>Please type question 3 here:.....</p> <p><u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u></p>		<p>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</p> <table border="1"> <tr> <td>Age</td> <td>15</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>no</td> </tr> <tr> <td>Pregnant</td> <td>no</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>		Age	15	BMI		Height		Weight		Breastfeeding	no	Pregnant	no	Spoken to doctor?	no
Age	15																
BMI																	
Height																	
Weight																	
Breastfeeding	no																
Pregnant	no																
Spoken to doctor?	no																
Would you supply alli® to this customer?																	
Yes																	
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....																

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Customer 23



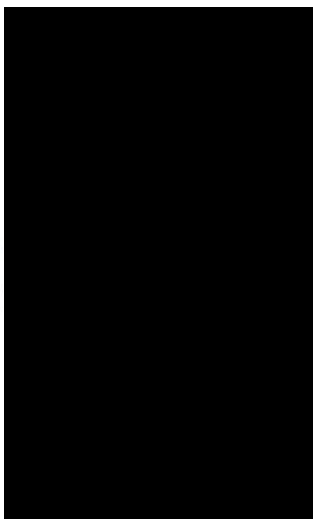
A teenage boy comes into the pharmacy wearing oil-stained jeans and baggy T-shirt. He seems uncomfortable and is unable to make eye contact. He tells you that he'd like to buy weight loss tablets. He is embarrassed when he explains that his size is making it difficult to do his job as a trainee mechanic; that it is awkward leaning over car engines. The other guys at the garage tease him and call him names. His unhappiness has been driving him to over-eat in private, which just makes the problem worse. He knows he needs to exercise, but he says he can't bear the thought of putting on a pair of shorts and running or going to the gym – he knows he will be laughed at. He is desperate to do something about his weight.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?	No														
Do you have any medical conditions/illnesses?	No														
<p>Are there any other questions you would like to ask this customer?</p> <p>Please type question 1 here:.....</p> <p>Please type question 2 here:.....</p> <p>Please type question 3 here:.....</p> <p><u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u></p>	<p>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</p> <table border="1"> <tr> <td>Age</td> <td>17</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>N/A</td> </tr> <tr> <td>Pregnant</td> <td>N/A</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>	Age	17	BMI		Height		Weight		Breastfeeding	N/A	Pregnant	N/A	Spoken to doctor?	no
Age	17														
BMI															
Height															
Weight															
Breastfeeding	N/A														
Pregnant	N/A														
Spoken to doctor?	no														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

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Customer 24



A heavily pregnant woman comes into the pharmacy with her husband and they ask to speak to the pharmacist. She has been advised to manage her weight carefully. She is finding this extremely difficult because she is too uncomfortable to exercise, and so busy looking after their toddler that she doesn't have time to think about feeding herself well. Her husband is worried because the midwife told her that she needs to be very careful with her weight because her blood pressure is quite high. They ask whether weight loss pills would be a good idea to reduce her weight.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?	No														
Do you have any medical conditions/illnesses?	No														
<p>Are there any other questions you would like to ask this customer?</p> <p>Please type question 1 here:.....</p> <p>Please type question 2 here:.....</p> <p>Please type question 3 here:.....</p> <p><u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u></p>	<p>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</p> <table border="1"> <tr> <td>Age</td> <td>28</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>no</td> </tr> <tr> <td>Pregnant</td> <td>Yes: 7 months</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>	Age	28	BMI		Height		Weight		Breastfeeding	no	Pregnant	Yes: 7 months	Spoken to doctor?	no
Age	28														
BMI															
Height															
Weight															
Breastfeeding	no														
Pregnant	Yes: 7 months														
Spoken to doctor?	no														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

	Document Name	204675 Protocol		
	Type	Version	Document Identifier	Effective Date
	eldo_clinical_doc	4.0; Most-Recent; Effective; CURRENT	090032d580bf3a40	26-Jul-2016 10:42:05
	Reason For Issue	Auto Issue		


Customer 25



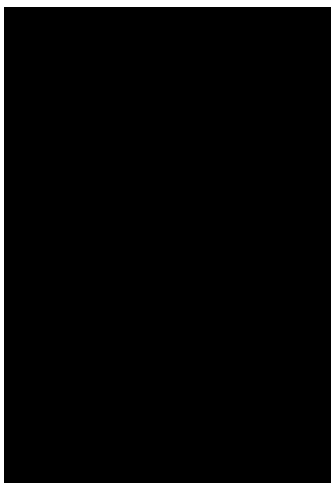
An acquaintance you haven't seen for a long time comes into the pharmacy. She looks like she has put on a little weight. When she approaches the counter and realises you are working today, she seems a little embarrassed and uncomfortable. After taking her into a private room she explains that over the past few months she has been gaining weight slowly but steadily and she is very unhappy about it. She feels she is over-eating but can't seem to stop. She swims regularly to keep fit, but needs more help to manage her weight and asks for weight loss tablets.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?	No														
Do you have any medical conditions/illnesses?	No														
<p>Are there any other questions you would like to ask this customer?</p> <p>Please type question 1 here:.....</p> <p>Please type question 2 here:.....</p> <p>Please type question 3 here:.....</p> <p><u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u></p>	<p>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</p> <table border="1"> <tr> <td>Age</td> <td>34</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>no</td> </tr> <tr> <td>Pregnant</td> <td>no</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>	Age	34	BMI		Height		Weight		Breastfeeding	no	Pregnant	no	Spoken to doctor?	no
Age	34														
BMI															
Height															
Weight															
Breastfeeding	no														
Pregnant	no														
Spoken to doctor?	no														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

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	Reason For Issue	Auto Issue		


Customer 26



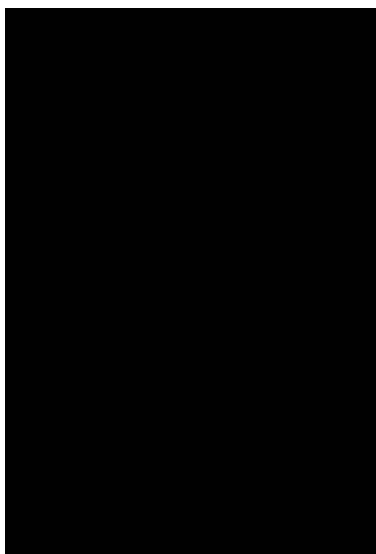
A tall young man comes into the pharmacy on a Monday morning, he looks a little self-conscious. At the counter he tells you that he's been trying to improve his lifestyle, his health is important to him now and he feels that he is a little "big". He says he has really been struggling to lose weight even though he is exercising regularly and has cut out alcohol. He explains that a friend recommended these weight loss pills and that they were safer than anything he could buy online, he would like to give them a go to see if they are the key to getting his weight down and being as healthy as he can be.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?	Atripla®														
Do you have any medical conditions/illnesses?	HIV														
Are there any other questions you would like to ask this customer? Please type question 1 here:..... Please type question 2 here:..... Please type question 3 here:..... <u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u>	<i>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</i> <table border="1"> <tr> <td>Age</td> <td>27</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>N/A</td> </tr> <tr> <td>Pregnant</td> <td>N/A</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>	Age	27	BMI		Height		Weight		Breastfeeding	N/A	Pregnant	N/A	Spoken to doctor?	no
Age	27														
BMI															
Height															
Weight															
Breastfeeding	N/A														
Pregnant	N/A														
Spoken to doctor?	no														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

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	Reason For Issue	Auto Issue		


Customer 27



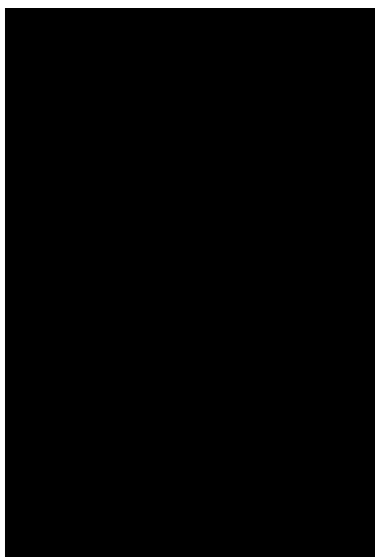
A sporty middle aged woman comes into the pharmacy, she is carrying a bag and tennis racket. At the counter she tells you that she is concerned about her 22 year old daughter who has recently finished university but she has put on a lot of weight during her exams and her mother feels this is not healthy and her clothes do not fit anymore. She explains that she wants to buy some weight loss pills for her daughter to help get her going so that she can feel motivated to get back to her healthy happy weight.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Is she (her daughter) taking any medication prescribed by her doctor or that she buys in pharmacy?	No														
Does she (her daughter) have any medical conditions/illnesses?	No														
<p>Are there any other questions you would like to ask this customer?</p> <p>Please type question 1 here:.....</p> <p>Please type question 2 here:.....</p> <p>Please type question 3 here:.....</p> <p><u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u></p>	<p><i>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</i></p> <table border="1"> <tr> <td>Age</td> <td>22</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>no</td> </tr> <tr> <td>Pregnant</td> <td>no</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>	Age	22	BMI		Height		Weight		Breastfeeding	no	Pregnant	no	Spoken to doctor?	no
Age	22														
BMI															
Height															
Weight															
Breastfeeding	no														
Pregnant	no														
Spoken to doctor?	no														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

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	Type	Version	Document Identifier	Effective Date
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	Reason For Issue	Auto Issue		


Customer 28



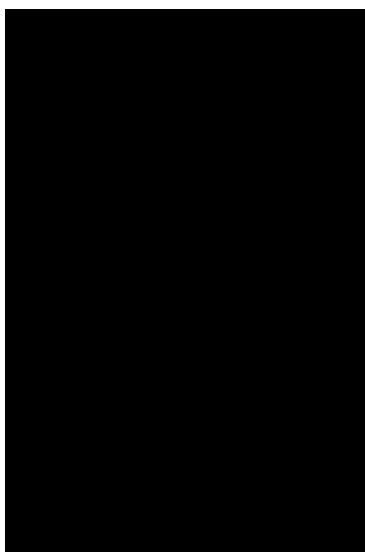
A man in jeans and a hoodie comes into the pharmacy at lunchtime, he picks up a salad and a diet drink then comes over to the counter. He explains that he has put on a lot of weight recently and wants to lose those extra kilos. He has always considered himself to be fairly fit but he thinks it might have something to do with some new tablets he has started. He explains that he wants to buy some weight loss pills because his normal gym visits really don't seem to be shifting it.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?	Sodium valproate Levetiracetam														
Do you have any medical conditions/illnesses?	Epilepsy														
Are there any other questions you would like to ask this customer? Please type question 1 here:..... Please type question 2 here:..... Please type question 3 here:..... <u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u>	<i>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</i> <table border="1"> <tr> <td>Age</td> <td>33</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>N/A</td> </tr> <tr> <td>Pregnant</td> <td>N/A</td> </tr> <tr> <td>Spoken to doctor?</td> <td>Yes: Doctor confirmed okay to take alli®</td> </tr> </table>	Age	33	BMI		Height		Weight		Breastfeeding	N/A	Pregnant	N/A	Spoken to doctor?	Yes: Doctor confirmed okay to take alli®
Age	33														
BMI															
Height															
Weight															
Breastfeeding	N/A														
Pregnant	N/A														
Spoken to doctor?	Yes: Doctor confirmed okay to take alli®														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

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	Reason For Issue	Auto Issue		


Customer 29



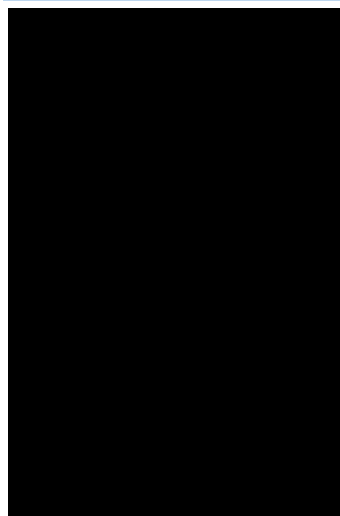
A slightly dishevelled woman comes into the pharmacy, carrying several shopping bags and clutching a notebook. She comes to the counter and says it is very important she speak to the pharmacist. She seems a little distracted. She tells you she is fat but she's just got too much to do to bother with a silly diet and wants to try those new weight loss pills she's seen on the poster in the window. She says they could be the key to getting her healthy.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?	Olanzapine														
Do you have any medical conditions/illnesses?	Bipolar disorder														
<p>Are there any other questions you would like to ask this customer?</p> <p>Please type question 1 here:.....</p> <p>Please type question 2 here:.....</p> <p>Please type question 3 here:.....</p> <p><u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u></p>	<p><i>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</i></p> <table border="1"> <tr> <td>Age</td> <td>36</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>no</td> </tr> <tr> <td>Pregnant</td> <td>no</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>	Age	36	BMI		Height		Weight		Breastfeeding	no	Pregnant	no	Spoken to doctor?	no
Age	36														
BMI															
Height															
Weight															
Breastfeeding	no														
Pregnant	no														
Spoken to doctor?	no														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

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Customer 30



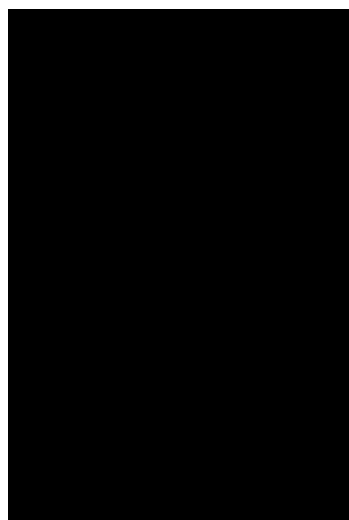
A woman comes into the pharmacy, she is quite large and wearing dark shapeless clothes, she looks a little harassed. At the counter she tells you she's been feeling really down on herself recently and is concerned about her weight, her doctor has said that exercise could help with both her mood and help with weight loss but she just feels so tired all the time, she has 3 children and a job and doesn't have time to get to a gym or class. She has tried a couple of diets but they just go out the window at the slightest stress. She explains that she wants to buy some weight loss pills because it just seems to be the simplest way to get started, after all once she loses some weight she might feel more like exercising.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?		Citalopram															
Do you have any medical conditions/illnesses?		Depression															
Are there any other questions you would like to ask this customer? Please type question 1 here:..... Please type question 2 here:..... Please type question 3 here:..... <u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u>		<i>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</i> <table border="1"> <tr> <td>Age</td> <td>45</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>no</td> </tr> <tr> <td>Pregnant</td> <td>no</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>		Age	45	BMI		Height		Weight		Breastfeeding	no	Pregnant	no	Spoken to doctor?	no
Age	45																
BMI																	
Height																	
Weight																	
Breastfeeding	no																
Pregnant	no																
Spoken to doctor?	no																
Would you supply alli® to this customer?																	
Yes																	
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....																

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Customer 31



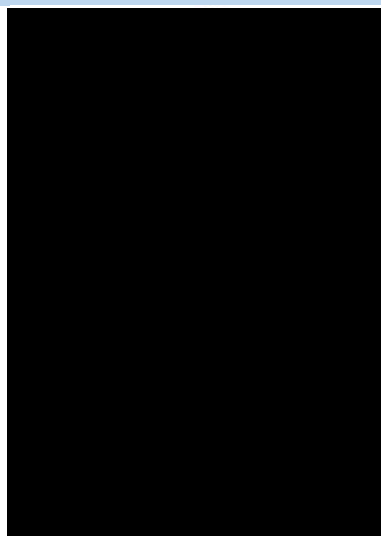
A smiling, rotund middle aged man walks into the pharmacy and straight up to the counter. He asks for some of those new weight loss pills you can buy now. He's been told by his doctor that he needs to lose a bit of weight and his wife agrees, she is concerned about his health these days. He has really cut down his drinking and is getting better at eating the right food but it is not really working and he feels he just needs a little more help to get rid of those extra kilos.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?	Metformin														
Do you have any medical conditions/illnesses?	Diabetes High cholesterol														
Are there any other questions you would like to ask this customer? Please type question 1 here:..... Please type question 2 here:..... Please type question 3 here:..... <u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u>	<i>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</i> <table border="1"> <tr> <td>Age</td> <td>58</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>N/A</td> </tr> <tr> <td>Pregnant</td> <td>N/A</td> </tr> <tr> <td>Spoken to doctor?</td> <td>Yes: Doctor confirmed okay to take alli®</td> </tr> </table>	Age	58	BMI		Height		Weight		Breastfeeding	N/A	Pregnant	N/A	Spoken to doctor?	Yes: Doctor confirmed okay to take alli®
Age	58														
BMI															
Height															
Weight															
Breastfeeding	N/A														
Pregnant	N/A														
Spoken to doctor?	Yes: Doctor confirmed okay to take alli®														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

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Customer 32



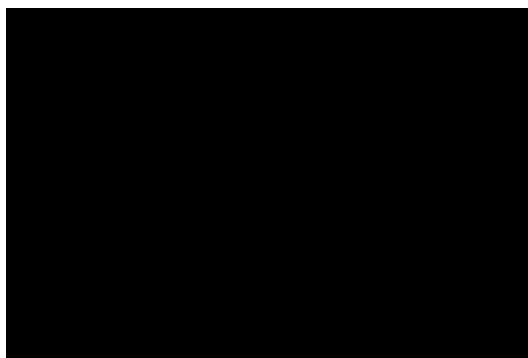
A middle aged man in a smart suit comes into the pharmacy just before closing. He is talking on his phone and carrying briefcase. As soon as he finishes his call he waves you over. At the counter he informs you that he would like to buy a packet of weight loss tablets. He's been told that he really needs to lose some weight but his job means he spends most of his days in meetings or driving so a regular diet and exercise routine is just impossible. Pills seem like a very sensible option to him.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?	Amiodarone														
Do you have any medical conditions/illnesses?	Previous myocardial infarction Atrial Fibrillation														
<p>Are there any other questions you would like to ask this customer?</p> <p>Please type question 1 here:.....</p> <p>Please type question 2 here:.....</p> <p>Please type question 3 here:.....</p> <p><u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u></p>	<p><i>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</i></p> <table border="1"> <tr> <td>Age</td> <td>54</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>N/A</td> </tr> <tr> <td>Pregnant</td> <td>N/A</td> </tr> <tr> <td>Spoken to doctor?</td> <td>no</td> </tr> </table>	Age	54	BMI		Height		Weight		Breastfeeding	N/A	Pregnant	N/A	Spoken to doctor?	no
Age	54														
BMI															
Height															
Weight															
Breastfeeding	N/A														
Pregnant	N/A														
Spoken to doctor?	no														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli®:.....														

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Customer 33




A worried looking woman comes into your pharmacy in the early afternoon. She is fidgeting with her handbag and walks all around the shop until she eventually comes to the counter. She asks if she can have a quiet word with the pharmacist. She explains that she is looking for help with weight loss and has heard about this tablet you can buy.

She lost her husband unexpectedly a year ago and has found herself eating more than she should as it calms her. She says none of her clothes really fit her anymore. She has tried going to an exercise class but it is quite a drive away and she worries about leaving the house empty for so long.

If you need more information before deciding whether or not to supply alli® to this customer, please use any of the questions below which are relevant.

Are you taking any medication prescribed by your doctor or that you buy in pharmacy?	Lorazepam														
Do you have any medical conditions/illnesses?	Anxiety														
Are there any other questions you would like to ask this customer? Please type question 1 here:..... Please type question 2 here:..... Please type question 3 here:..... <u>IF YOU HAVE ANY FURTHER QUESTIONS FOR THIS CUSTOMER, PLEASE TYPE THEM BELOW:</u>	<i>The programming for the free text questions will be constructed to recognise the terms below and provide the relevant data for each virtual customer if requested:</i> <table border="1"> <tr> <td>Age</td> <td>57</td> </tr> <tr> <td>BMI</td> <td></td> </tr> <tr> <td>Height</td> <td></td> </tr> <tr> <td>Weight</td> <td></td> </tr> <tr> <td>Breastfeeding</td> <td>no</td> </tr> <tr> <td>Pregnant</td> <td>no</td> </tr> <tr> <td>Spoken to doctor?</td> <td>Yes: Doctor confirmed okay to take alli®</td> </tr> </table>	Age	57	BMI		Height		Weight		Breastfeeding	no	Pregnant	no	Spoken to doctor?	Yes: Doctor confirmed okay to take alli®
Age	57														
BMI															
Height															
Weight															
Breastfeeding	no														
Pregnant	no														
Spoken to doctor?	Yes: Doctor confirmed okay to take alli®														
Would you supply alli® to this customer?															
Yes															
No	Please briefly explain the main reason why, in your opinion, this customer is not suitable for alli:														

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	Reason For Issue	Auto Issue		

SIGNATURE PAGE

204675 Protocol

Date	Signed By
25-Jul-2016 02:38:14	
Justification	Approved

Date	Signed By
25-Jul-2016 07:36:23	
Justification	Approved

Date	Signed By
26-Jul-2016 04:14:01	
Justification	Biostatistics Approval

Date	Signed By
26-Jul-2016 10:41:56	
Justification	Clinical Operations Approval

Date	Signed By
Justification	

Date	Signed By
Justification	