Annex 1. List of stand-alone documents

No.	Document Reference No	Date	Title
1.	Not Applicable		ENCePP Checklist of study protocols
2.	Not Applicable		Strattera Effectiveness Survey Questionnaire

Annex 2. ENCePP Checklist for study protocols

Doc.Ref. EMA/540136/2009

ENCePP Checklist for Study Protocols (Revision 2, amended)

Adopted by the ENCePP Steering Group on 14/01/2013

The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) welcomes innovative designs and new methods of research. This Checklist has been developed by ENCePP to stimulate consideration of important principles when designing and writing a pharmacoepidemiological or pharmacovigilance study protocol. The Checklist is intended to promote the quality of such studies, not their uniformity. The user is also referred to the ENCePP Guide on Methodological Standards in Pharmacoepidemiology which reviews and gives direct electronic access to guidance for research in pharmacoepidemiology and pharmacovigilance.

For each question of the Checklist, the investigator should indicate whether or not it has been addressed in the study protocol. If the answer is "Yes", the page number(s) of the protocol where this issue has been discussed should be specified. It is possible that some questions do not apply to a particular study (for example in the case of an innovative study design). In this case, the answer 'N/A' (Not Applicable) can be checked and the "Comments" field included for each section should be used to explain why. The "Comments" field can also be used to elaborate on a "No" answer.

This Checklist should be included as an Annex by marketing authorisation holders when submitting the protocol of a non-interventional post-authorisation safety study (PASS) to a regulatory authority (see the Guidance on the format and content of the protocol of non-interventional post-authorisation safety studies). Note, the Checklist is a supporting document and does not replace the format of the protocol for PASS as recommended in the Guidance and Module VIII of the Good pharmacovigilance practices (GVP).

Study title: Physician Survey to Re-assess Effectiveness of Strattera Risk Minimisation Activities

Study reference number:

Section 1: Milestones	**Yes**	**No**	**N/A**	**Page Number(s)**
1.1 Does the protocol specify timelines for				
1.1.1 Start of data collection[2]	☒	☐	☐	
1.1.2 End of data collection[3]	☒	☐	☐	
1.1.3 Study progress report(s)	☐	☐	☒	
1.1.4 Interim progress report(s)	☐	☐	☒	
1.1.5 Registration in the EU PAS register	☐	☒	☐	
1.1.6 Final report of study results.	☒	☐	☐	

Comments:

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

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

Section 2: Research question	**Yes**	**No**	**N/A**	**Page Number(s)**
2.1.5 If applicable, that there is no *a priori* hypothesis?	☒	☐	☐	

Comments:

Section 3: Study design	**Yes**	**No**	**N/A**	**Page Number(s)**
3.1 Is the study design described? (e.g. cohort, case-control, randomised controlled trial, new or alternative design)	☒	☐	☐	
3.2 Does the protocol specify the primary and secondary (if applicable) endpoint(s) to be investigated?	☒	☐	☐	
3.3 Does the protocol describe the measure(s) of effect? (e.g. relative risk, odds ratio, deaths per 1000 person-years, absolute risk, excess risk, incidence rate ratio, hazard ratio, number needed to harm (NNH) per year)	☐	☐	☒	

Comments:

Section 4: Source and study populations	**Yes**	**No**	**N/A**	**Page Number(s)**
4.1 Is the source population described?	☒	☐	☐	
4.2 Is the planned study population defined in terms of:				
4.2.1 Study time period?	☒	☐	☐	
4.2.2 Age and sex?	☐	☐	☒	
4.2.3 Country of origin?	☒	☐	☐	
4.2.4 Disease/indication?	☐	☐	☒	
4.2.5 Co-morbidity?	☐	☐	☒	
4.2.6 Seasonality?	☐	☐	☒	

Section 4: Source and study populations	**Yes**	**No**	**N/A**	**Page Number(s)**
4.3 Does the protocol define how the study population will be sampled from the source population? (e.g. event or inclusion/exclusion criteria)	☒	☐	☐	

Comments:

Section 5: Exposure definition and measurement	**Yes**	**No**	**N/A**	**Page Number(s)**
5.1 Does the protocol describe how exposure is defined and measured? (e.g. operational details for defining and categorising exposure)	☐	☐	☒	
5.2 Does the protocol discuss the validity of exposure measurement? (e.g. precision, accuracy, prospective ascertainment, exposure information recorded before the outcome occurred, use of validation sub-study)	☐	☐	☒	
5.3 Is exposure classified according to time windows? (e.g. current user, former user, non-use)	☐	☐	☒	
5.4 Is exposure classified based on biological mechanism of action and taking into account the pharmacokinetics and pharmacodynamics of the drug?	☐	☐	☒	
5.5 Does the protocol specify whether a dose-dependent or duration-dependent response is measured?	☐	☐	☒	

Comments:

Section 6: Endpoint definition and measurement	**Yes**	**No**	**N/A**	**Page Number(s)**
6.1 Does the protocol describe how the endpoints are defined and measured?	☒	☐	☐	

Section 6: Endpoint definition and measurement	**Yes**	**No**	**N/A**	**Page Number(s)**
6.2 Does the protocol discuss the validity of endpoint measurement? (e.g. precision, accuracy, sensitivity, specificity, positive predictive value, prospective or retrospective ascertainment, use of validation sub-study)	☐	☐	☒	

Comments:

This survey will provide descriptive statistics and no inferential statistics.

Section 7: Confounders and effect modifiers	**Yes**	**No**	**N/A**	**Page Number(s)**
7.1 Does the protocol address known confounders? (e.g. collection of data on known confounders, methods of controlling for known confounders)	☐	☐	☒	
7.2 Does the protocol address known effect modifiers? (e.g. collection of data on known effect modifiers, anticipated direction of effect)	☐	☐	☒	

Comments:

This survey will provide descriptive statistics and no inferential statistics.

Section 8: Data sources	**Yes**	**No**	**N/A**	**Page Number(s)**
8.1 Does the protocol describe the data source(s) used in the study for the ascertainment of:				
8.1.1 Exposure? (e.g. pharmacy dispensing, general practice prescribing, claims data, self-report, face-to-face interview, etc.)	☒	☐	☐	
8.1.2 Endpoints? (e.g. clinical records, laboratory markers or values, claims data, self-report, patient interview including scales and questionnaires, vital statistics, etc.)	☒	☐	☐	
8.1.3 Covariates?	☐	☐	☒	
8.2 Does the protocol describe the information available from				

Section 8: Data sources	**Yes**	**No**	**N/A**	**Page Number(s)**
the data source(s) on:				
8.2.1 Exposure? (e.g. date of dispensing, drug quantity, dose, number of days of supply prescription, daily dosage, prescriber)	☒	☐	☐	
8.2.2 Endpoints? (e.g. date of occurrence, multiple event, severity measures related to event)	☒	☐	☐	
8.2.3 Covariates? (e.g. age, sex, clinical and drug use history, co-morbidity, co-medications, life style, etc.)	☐	☐	☒	
8.3 Is a coding system described for:				
8.3.1 Diseases? (e.g. International Classification of Diseases (ICD)-10)	☐	☐	☒	
8.3.2 Endpoints? (e.g. Medical Dictionary for Regulatory Activities (MedDRA) for adverse events)	☐	☐	☒	
8.3.3 Exposure? (e.g. WHO Drug Dictionary, Anatomical Therapeutic Chemical (ATC)Classification System)	☐	☐	☒	
8.4 Is the linkage method between data sources described? (e.g. based on a unique identifier or other)	☐	☐	☒	

Comments:

Exposure is defined as healthcare providers who prescribe and/or manage patients using Strattera

Section 9: Study size and power	**Yes**	**No**	**N/A**	**Page Number(s)**
9.1 Is sample size and/or statistical power calculated?	☐	☐	☒	

Comments:

Section 10: Analysis plan	**Yes**	**No**	**N/A**	**Page Number(s)**
10.1 Does the plan include measurement of excess risks?	☐	☒	☐	
10.2 Is the choice of statistical techniques described?	☒	☐	☐	
10.3 Are descriptive analyses included?	☒	☐	☐	
10.4 Are stratified analyses included?	☒	☐	☐	
10.5 Does the plan describe methods for adjusting for confounding?	☐	☒	☐	
10.6 Does the plan describe methods addressing effect modification?	☐	☒	☐	

Comments:

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

Comments:

Section 12: Limitations	**Yes**	**No**	**N/A**	**Page Number(s)**
12.1 Does the protocol discuss: 12.1.1 Selection biases? 12.1.2 Information biases? (e.g. anticipated direction and magnitude of such biases, validation sub-study, use of validation and external data, analytical methods)	☒ ☒	☐ ☐	☐ ☐	
12.2 Does the protocol discuss study feasibility? (e.g. sample size, anticipated exposure, duration of follow-up in a cohort study, patient recruitment)	☒	☐	☐	
12.3 Does the protocol address other limitations?	☒	☐	☐	

Comments:

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

Comments:

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

Comments:

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

Comments:

Name of the main author of the protocol: ____Nicole Kellier_____

Date: / /

Signature: __ Signature on file_____

Annex 3. Physician Assessment Survey

Good morning / afternoon, Dr. .....

GfK Health - an independent agency - is conducting a research study on behalf of Eli Lilly and Company, a pharmaceutical company who developed the medicinal product Strattera (atomoxetine) for the treatment of ADHD. The information obtained from this study will be used to assess the effectiveness of the important product safety information provided to prescribers and those who monitor patients on Strattera. We would appreciate your assistance in this important research study.

Please be assured that any information you give will be treated in confidence. This research conforms to the Data Protection Act, and any information you provide will be combined with responses received from other survey participants in order to provide an overall picture of views. Your identity will not be revealed to the company sponsoring this research. Aggregate results will be provided to regulatory agencies and the company sponsoring this research. This research doesn't involve any promotional material.

You have the right to withdraw from the study at any time during the survey process and to withhold information. Your answers will not affect your ability to prescribe Strattera. You will not be contacted for marketing purposes based on your answers to the survey. Neither the survey sponsor nor its contractors will sell or rent your information.

Prog UK only

We are required to pass on to our client, the company sponsoring this study, details of adverse events/product complaints that are mentioned during the course of market research. Although what you say will, of course, be treated in confidence, should you raise during the discussion an adverse event/product complaint in a specific patient or group of patients, we will need to report this even if it has already been reported by you directly to the company or the regulatory authorities using the MHRA's 'Yellow Card' system.

In such a situation you will be asked whether or not you are willing to waive confidentiality given to you under the Market Research Codes of conduct specifically in relation to that adverse event/product complaint. Everything else you say during the course of the survey will continue to remain confidential, and you will still have the option to remain anonymous if you so wish.

Prog all

Now we would like to ask you a few questions to ensure you qualify to complete the survey.

Thank you!

A. Screening

S1 What is your primary medical specialty?

(1) Child/Adolescent Psychiatrist
(2) Other Non-Pediatricians Psychiatrist
(3) Pediatrician
(4) General Practitioner (GP)
(5) Other, namely _____
➔ **end if "(5)"**

S2 Are you currently employed or contracted by regulatory bodies (e.g. EMA or [UK: MHRA; add name of local regulatory agency], Lilly, or GfK Healthcare?

(1) Yes ➔ **end if "(1) yes"**
(2) No

S3 Do you prescribe Strattera, or manage/monitor patients using Strattera?

(1) Yes
(2) No
➔ **end if "no"**

S4 Do you typically….:

(1) … Both prescribe Strattera AND monitor patients taking Strattera
(2) … Only prescribe Strattera but NOT monitor patients taking Strattera
(3) … Only monitor patients who have already initiated Strattera treatment but NOT prescribe Strattera
(4) …. Neither prescribe Strattera nor monitor patients taking Strattera

➔ **end if #4 is selected**

Introduction

Thank you for agreeing to participate in this study.
The survey should take up to a maximum of 10 minutes to complete.
You may receive compensation of [Please insert] which is commensurate with the time needed to complete this survey. You may also choose not to accept the monetary compensation.

We would be very grateful if you could spend these 10 minutes of your valuable time to assist in our understanding of the effectiveness of Strattera product literature.

Prog all countries

If you wish to contact us about this survey, please contact:_____

If you are interested in GfK's privacy policy, we will provide you with this information upon your request. GfK adheres to the official European Society for Opinion and Market Research (ESOMAR) code of conduct for market research:
http://www.esomar.org/index.php/codes-guidelines.html

Prog UK only

You are about to enter a market research survey.

We are required to pass on to our client, the company sponsoring this study, details of adverse events/product complaints that are mentioned during the course of market research. Although what you say will, of course, be treated in confidence, should you raise during the discussion an adverse event/product complaint in a specific patient or group of patients, we will need to report this even if it has already been reported by you directly to the company or the regulatory authorities using the MHRA's 'Yellow Card' system.

In such a situation you will be asked whether or not you are willing to waive confidentiality given to you under the Market Research Codes of conduct specifically in relation to that adverse event/product complaint. Everything else you say during the course of the survey will continue to remain confidential, and you will still have the option to remain anonymous if you so wish.

Are you happy to proceed with the survey on this basis?

(1) Yes – **Proceed**
(2) No – **Terminate**

"Please click the ""YES"" button, if you agree to participate in the survey.

Prog all countries but UK

You are about to enter a market research survey.

We are required to pass on to our client, the company sponsoring this study, details of adverse events/product complaints that are mentioned during the course of market research. Although what you say will, of course, be treated in confidence, should you raise during the discussion an adverse event/product complaint in a specific patient or group of patients, we will need to report this even if it has already been reported by you directly to the company or the regulatory authorities.

In such a situation you will be asked whether or not you are willing to waive confidentiality given to you under the Market Research Codes of conduct specifically in relation to that adverse event/product complaint. Everything else you say during the course of the survey will continue to remain confidential, and you will still have the option to remain anonymous if you so wish.

Are you happy to proceed with the survey on this basis?

(1) Yes – **Proceed**
(2) No – **Terminate**

Prog all countries

We ask you to consider completing this survey in one sitting. If you should need to interrupt and continue with the survey at a later stage, please be sure to click the original link you received for this survey and you will return to where you left off. Please note that you will not be able to go back to questions once you have submitted a response."

Main Questionnaire

Prog:

1. ***Response time per question to be measured***
2. ***No back buttons***
3. ***, Netherlands; DENMARK: Address base split – first half of addresses for first wave; 2nd half for 2nd wave.***

Q1 What percentage of your ADHD patients do you either prescribe Strattera and/or monitor on Strattera (atomoxetine)?

(1) <25%
(2) 25-50%
(3) 51-75%
(4) >75%

Q2 Please state the percentage (%) of Strattera patients for whom you carry out the following examinations prior to initiating treatment (prescribing) Strattera.

(1) None (0%)
(2) Some (less than 50%)
(3) Most (50% or more but less than 100%)
(4) All (100%)

Do not Prog this comment: This section addresses adherence to SmPC warnings and precautions

	Relevant steps before treatment	**Response**
Q2.1	Careful consideration of cardiovascular family medical history	
Q2.2	Comprehensive medical history of the patient's past and present co-morbid medical disorders or symptoms	
Q2.3	Check thyroid hormones with lab test	
Q2.4	Cardiovascular risk assessment (heart problems, heart defects, irregular heartbeat, high blood pressure, or low blood pressure)	
Q2.5	Physical examination to assess for the presence of cardiac disease.	
Q2.6	Check bone age on X-rays	
Q2.7	Measurement and recording of heart rate	
Q2.8	Measurement and recording of blood pressure	
Q2.9	Check testosterone and estradiol circulating levels	

*Note: Relevant answers in green font

Do not Prog this comment: This section addresses awareness of contraindications

Q3 When would you **not** prescribe Strattera?
Please select all that apply

		Response
Q3.	**When a patient has….**	
Q3.1	Pheochromocytoma	☐
Q3.2	Severe cardiovascular or cerebrovascular disorders	☐
Q3.3	Thyroid hormone replacement drug treatment	☐
Q3.4	Mild and well controlled hypertension	☐
Q3.5	A history of febrile seizures	☐
Q3.6	Comorbid tics	☐
Q3.7	Narrow angle glaucoma	☐

*Note: Correct answers in green font

Q4 Please read the clinical practices described below. Please indicate how often these clinical practices should be performed after Strattera is prescribed to a patient?

Prog: ask per medication. Build Grid
Do not prog: This section addresses awareness of the contents of the monitoring checklist for monitoring to manage CV risks with Strattera treatment

(1) At each visit
(2) Every 6 months
(3) Every 12 months
(4) After each dose adjustment and then every 6 months
(5) After each dose adjustment and then every 12 months
(6) None of these

	Actions taken	Strattera (atomoxetine) *Prog: do not program this column*
Q4.1	Re-evaluate the need for continued therapy.	Every 12 months
Q4.2	Checks of the heart rate and blood pressure	After each dose adjustment and then every 6 months
Q4.3	Check for signs/symptoms for the development of new neurologic signs /symptoms	At each visit
Q4.4	Check for signs/symptoms of the development of new cardiovascular disorder or worsening of a pre-existing cardiovascular disorder	At each visit

Awareness of RMP (Prog: do not show this headline)

P1 Please consider the point at which you initiate treatment with Strattera and the subsequent period of monitoring of the patient receiving treatment and indicate which of these statements represent the latest recommended practice.

Prog: grid format

[Prog: Randomize order of items]

(1) Yes
(2) No
(3) Do not know

	Information	***Prog: do not program this column*** **Response**
P1.1	There is a risk of increased blood pressure and increased heart rate with the use of Strattera	Y
P1.2	Strattera should not be used in patients with severe cardiovascular or cerebrovascular disorders	Y
P1.3	Strattera should be used with caution in patients whose underlying medical conditions could be worsened by increases of blood pressure or heart rate (e.g. patients with hypertension, tachycardia, or cardiovascular or cerebrovascular disease)	Y
P1.4	A baseline patient history and physical examination is needed to assess for the presence of cardiac disease before prescribing Strattera	Y
P1.5	Heart rate and blood pressure should be measured and recorded in all patients before the Strattera treatment / after each adjustment of dose	Y
P1.6	If Strattera patients develop symptoms suggestive of cardiac disease during treatment they should be referred for prompt specialist cardiac evaluation	Y
P1.7	Adverse reactions suspected to be associated with the use of Strattera should be reported via the national reporting system	Y
P1.8	Patients should be referred for specialist cardiac evaluation if initial findings suggest a history or presence of cardiac disease	Y
P1.9	Heart rate and blood pressure should be measured and recorded in all Strattera patients at least every 6 months during treatment	Y
P1.10	A checklist for actions to take before prescribing/dispensing or administering Strattera should be followed	Y
P1.11 a	If Strattera is considered, a detailed history and careful physical examination is needed to assess for the presence of cardiac disease of concomitant medications including past and present	Y for all

	co-morbid medical disorders or symptoms	
P1.11b	If Strattera is considered, a detailed history and careful physical examination is needed to assess for the presence of cardiac disease of concomitant medications including family history of sudden cardiac or unexplained death or malignant arrhythmia	Y for all
P1.11c	If Strattera is considered, a detailed history and careful physical examination is needed to assess for the presence of cardiac disease of concomitant medications including physical examination is needed to assess for the presence of cardiac disease	Y for all
P1.12	It is not necessary to use Strattera cautiously with pressor agents or medications that may increase blood pressure	N
P1.13	A re-evaluation of the need for ADHD therapy is recommended when patients are continuing treatment with Strattera at 3 months.	N
P1.14	For patients receiving Strattera, a checklist for monitoring cardiovascular risks should be followed	Y
P1.15	Patients should be referred to further specialist evaluation if they develop new neurologic signs or symptoms	Y
P1.16	Patient should be referred for further specialist evaluation in the event the patient developed a new cardiovascular disorder or a worsening of a pre-existing cardiovascular disorder	Y
P1.17	Heart rate and blood pressure should be only measured by a cardiac specialist	N
P1.18	Before prescribing/dispensing or administering Strattera, an echocardiography is needed	N

We want to focus on your awareness of medical information regarding the treatment of ADHD patients with Strattera.

P3 Please have a look at the following documents. In general, how knowledgeable are you with the content of the following medical information provided for **Strattera**? Please tick the answer that apply
(Single answer per item)

Prog: please show screenshot of these documents

Medical Information	Response
Physicians guide for assessing and monitoring cardiovascular risks when prescribing Strattera	☐
Checklist for actions to take before prescribing/dispensing or administering Strattera	☐
Checklist for monitoring to manage cardiovascular risks with Strattera treatment	☐
Measurements recording chart (for blood pressure and heart rate)	☐

(1) Not knowledgeable
(2) Somewhat knowledgeable
(3) Very knowledgeable

Filter: Ask If awareness is "not knowledgeable" (Code 1) in P3 for Strattera

P3_A. Which statement best describes why you are not knowledgeable *of the content of the following medical information provided for Strattera*:
(1) I was not aware this information is available
(2) I am aware this information is available but do not remember the content

Filter: Ask If awareness at least "somewhat knowledgeable" (Code 2-3) in P3 for Strattera
Prog: please show screenshot of these documents

P4. What best describes your use of the following tools, provided to physicians, when prescribing Strattera or managing/monitoring treatment with Strattera?

Tools	Response
Physicians guide for assessing and monitoring cardiovascular risks when prescribing Strattera	☐
Checklist for actions to take before prescribing/dispensing or administering Strattera	☐

Checklist for monitoring to manage cardiovascular risks with Strattera treatment	☐
Measurements recording chart (for blood pressure and heart rate)	☐

(1) Never use
(2) Sometimes use
(3) Frequently use
(4) Always use

>>**All documents are available upon request via your local Lilly affiliate.**<<

Demographics

DEMOGRAPHICS

office-based, hospital-based physicians

Finally, we have some demographic questions about you. We will use this information for classification only.

General questions

A1. Gender
[1] male
[2] female

A2. Year of birth (YYYY)
_____

A3. Region (please tick one box only) (country specific)

[UK]

(1) Greater London
(2) South East (Kent, Surrey, Sussex, Hampshire, Isle of Wight, Berks, Bucks, Oxfordshire, Northants)
(3) South West (Avon, Gloucestershire, Wiltshire, Somerset, Dorset, Devon, Cornwall, Isles of Scilly)
(4) Northern (Northumberland, Durham, Cleveland, North Yorkshire, West Yorkshire

A4. What proportion of your time do you spend in the office practice and/or hospital?

_____ % in the office

_____ % in hospital

.....

Total = 100 %

A5. When did you start working in your profession?
_____ (year)

A6. In addition to your indicated primary specialty, do you have a secondary specialty? If so please list:_____

Humberside)

(5) North West (Cumbria, Merseyside, Lancashire, Greater Manchester, Cheshire)

(6) West Midlands (Birmingham, Worcestershire, Warwickshire, Staffordshire, Shropshire)

(7) Trent (South Yorkshire, Nottinghamshire, Derbyshire, Lincolnshire, Rutland, Leicestershire)

(8) Eastern (Bedfordshire, Cambridgeshire, Essex, Hertfordshire, Norfolk, Suffolk)

(9) Wales

(10) Scotland

(11) Northern Ireland

[Spain]

(1) Andalucia

(2) Aragón

(3) Asturias

(4) Islas Baleares

(5) País Vasco

(6) Extremadura

(7) Galicia

(8) Islas Canarias

(9) Cantabria

(10) Castilla La Mancha
(11) Castilla León
(12) Cataluña
(13) La Rioja
(14) Madrid
(15) Murcia
(16) Navarra
(17) Valencia

[Sweden]

(1) Götaland
(2) Svealand
(3) Norrland
(4) Malmö
(5) Göteborg
(6) Stockholm

[Denmark]

(1) Region Hovedstaden
(2) Region Sjaelland
(3) Region Syddanmark
(4) Region Midtjylland
(5) Region Nordjylland

[NL]

(1) Noord
(2) Oost

(3) Midden

(4) Zuid

(5) West

Prog: show for all:

Thank you very much for participating in this survey!

Prog: Spain only

"LA EMPRESA asume el compromiso de informar a todos los profesionales sanitarios entrevistados en sus estudios, de la obligación por parte de los mismos de comunicar a las compañías oportunas, los posibles efectos adversos que pudiesen acaecer de sus productos, por motivos de fármaco-vigilancia"

Leo Document ID = de0393d3-238a-40d3-8a52-cd1a7ef29c12

Approver: Valerie Elizabeth Simmons (EMA\YE74498)
Approval Date & Time: 18-Sep-2013 11:44:06 GMT
Signature meaning: Approved

Approver: Vladimir Kopernicky (EMA\YP79330)
Approval Date & Time: 20-Sep-2013 13:28:31 GMT
Signature meaning: Approved