Division: Worldwide Development
Retention Category: GRS019
Information Type: Worldwide Epidemiology Study Protocol

Title: Prescriber and Pharmacist Understanding of the Risk of Urinary Retention with POTIGA™

Compound Number: GW582892

Development Phase IV

Effective Date: 22-APR-2013

Description: This is a cross-sectional survey of physicians and pharmacists that aims to assess their understanding of the risk of urinary retention and the symptoms of acute urinary retention with POTIGA. This forms part of the Risk Evaluation and Mitigation Strategy (REMS) requirements as detailed in the POTIGA REMS approved by the FDA on 10 June 2011.

Subject: Physician and pharmacist survey of the understanding of the risk of urinary retention with POTIGA, Risk Evaluation and Mitigation Strategy (REMS)

Author(s): [redacted]

Revision Chronology:

2011N126225_00	2012-SEP-18	Original
2011N126225_01	2013-MAR-15	Amendment No.:01 The survey will now focus on POTIGA prescribers and pharmacists only.
2011N126225_02	2013-APR-22	Amendment No.:02 Honoraria has been increased for POTIGA prescribers and screening question (Q7) has been revised to include only a subset of products based on issues identified during recruitment and lower than expected completion rates.

SPONSOR SIGNATORY:

STUDY TITLE: Prescriber and Pharmacist Understanding of the Risk of Urinary Retention with POTIGA

Study: WEUKBRE5993 Development Phase: IV

Name of Sponsor Signatory: [redacted]

Title of Sponsor Signatory: Safety Physician [redacted]

Signature:

Date: 22 APRIL 2013

SPONSOR INFORMATION PAGE

Worldwide Epidemiology
Study Identifier:
WEUKBRE5993

GlaxoSmithKline
1-3 Iron Bridge Road
Stockley Park West
Uxbridge, Middlesex UB11 1BT, UK
Telephone [redacted]

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LIST OF ABBREVIATIONS

AE	Adverse Event
AED	Anti-epileptic drug
DHCP	Dear Healthcare Provider (Letter)
GSK	GlaxoSmithKline
HCP	Healthcare Provider
REMS	Risk Evaluation and Mitigation Strategy
US	United States

Trademark Information

Trademarks of the GlaxoSmithKline group of companies
POTIGA
LAMICTAL
LAMICTAL ODT
LAMICTAL XR
TREXIMET

Trademarks not owned by the GlaxoSmithKline group of companies
None

PROTOCOL SUMMARY

Rationale

As part of a post-marketing commitment, GSK will conduct a survey of prescribers' and pharmacists' understanding of the risk of urinary retention with POTIGA™ products. This is to address the effectiveness of the Risk Evaluation and Mitigation Strategy (REMS) as outlined in the REMS approved by the FDA on 10th June 2011.

Objective(s)

The objectives of this survey are to assess prescribers' and pharmacists' understanding of the risk of urinary retention and the symptoms of acute urinary retention potentially associated with POTIGA use as evaluated by a survey instrument.

Study Design

This is a cross-sectional study of approximately:

1. 200 physicians (e.g. neurologists/epileptologists/neurosurgeons) who have prescribed POTIGA at least once in the last 12 months.
2. 200 pharmacists who have dispensed an anti-epileptic drug (AED) at least once in the last 3 months.

Individuals eligible for the survey will be asked to take the survey online or via a telephone interview if the latter is preferred.

Study Endpoints/Assessments

The primary outcome of the survey is the proportion of physicians and pharmacists providing correct responses to a series of questions concerning the risk of urinary retention and the symptoms of acute urinary retention that may be associated with POTIGA. The risks captured will be those described in the POTIGA Dear Healthcare Provider (DHCP) letters, specifically risks of urinary retention.

1. INTRODUCTION

POTIGA was approved with a FDA requirement for a Risk Evaluation and Mitigation Strategy (REMS). The goal of the REMS for POTIGA is to inform healthcare professionals of the risk of urinary retention and the symptoms of acute urinary retention in patients taking POTIGA. The REMS is comprised of a communication plan for healthcare professionals that is designed to disseminate information about the risk of urinary retention with POTIGA and highlight this potential risk and the need to inform patients to seek immediate medical attention for symptoms of urinary retention, inability to urinate, and/or pain with urination. There are two elements of the communication plan: (1) A Dear Healthcare Professional (HCP) Letter designed to disseminate information about the risk of urinary retention with POTIGA; letters are disseminated within 4 weeks of first retail availability (actual – May 7, 2012) and annually for the next two years (2) a REMS Program Website (available at time of launch; actual -April 16, 2012).

The target audience for these communications is: (1) Prescribing physicians i.e., Epileptologists, Neurologists and Neurosurgeons, (2) Pharmacists dispensing POTIGA tablets and the Medication Guide.

As a condition of approval, FDA requires that GlaxoSmithKline (GSK) assess the effectiveness of the communication plan. Accordingly, a survey will be conducted among a sample of prescribing physicians to evaluate whether they can recall the risk of urinary retention with POTIGA. In addition, the survey will evaluate where HCPs prefer to seek information for POTIGA, for example Dear HCP letters, website, or product labeling. The survey will concentrate on the risks described in the DHCP letter for POTIGA, though it is recognised that the DHCP letter is not the only source of information concerning risks associated with medication use. The design for this study is based on previous experience of risk management programs for GSK products.

A survey will also be conducted among a sample of pharmacists to evaluate whether they can recall the risk of urinary retention with POTIGA.

Although the Marketing Application was approved June 10, 2011, initial retail availability could not commence until after the Drug Enforcement Administration (DEA) had completed rule making placing POTIGA into Schedule V under of the Controlled Substances Act. The drug did not become available to patients until early May 2012 (first distribution to wholesalers April 19, 2012). FDA has agreed that with such delayed retail availability of POTIGA, an assessment of HCP understanding submitted on June 10, 2012 would provide little meaningful information. Therefore, the first assessment of the REMS survey will be included with the report due on June 10, 2013.

Originally, ER physicians and urologists were planned to be included in the survey as well. Given the survey will target prescribers only, as of FDA feedback received on January 25, 2013, ER physicians and urologists will no longer be targeted in the survey.

POTIGA was generally available to prescribers and patients for the first time in May 2012 and to date, there has been modest prescribing of the product. The impact of this on

the recruitment goals is uncertain but represents a potential challenge for GSK in this first assessment of HCP knowledge.

2. OBJECTIVE(S)

The objectives of this study are:

1. To assess prescribers' understanding of the risk of urinary retention and the symptoms of acute urinary retention with POTIGA as evaluated by a survey instrument.
2. To assess pharmacists' understanding of the risk of urinary retention and the symptoms of acute urinary retention with POTIGA as evaluated by a survey instrument.

3. INVESTIGATION PLAN

3.1. Study Design

This study is sponsored by GlaxoSmithKline (GSK), and will be conducted by Concentrics Research LLC, a contract research organization, on behalf of GSK.

This is a cross-sectional study of individuals prescribing POTIGA or dispensing AEDs.

Physicians and pharmacists will be recruited using a multi-modal approach:

1. Telephone
2. Email
3. Fax

Screening interviews will take place via telephone, email or fax using a standardized screening questionnaire to assess whether the physician or pharmacist is eligible for and interested in participating in the study. Also, demographic information including clinical specialty and geographic location will be collected at screening.

Following recruitment, physicians' and pharmacists' understanding of the risk of urinary retention and the symptoms of acute urinary retention with POTIGA products will be evaluated using an online survey or the same survey instrument delivered during a telephone interview. If the healthcare provider (HCP) qualifies and is interested in participating, the survey recruiter will schedule an appointment for the interview if the HCP states a preference for the telephone survey, or will send an email including a link to the online survey with their unique passcode. The telephone option will be made available to accommodate individuals who would prefer a telephone call to participate in the survey. It is estimated that approximately 85% will complete the internet survey and the remaining 15% will complete the survey via telephone interview. HCPs will be allowed to respond throughout the entire data collection period, and non-responders will receive up to 5 follow-up messages (sent either via email or phone call) to remind them to participate in the survey.

All physicians and pharmacists will be asked to re-confirm their clinical specialty at the start of the interview (whether online or via telephone). Prescribing physicians (e.g. neurologists, neurosurgeons, epileptologists) will be asked medications prescribed again as well, and pharmacists will similarly be asked to confirm medications dispensed again. Any prescribing physician or pharmacist will be excluded from the survey if he/she gives an answer to these screening questions that would be inconsistent with an answer provided previously during the telephone screening and would also meet an exclusion criteria.

To ensure consistency across interviews, all HCP assessments will be conducted in a structured manner, where all interviews (telephone and on-line) follow a standardized script, and both telephone and on-line surveys will provide the same response options for each question for each participant. Telephone interviewers will be trained on the protocol and questionnaire, as well as following general interviewing practice and quality standards. Telephone interviewers will not be allowed to deviate from the survey procedure or supply additional information or instructions.

Prior to start of the survey, HCPs will be asked to electronically sign a Confidentiality and Consent Agreement, which describes the purpose of the study, data handling, storage and security, expectations of confidentiality of study data and participation, honoraria for study participation, and their rights as a survey subject. All HCPs completing the survey will be required to confirm that he/she is the same HCP who was screened previously to help safeguard against delegation of participation to other colleagues or staff in the HCP's office/pharmacy. Following the HCP's agreement with the Confidentiality and Consent form, the interviewer will administer the telephone survey or the internet survey will begin.

Prior to implementation of the full survey, a pilot study will be conducted involving 30 healthcare providers (HCPs) (10 prescribing physicians, 5 urologists, 5 emergency room physicians and 10 pharmacists), enrolled to complete the survey via telephone. Approximately 5 of the prescribing physicians included in the pilot will have prescribed POTIGA. The objectives of the pilot are to test the physicians' and pharmacists' understanding of the draft questions and follow-up responses, in order to understand the nature of the responses and why specific responses were selected. Feedback from HCPs is intended to improve the clarity of the survey questions and answers. Following the completion of the pilot, all study implementation procedures and assumptions will be reviewed to determine if changes in study procedures and/or training of survey administrators will be required prior to implementation of the full survey.

3.2. Study Population

A listing of physicians eligible to complete the survey will be compiled at one research center utilizing a custom database of approximately 500,000 geographically and therapeutically diverse physicians from all 50 states. Working with a partner, this research center also has access to over 168,000 geographically diverse pharmacists from all 50 states.

Pharmacists and physicians in the targeted specialties will be contacted initially via multiple methods, including, telephone, e-mail, and/or fax, with an invitation to participate in the study. Interested physicians will be asked to contact the market research center staff on the study, who will then complete a telephone screening process to determine if the physician meets all of the study protocol-defined eligibility criteria (see Section 4.2.1 and Section 4.2.2) and, to confirm their interest in participating in the survey if they do meet the eligibility criteria. Eligible physicians who agree to participate will be scheduled for either an appointment with an interviewer to complete the survey via telephone or they will be provided an email containing a link to an on-line survey for completion along with their unique access passcode.

For prescribing physicians, the honorarium for completing the survey will be $125, and for pharmacists, the honorarium will be $50. The honorarium for the prescribing physicians was increased from $100 to $125 after the start of the study, due to recruitment being significantly lower than expected.

3.3. Discussion of Design

The final study design is based on experience from risk management studies previously completed by GSK.

3.3.1. Risk management studies for other GSK medications

Experience from previous risk management studies was used to determine the threshold for the proportion of correct responses per individual survey question against which to base sample size calculations and precision estimates.

The REMS post marketing commitments for LAMICTAL™ (NDA 022115) included:

a. A survey of patients' understanding of the serious risks of Lamictal (lamotrigine) Orally Disintegrating Tablets

b. A report on periodic assessments of the distribution and dispensing of the Medication Guide in accordance with 21 CFR 208.24

c. A report on failures to adhere to distribution and dispensing requirements, and corrective actions taken to address noncompliance

The REMS post marketing commitments for TREXIMET™ (NDA 21-926) included:

a. Survey of patients' understanding of the serious risks of TREXIMET;

b. Report on periodic assessments of the distribution and dispensing of the Medication Guide in accordance with 21 CFR 208.24; and,

c. Report on failures to adhere to distribution and dispensing requirements, and corrective actions taken to address non-compliance.

Based on these studies, a threshold of 80% was determined to be acceptable for the proportion of subjects answering correctly the questions regarding risks associated with POTIGA. This threshold will be imposed for prescribers and pharmacists, not urologists

nor emergency room doctors. Prescribers and pharmacists are the HCPs who will play an important role in re-enforcing the safety messages for POTIGA.

It should be noted that TREXIMET and POTIGA REMS have since been revised, because the FDA determined that a Medication Guide is not necessary to ensure the benefits of the drug outweigh the risks described above because labeling and a REMS that includes a communication plan will be adequate to describe these serious risks. The Medication Guide will be part of the approved labeling and be subject to the requirements under 21 CFR 208.

4. SUBJECT SELECTION AND ELIGIBILITY

4.1. Number of Subjects

This survey aims to recruit approximately 400 total POTIGA prescribers and pharmacists. These numbers reflect a trade-off between what is practical in terms of recruitment, given the relatively low predicted uptake of POTIGA, and providing sufficient precision around outcome estimates (proportion giving correct responses per question) (Section 8).

Ideally, this study aims to recruit a sample of physicians and pharmacists from a demographically representative population database who prescribe POTIGA (neurologists, neurosurgeons, epileptologists), and dispense POTIGA (pharmacists). In order to achieve 400 completed interviews, it is anticipated that approximately 4,000 potential physicians or pharmacists may be contacted for potential recruitment for this study.

4.2. Inclusion and Exclusion criteria

4.2.1. Inclusion criteria

Physicians and pharmacists will be required to meet all the following inclusion criteria:

1. Able to read, speak, and understand English.
2. Willing to take the online survey or have the survey administered via a telephone interview, including electronically signing a Confidentiality & Consent agreement and completing all study protocol-specified procedures.
3. Prescribing physicians and pharmacists:
    a. Practicing physician or pharmacist who sees and treats, or fills prescriptions for, patients with epilepsy, currently (within the past 12 months).
    b. Prescribed POTIGA within the past 12 months (prescribing physicians)
    c. Filled a prescription for at least one AED within the previous three months (pharmacists).

4.2.2. Exclusion criteria

Physicians or pharmacists meeting any of the following criteria will not be eligible to take the survey:

a. The physician or pharmacist is currently employed by, or is a representative of any of the following:
    A A pharmaceutical company or manufacturer of medicines or healthcare products.
    B Contributor/editor to published guideline committees for epilepsy or UR.
b. The physician or pharmacist has a visual impairment that would prevent him or her from being able to read independently.
c. The physician or pharmacist participated in the Pilot REMS study for POTIGA.
d. The physician or pharmacist is an employee of GSK or Concentrics Research.

5. STUDY ASSESSMENTS AND PROCEDURES

5.1. Screening and baseline assessments

Subjects participating in the pilot study will be removed programmatically from the sample list in order to avoid bias in the screener by specifically mentioning the drug name, even in a masked approach, during screening which may heighten awareness prior to the interview.

After accepting the initial recruitment invitation to participate in the study, individuals will be scheduled for a telephone screening interview. The screener will assess:

- Inclusion/exclusion criteria
    - The screener was amended after the study began to ask physicians a subset of epilepsy drugs at Q7 instead of the full list previously included. This subset still allows for masking of the drug to be studied (POTIGA), but shortens the burden on the physician to respond to the full listing during recruitment. This revision was made based on qualitative feedback during recruitment where physicians were not continuing with screening due to frustration with the length of this question. After reviewing data gathered to date, the most common responses to the drugs prescribed were included in the remaining listing, along with POTIGA.
- Whether POTIGA has been prescribed within the past 12 months (physicians) or whether AEDs have been dispensed within the past 3 months (pharmacists).
- Demographics: geographic region and type of healthcare provider. Additional prescribing or dispensing-related questions will be asked in the main survey questionnaire.

5.2. Outcomes

Subject understanding of the risk of urinary retention and the symptoms of acute urinary retention associated with POTIGA will be assessed using the survey instrument.

The primary outcome of this study is the proportion of subjects that correctly respond to individual survey questions concerning the risk of urinary retention and the symptoms of acute urinary retention associated with POTIGA. The order in which potential responses to survey questions appear will be randomized. The proportion responding correctly will be tabulated separately for each item in the subject understanding survey instrument. These risks represent those described in the DHCP letter.

At the conclusion of the online survey, the final screen will display a summary of the relevant information from the POTIGA prescribing information, and a link to http://www.potiga.com. The phone respondents will be offered materials by email or the POTIGA website, but will also be given the toll-free number for the POTIGA response center 1866- 4-Potiga (1866-476-8442).

5.3. Adverse drug experience/event measures

This study will not investigate adverse events associated with the use of POTIGA. Whilst it is not the intention of the survey to solicit adverse events (AEs), it is possible that a respondent may spontaneously provide information that meets the criteria of an adverse event. Any reported adverse events will be entered into the GSK Safety Database:

- Online respondents will be provided with the number for the GSK Global Clinical Safety and Pharmacovigilance Response Center at the end of the online survey and will be directed to call the Center to report any adverse events potentially associated with POTIGA.
- If, at any time during the telephone interview, the subject describes an adverse event associated with POTIGA or any GSK product, the interviewer will complete an adverse event form and fax it to GSK Global Clinical Safety and Pharmacovigilance at 919-483-5404 within 24 hours of receiving the information.

At the end of the project, Concentrics shall provide a summary of all AEs that it has submitted to GSK to enable the reports to be reconciled.

6. DATA COLLECTION AND MANAGEMENT

Subject data from the screening and survey response parts of the questionnaire will be stored confidentially in password protected systems maintained by Concentrics Research.

In all cases, subject identifiers will not be collected or transmitted to GSK according to GSK policy. All subjects will be given a numeric subject identifier.

7. DATA ANALYSIS

7.1. Analysis Populations

The population for analysis will comprise all physicians and pharmacists recruited into the study, meeting eligibility criteria as assessed in the survey screener, and completing the survey.

7.2. Analyses

Demographics including geographic location, HCP specialty and prescribing/dispensing of POTIGA and other AEDs will be summarized using descriptive statistics for continuous data and proportions for categorical data.

The primary outcome is the proportion of HCPs answering each question of understanding of the risks associated with POTIGA correctly. Point estimates for the proportion with correct responses, and associated 95% confidence intervals, will be calculated for each question about the awareness of risks of POTIGA. In the case of multiple choice questions, the number and proportion of subjects reporting each response will also be provided.

GSK considers a proportion (%) of correct responses of at least 80% for each individual question to represent sufficient subject understanding of the risks associated with POTIGA. This is based on previous studies by GSK including the risk management program for LAMICTAL and TREXIMET. This threshold will be imposed for prescribers and pharmacists. Prescribers and pharmacists are the HCPs who will play an important role in re-enforcing the safety messages for POTIGA.

The proportion of correct answers to survey questions will be summarized overall and by demographic subgroups. Consideration of these subgroups may highlight differences in subjects' responses. Although the sample size in some subgroups may be relatively small and have low precision, data will be grouped into 2-3 sub-categories as appropriate to identify potential trends in subject understanding including:

- Demographics (geographic location)
- Type of HCP
- POTIGA prescribing/dispensing (yes or no, months prescribing POTIGA)
- Other practice/prescribing characteristics (years in practice, years prescribing AEDs, size of patient population)

This study is descriptive; hence there will be no formal statistical testing completed.

8. PRECISION BY SAMPLE SIZE

If the estimate of the percentage of subjects indicating a correct response to an individual survey question is 80%, then a sample of 200 subjects will provide a margin of error of ± 5.5 percentage points of this estimate with a 95% confidence interval. The margin of error reduces to ±4.7percentage points if the sample size increases to 300. Subgroups of the total sample will have smaller numbers of subjects, resulting in larger margins of error and therefore provide estimates with lower precision. The following table indicates the margin of error at the 95% confidence level provided by varying sample sizes and estimates of percentage of subjects indicating a correct response.

Table 1 Sample size and precision estimates

Sample Size	**Proportion of Correct Responses to Each Question**						
	50	**60**	**70**	**75**	**80**	**85**	**90**
	Precision/ Margin of Error (±%) with 95% Confidence Interval						
50	14	14	12	11	10	9.0	8.0
100	10	10	9.0	8.0	8.0	7.0	6.0
150	8.0	8.0	7.3	7.0	6.7	5.7	4.7
200	**7.0**	**7.0**	**6.5**	**6.0**	**5.5**	**5.0**	**4.0**
250	6.0	6.0	5.6	5.4	4.8	4.6	3.6
300	5.7	5.7	5.3	5.0	4.7	4.0	3.3
350	5.1	5.1	4.9	4.4	4.3	3.9	3.1
400	5.0	4.8	4.5	4.3	4.0	3.5	3.0
450	4.7	4.4	4.2	3.9	3.8	3.2	2.7
500	4.4	4.2	4.0	3.8	3.6	3.2	2.6

9. STUDY LIMITATIONS

There are some limitations inherent in the study design. The sample may not be fully representative of prescribers and pharmacists typically prescribing/dispensing POTIGA. However, this limitation will be addressed to the extent possible via recruitment across many geographical regions recruiting a demographically diverse sample. This study aims to limit this potential bias by accessing HCPs via one of the largest online databases of healthcare professionals in the US rather than targeting high POTIGA prescribing physicians or those known to GSK through previous collaborations or participation in clinical studies.

Since this is an online survey, we cannot detect whether or not HCPs attempt to utilize any reference materials while taking the survey. They will not be provided with any reference materials.

10. STUDY MANAGEMENT

10.1. Ethical approval and subject consent

Subject participation is voluntary. Subject consent will be implied by the subject completing the survey online or via a telephone interview.

As neither GSK nor Concentrics will have any contact with, nor details of, subjects prior to the subject initiating the survey, IRB approval is not deemed necessary.

10.2. Subject confidentiality

Privacy issues will be addressed and respected at each stage of the study. Concentrics will maintain strict confidentiality in handling all HCP identification information. All data provided to GSK will be de-identified; no individual HCP-level data or protected health information will be communicated to GSK.

10.3. Reporting of adverse drug events

See Section 5.3.

10.4. Study reporting and publications

A final report will be written and submitted to FDA.

11. APPENDICES

11.1. Screener

PHYSICIAN/PHARMACIST STUDY

PRE-RECRUIT SCREENER

Thank you for your interest in our research study. I'm _____ with (FIELD AGENCY), and I would like to start by asking you a few questions. Your answers may qualify you to participate in this important research study. May I proceed?

CONTINUE→	YES	1
THANK AND TERMINATE→	NO	2

1) Just to confirm, can you read, speak and understand English?

CONTINUE →	YES	1
TERMINATE →	NO	2

2) Are you currently employed by, or are you a representative of, any of the following?

READ LIST ONE AT A TIME. CIRCLE "NO", "YES" OR "DON'T KNOW" FOR EACH ONE.

		NO	YES	DON'T
A	A pharmaceutical company or manufacturer of medicines or healthcare products	1	2	3
B	Contributor/editor to published guidelines committees for epilepsy or urinary retention	1	2	3
C	Concentrics Research	1	2	3

IF RESPONDENT SAYS "YES" OR "DON'T KNOW (DK)" TO ANY, THEN THANK AND TERMINATE, OTHERWISE CONTINUE.

3) How would you classify your primary specialty? **ALLOW ONE RESPONSE.**

CONTINUE TO Q4→	Neurology	1
CONTINUE TO Q4→	Neurosurgery	2
CONTINUE TO Q4→	Epileptology	3
SKIP TO Q6 →	Pharmacy (Community/Retail)	4
SKIP TO Q6 →	Pharmacy (Hospital/Clinical)	5
TERMINATE →	Other (Specify)	6

IF Q3 = PUNCH 1, 2, OR 3 – ASK Q4.

4) Are you a currently practicing physician? (**IF NEEDED, CLARIFY:** within the past 12 months)

CONTINUE →	YES	1
TERMINATE →	NO	2
TERMINATE →	DON'T KNOW	3

IF Q3 = PUNCH 1, 2, OR 3 – ASK Q5.

5) Do you currently see and treat patients with epilepsy? (**IF NEEDED, CLARIFY:** within the past 12 months)

SKIP TO Q7 →	YES	1
TERMINATE →	NO	2
TERMINATE →	DON'T KNOW	3

IF Q3 = PUNCH 4 OR 5 – ASK Q6.

6) Do you currently fill prescriptions for patients with epilepsy? (**IF NEEDED, CLARIFY:** within the past 12 months)

SKIP TO Q8 →	YES	1
TERMINATE →	NO	2
TERMINATE →	DON'T KNOW	3

IF Q3 = PUNCH 1, 2, OR 3, ASK Q7.

7) I will now read you a list of medicines. Please tell me all of the medicines, if any, for which you have written at least one prescription in the past 12 months.

READ LIST. ALLOW MULTIPLE RESPONSES.

Ativan (*Lorazepam)*	1
Depakote/Depakote ER/Depakote Sprinkle *(Divalproex Sodium)*	5
Dilantin *(Phenytoin)*	9
Keppra *(Levetiracetam)*	12
Lamictal *(Lamotrigine)*	14
Neurontin *(Gabapentin)*	19
Potiga *(Ezogabine)*	**21**
Topamax *(Topiramate)*	23
NONE OF THESE - TERMINATE	28

MUST SAY YES TO PUNCH 21 (POTIGA) TO BE CLASSIFIED AS A POTIGA PRESCRIBER. OTHERWISE, TERMINATE.

IF Q3 = PUNCH 4 (PHARMACY COM/RET) OR 5 (PHARMACY HOS/CLIN), ASK Q8.

8) I will now read you a list of medicines. Please tell me all of the medicines, if any, for which you have filled at least one prescription in the past 3 months.

READ LIST. ALLOW MULTIPLE RESPONSES.

Ativan (*Lorazepam)*	1
Carbatrol *(Carbamazepine)*	2
Celontin *(Methsuximide)*	3
Cerebyx *(Fosphenytoin sodium)*	4
Depakote/Depakote ER/Depakote Sprinkle *(Divalproex Sodium)*	5
Depacon *(Valproate sodium)*	6
Depakene *(Valproic acid)*	7
Diastat *(Diazepam)*	8
Dilantin *(Phenytoin)*	9
Felbatol *(Felbamate)*	10
Gabitril *(Tiagabine hydrochloride)*	11
Keppra *(Levetiracetam)*	12
Klonopin *(Clonazepam)*	13
Lamictal *(Lamotrigine)*	14
Lorazepam Intensol *(Lorazepam)*	15
Lyrica *(Pregabalin)*	16
Mebaral *(Mephobarbital)*	17
Mysoline *(Primidone)*	18
Neurontin *(Gabapentin)*	19
Peganone *(Ethotoin)*	20
Potiga *(Ezogabine)*	21
Tegretol/Tegretol XR *(Carbamazepine)*	22
Topamax *(Topiramate)*	23
Tranxene *(Clorazepate dipotassium)*	24
Trileptal *(Oxcarbazepine)*	25
Valium *(Diazepam)*	26
Zonegran *(Zonisamide)*	27
NONE OF THESE - TERMINATE	28

MUST SAY YES TO ANY IN ORDER TO CONTINUE; OTHERWISE, TERMINATE.

9) Do you normally wear corrective lenses, contacts, or glasses to read?

CONTINUE TO Q10a →	YES	1
SKIP TO Q10b →	NO	2

10a) Other than needing glasses or contacts to read, do you have <u>any</u> other visual impairment that would prevent you from being able to read on your own?

TERMINATE →	YES	1
SKIP TO INVITATION →	NO	2

10b) Do you have <u>any</u> visual impairment that would prevent you from being able to read on your own?

TERMINATE →	YES	1
CONTINUE →	NO	2

IF RESPONDENT MENTIONS HAVING ANY TROUBLE READING THEN TERMINATE, OTHERWISE CONTINUE.

INVITATION:

Thank you very much for your time today. We would like to invite you to participate in our research survey where we would ask you about current prescribing information and practices for a prescription product used to treat epilepsy. The survey is offered as an internet survey at your convenience and should take <u>no more than 15-20 minutes</u> to complete. Because we know your time is valuable, we will be offering an honorarium of $X for completing the survey. Are you willing to participate?

SEE SCRIPT BELOW→	YES	1
QUALIFIED REFUSED→	NO	2

Thank you for your interest and willingness to participate in this survey.

IF INTERESTED, CONFIRM EMAIL ADDRESS. OFFER TELEPHONE OPTION IF REQUESTED.

11.2. Questionnaire

PHYSICIAN/PHARMACIST ASSESSMENT

Quantitative Questionnaire

All programming notes are presented in **BOLD CAPS** throughout the document. These are instructions only and will not be visible to respondents in the survey.

The following are the sections of the survey and items included in this document:

- Introduction
- Screener Profile
- Confidentiality & Consent Agreement
- Physician Assessment Survey
- Additional Demographic Profile

Introduction

Thank you for your interest in participating in our research survey. Your time and opinions are greatly valued, as your responses will help us better understand the perspectives of physicians and pharmacists such as yourself.

This survey is being conducted to evaluate your understanding of prescribing information and practice habits related to a medication used to treat epilepsy. Please be assured that your individual answers will be kept strictly confidential. This survey will take approximately 15-20 minutes to complete.

Screener Profile

We would like to begin by re-confirming 1-2 questions about you.

A. How would you classify your primary specialty? **ALLOW ONE RESPONSE.**

CONTINUE TO QB	Neurology	1
CONTINUE TO QB	Neurosurgery	2
CONTINUE TO QB	Epileptology	3
SKIP TO QD	Pharmacy (Community/Retail)	4
SKIP TO QD	Pharmacy (Hospital/Clinical)	5
TERMINATE	Other (Specify)	6

ASK QB ONLY IF QA = PUNCH 1, 2, OR 3.

B. Approximately how many patients have you prescribed AEDs for in the past 12 months? **ALLOW ONE RESPONSE.**

None **TERMINATE**	1
1-2	2
3-10	3
11-20	4
More than 20 patients	5

ASK QC ONLY IF QA = PUNCH 1, 2, OR 3.

C. Please confirm which of the following medicines, if any, you have written at least one prescription for in the past 12 months. **READ LIST. ALLOW MULTIPLE RESPONSES.**

Lamictal (*Lamotrigine*)	1
Lyrica (*Pregabalin*)	2
Potiga *(Ezogabine)*	3
Tegretol/Tegretol XR *(Carbamazepine)*	4
Topamax *(Topiramate)*	5
None of the above **TERMINATE**	6

TERMINATE IF PUNCH 3 (POTIGA) <u>NOT</u> SELECTED.

ASK QD ONLY IF QA = PUNCH 4 OR 5.

D. Approximately how many prescriptions for AEDs have you filled in the past 3 months? **ALLOW ONE RESPONSE.**

None **TERMINATE**	1
1-2	2
3-10	3
11-20	4
More than 20 prescriptions	5

Thank you. Based on your responses, you qualify for the survey. In order to participate, you will need to read and electronically sign a Confidentiality & Consent Agreement on the following pages.

Confidentiality & Consent Agreement

The purpose of this survey is to assess physician and pharmacist understanding of prescribing information and practice habits related to a medication used to treat epilepsy.

By signing this agreement, you agree not to disclose your participation to anyone unless required by law and to treat what you see confidentially for a period of two (2) years. Any answers, information, and suggestions you may offer are given without obligation of any kind, and your answers to the survey will not affect your ability to [INSERT: prescribe (IF QA = 1/2/3) / dispense (IF QA = 4/5)] the drug.

During your participation in this study, you will be asked a minimal amount of demographic information about yourself. All of this information will be kept confidential and your information will be linked only to your participant number and not directly to you.

Records about you and your part in this survey will be kept private so far as permitted by law. If results of this survey are published, you will not be identified by name. All information recorded during the course of this survey, except your name and contact information, may be provided to the study Sponsor and/or the Food and Drug Administration (FDA).

There are no costs to you for being in this survey. When you have finished all of the survey, you will be paid [INSERT: $125 (IF QA = 1/2/3) / $50 (IF QA = 4/5)] for your time.

It is completely up to you if you wish to take part in this survey. You can stop participating in this survey at any time.

After reading the agreement, please select one option below:

☐ I affirm my understanding of the Confidentiality & Consent agreement and checking this box represents my electronic signature.

OR

☐ I would not like to participate in this study.

RECONFIRM IF CLICK 'I WOULD NOT LIKE TO PARTICIPATE IN THIS STUDY'. IF STILL YES – TAKE TO CLOSING SCREEN.

We would also like to confirm that you are the [INSERT: physician/pharmacist] on record for this survey. Please select one of the following options:

- ☐ 1. I affirm that I am the same [INSERT: physician/pharmacist] who was screened and sent the survey passcode. [INSERT NAME]
- ☐ 2. I am not [INSERT NAME], but I work in this [INSERT: physician's office/pharmacy].

IF PUNCH 1 (SAME PHYSICIAN/PHARMACIST), CONTINUE.

IF PUNCH 2 (NOT PHYSICIAN OR PHARMACIST, BUT WORK IN SAME OFFICE/PHARMACY), SHOW SCREEN WITH MESSAGE: 'THANK YOU FOR YOUR TIME. UNFORTUNATELY, ONLY THE HEALTHCARE PROVIDER ON RECORD MAY PARTICIPATE IN THIS STUDY. IF YOU BELIEVE YOU HAVE RECEIVED THIS MESSAGE IN ERROR, PLEASE CONTACT [INSERT NAME & PHONE #] FOR FURTHER INSTRUCTIONS.' DO NOT ALLOW SUBJECT TO CONTINUE.

Survey

The following questions are being asked about your understanding of the prescribing information and practices related only to POTIGA (ezogabine). Please respond only about this medication, based on what you know at this time.

Please take your time and read each question carefully.

Please do not guess - if you do not know the answer, please just select 'I don't know'.

1. According to U.S. prescribing information, what is the FDA-approved indication for POTIGA? (Please select all that apply)

ALLOW MULTIPLE RESPONSES, EXCEPT PUNCH 4 OR 5.

Migraine	1
Partial-onset seizures	2
Generalized tonic clonic seizures	3
None of the above	4
I don't know	5

2. True or False: According to U.S. prescribing information, POTIGA can be used as monotherapy.

ALLOW ONE RESPONSE.

True	1
False	2
I don't know	3

3. According to U.S. prescribing information, which of the following are potential risks associated with POTIGA? (Please select all that apply)

ALLOW MULTIPLE RESPONSES, EXCEPT PUNCH 5 OR 6.

Urinary retention	1
Pancreatitis	2
Ischemic colitis	3
I don't know	4

4. According to U.S. prescribing information, what is the maximum recommended daily maintenance dose of POTIGA for the General Population?

ALLOW MULTIPLE RESPONSES, EXCEPT PUNCH 5 OR 6.

600mg	1
900mg	2
1200mg	3
2000mg	4
None of the above	5
I don't know	6

5. According to U.S. prescribing information, which of the following statements, if any, is true? (Please select all that apply)

ALLOW MULTIPLE RESPONSES, EXCEPT PUNCH 5 OR 6.

The oldest age at which POTIGA can be used is 65	1
There are no lower age limits for POTIGA	2
The youngest age at which POTIGA can be used is 12	3
The youngest age at which POTIGA can be used is 18	4
None of the above	5
I don't know	6

6. According to U.S. prescribing information, which of the following statements, if any, is true? (Please select all that apply)

ALLOW MULTIPLE RESPONSES, EXCEPT PUNCH 4 OR 5.

POTIGA should always be taken with food	1
POTIGA should always be taken on its own, without food	2
POTIGA can be taken with or without food	3
None of the above	4
I don't know	5

7. Which of the following urinary symptoms, if any, should you specifically advise patients taking POTIGA to watch out for? (Please select all that apply)

ALLOW MULTIPLE RESPONSES, EXCEPT PUNCH 5 OR 6.

Pain when urinating	1
Difficulty starting urination	2
Renal colic	3
Inability to urinate	4
None of the above	5
I don't know	6

8. If a patient on POTIGA experiences inability to pass urine, what would you advise them to do? (Please select all that apply)

ALLOW MULTIPLE RESPONSES, EXCEPT PUNCH 5 OR 6.

Report the issue at their next doctor's appointment	1
Drink more water	2
Seek immediate medical attention	3
Stop taking POTIGA	4
None of the above	5
I don't know	6

9. According to U.S. prescribing information, when increasing the dose, what is the maximum total daily dose at which POTIGA can be increased once every 7 days?

ALLOW MULTIPLE RESPONSES, EXCEPT PUNCH 5 OR 6.

Total daily dose increased by 50mg/day	1
Total daily dose increased by 150mg/day	2
Total daily dose increased by 200mg/day	3
Total daily dose increased by 300mg/day	4
None of the above	5
I don't know	6

10. True or False: According to U.S. prescribing information, for the General Population, the recommended total initial dosage should be 150mg per day for one week.

ALLOW ONE RESPONSE.

True	1
False	2
I don't know	3

11. The label for POTIGA recommends caution when prescribing for patients with which of the following conditions, if any?

		Yes	**No**	**Don't Know**
A	Moderate to severe renal or hepatic impairment	1	2	3
B	Moderate to severe Crohn's disease	1	2	3
C	Moderate to severe asthma	1	2	3
D	Patients over the age of 65 years	1	2	3
E	Moderate to severe glaucoma	1	2	3

12. True or False: It is known from controlled studies that adverse events related to voiding dysfunction generally tend to be reported within the first 6 months after starting POTIGA.

ALLOW ONE RESPONSE.

True	1
False	2
I don't know	3

13. Which of the following patient groups are recommended to have closer monitoring (including comprehensive evaluation of urologic symptoms) for urinary retention? (Please select all that apply)

ALLOW MULTIPLE RESPONSES, EXCEPT PUNCH 6 OR 7.

Patients with benign prostatic hyperplasia (BPH)	1
Patients who are unable to communicate clinical symptoms (e.g. cognitively impaired patients)	2
Patients who use concomitant medications that may affect voiding (e.g. anti-cholinergics)	3
Patients who use non-steroidal anti-inflammatory drugs (NSAIDs)	4
Patients who are obese	5
None of the above	6
I don't know	7

SHOW SECTION B ONLY IF ANY RESPONSES (Q1-13) WERE INCORRECT

SECTION B: For the next set of questions, I'd like to ask you to provide some further information on some of your responses. Please provide as much detail of your thought process as possible when responding.

SHOW Q1_1 THROUGH Q13_1 ONLY FOR ANY INCORRECT RESPONSES AT Q1-13. THESE ARE OPTIONAL QUESTIONS. SHOW QUESTION TEXT FOR EACH, THEN THE QUESTION (1_1 – 13_1).

1_1) Previously, at Question 1, you responded [INSERT Q1 RESPONSE]. What led you to choose that response?

_____

2_1) Previously, at Question 2, you responded [INSERT Q2 RESPONSE]. What led you to choose that response?

_____

3_1) Previously, at Question 3, you responded [INSERT Q3 RESPONSE]. What led you to choose that response?

_____

4_1) Previously, at Question 4, you responded [INSERT Q4 RESPONSE]. What led you to choose that response?

_____

5_1) Previously, at Question 5, you responded [INSERT Q4 RESPONSE]. What led you to choose that response?

_____

6_1) Previously, at Question 6, you responded [INSERT Q6 RESPONSE]. What led you to choose that response?

_____

7_1) Previously, at Question 7, you responded [INSERT Q7 RESPONSE]. What led you to choose that response?

_____

8_1) Previously, at Question 8, you responded [INSERT Q8 RESPONSE]. What led you to choose that response?

_____

9_1) Previously, at Question 9, you responded [INSERT Q9 RESPONSE]. What led you to choose that response?

_____

10_1) Previously, at Question 10, you responded [INSERT Q10 RESPONSE]. What led you to choose that response?

_____

11_1) Previously, at Question 11, you responded [INSERT Q11 RESPONSE]. What led you to choose that response?

_____

12_1) Previously, at Question 12, you responded [INSERT Q12 RESPONSE]. What led you to choose that response?

_____

13_1) Previously, at Question 13, you responded [INSERT Q13 RESPONSE]. What led you to choose that response?

_____

SKIP TO DEMOGRAPHICS (B) IF QA = PUNCH 4 OR 5. CONTINUE TO DEMOGRAPHICS (A) IF QA = PUNCH 1, 2 OR 3.

DEMOGRAPHICS (A)

The next sets of questions are about your practice history so that we can group your responses with others like you.

14. How long have you been practicing medicine?

ALLOW ONE RESPONSE.

Less than 5 years	1
5-15 years	2
16-25 years	3
26-35 years	4
More than 35 years	5

15. How long have you been prescribing anti-epileptic drugs (AEDs)?

ALLOW ONE RESPONSE.

Less than 5 years	1
5-15 years	2
16-25 years	3
26-35 years	4
More than 35 years	5

16. How many months have you been prescribing POTIGA?

ALLOW ONE RESPONSE.

Less than 1	1
1-3	2
4-6	3
7-9	4
10-12	5
More than 12 months	6
I don’t know/don’t remember	7

17. Approximately how many patients have you prescribed POTIGA for in the past 12 months?

ALLOW ONE RESPONSE.

1-2	1
3-10	2
11-20	3
More than 20 patients	4

18. On a monthly basis, approximately how many prescriptions for AEDs (including new prescriptions and refills) have you written in the past 12 months?

ALLOW ONE RESPONSE

1–10	1
11–30	2
31–50	3
More than 50	4

19. What is the age range of your current patient population? Please select all categories that you treat.

ALLOW MULTIPLE RESPONSES.

Pediatric (Under 18)	1
18-34	2
35-64	3
65 +	4

20. Approximately what is the size of your current total patient population?

ALLOW ONE RESPONSE.

Less than 100 patients	1
100 – 500 patients	2
501 – 1000 patients	3
More than 1000 patients	4

21. Approximately what is the size of your current epilepsy patient population?

ALLOW ONE RESPONSE.

Less than 10 patients	1
10 – 50 patients	2
51 – 100 patients	3
101+ patients	4
I do not treat patients with epilepsy	5

SKIP TO SECTION C IF QA = PUNCH 1, 2 OR 3. CONTINUE TO DEMOGRAPHICS (B) IF QA = PUNCH 4 OR 5.

DEMOGRAPHICS (B)

The next sets of questions are about your pharmacy history so that we can group your responses with others like you.

22. How long have you been a practicing pharmacist?

ALLOW ONE RESPONSE.

Less than 5 years	1
5-15 years	2
16-25 years	3
26-35 years	4
More than 35 years	5

23. How long have you been dispensing and/or answering patient questions regarding prescribed AEDs?

ALLOW ONE RESPONSE.

Less than 5 years	1
5-15 years	2
16-25 years	3
26-35 years	4
More than 35 years	5

24. Have you answered any patient questions related to POTIGA in the past 12 months?

ALLOW ONE RESPONSE.

Yes	1
No	2
I don’t know/don’t remember	3

25. Have you dispensed POTIGA in the past 12 months?

ALLOW ONE RESPONSE.

Yes	1
No	2
I don’t know/don’t remember	3

IF Q25 IS NO OR DK/DR, SKIP TO Q28.

26. How many months have you been dispensing POTIGA?

ALLOW ONE RESPONSE.

Less than 1	1
1-3	2
4-6	3
7-9	4
10-12	5
More than 12 months	6
I don’t know/don’t remember	7

27. Approximately how many patients have you dispensed POTIGA for in the past 12 months?

ALLOW ONE RESPONSE.

1-2	1
3-10	2
11-20	3
More than 20 patients	4
I don’t know/don’t remember	5

28. On a monthly basis, approximately how many prescriptions for anti-epileptic drugs (AEDs) (including new prescriptions and refills) have you filled in the past 12 months?

ALLOW ONE RESPONSE.

1 – 10	1
11 – 30	2
31 – 50	3
More than 50 prescriptions	4

SECTION C: The remaining questions are about your own personal experience, specifically regarding your awareness, receipt and dissemination of information about POTIGA.

29. Have you learned about the risks associated with use of POTIGA from any of the following sources?

	Yes	No	Don't Know
POTIGA Dear HCP Letter	1	2	3
GlaxoSmithKline Medical Information	1	2	3
Other Healthcare Professionals	1	2	3
GlaxoSmithKline Promotional Materials	1	2	3
GSK Website: POTIGA.com	1	2	3
GlaxoSmithKline Sales Representatives	1	2	3
GlaxoSmithKline-sponsored Educational Meeting	1	2	3
POTIGA Product Labeling (including Prescribing Information, Medication Guide)	1	2	3

30. How would you prefer to learn about the risks associated with use of POTIGA in the future? Please select up to 3 options.

POTIGA Dear HCP Letter	
GlaxoSmithKline Medical Information	
Other Healthcare Professionals	
GlaxoSmithKline Promotional Materials	
GSK Website: POTIGA.com	
GlaxoSmithKline Sales Representatives	
GlaxoSmithKline-sponsored Educational Meeting	
POTIGA Product Labeling (including Prescribing Information, Medication Guide)	

CLOSING: Those are all of our questions. Thank you very much for your time and for sharing your responses with us today. As you may know, medication manufacturers conduct surveys, such as this one, from time to time to learn how well they have communicated to healthcare providers regarding the risks that may be associated with that medication.

We would now like for you to take a moment to review some important information about POTIGA. This information can be found in the Prescribing Information, which can be found online at:
http://us.gsk.com/products/assets/us_potiga.pdf

The Dear Healthcare Professional Letters (for prescribing physicians and pharmacists) can be found online at:

Prescribing Physicians:
https://www.gsksource.com/gskprm/en/US/images/gsk_content/POTIGA/PGA056R0_REMS_HCP_Letter_DC.pdf

Pharmacists:
https://www.gsksource.com/gskprm/en/US/images/gsk_content/POTIGA/PGA055R0_REMS_PharmLetter_DC.pdf

11.3. GlaxoSmithKline Adverse Drug Reaction Form – Revised Nov 30, 2009

Global Adverse Event Report Reporting Form for Marketing Research

To be completed by Market Research Agency – this form applies to both patients and HCPs.
This form is to be used for AEs mentioned worldwide in market research commissioned by GSK global.
Minimum criteria - A Reporter, at least one patient detail, suspect drug and adverse event
Please complete with as much detail as possible and forward within one business day (24 hours) to your Pharmaceutical company contact via fax to:

For drugs	GSK Case Management Group	Reports from Americas: +1 919 483 5404 (US fax #) Reports outside of Americas: +44 208 754 7821 (UK fax #)
For vaccines	GSK Biologicals Case Management Group	Reports from US & Canada: +1 919 483 5404 (US fax #) Reports outside US & Canada: +32 2 656 8009 (Belgium fax #)

Market Research Agency:	**Date aware of the adverse event/product complaint:** ***Month: Date: Year:***
Agency Address (include country):	**Project Title and Agency Reference/Project No:**
Agency Telephone No:	**Researchers Name:**
Agency Fax No:	**Researchers Signature:**

Drug(s)/ Vaccine(s) and Event(s) Details

Drug/ Vaccines Name(s):	**Adverse Event(s)/Product Complaint details:**
Indication (condition for which the drug(s)/ vaccine(s) has been prescribed): Unknown ☐ **Was the patient pregnant?** Yes ☐ No ☐ Unknown ☐	**Reported to the local regulatory agency?** Yes ☐ No ☐ Unknown ☐ **Lot/Batch number:** Unknown ☐
Dose: **Unknown** ☐	**Did the HCP/patient consider that the event was possibly related to the drug/ vaccine?** Yes ☐ No ☐ Unknown ☐

Patient Details (At least one of these patient details MUST be completed)	
Age:	**Other (approx. age of patient)**
Sex: Male ☐ Female ☐	

Respondent Details **If consent not given to disclose personal details, just complete the type of reporter (i.e., Dr., nurse, patient, pharm.)**	
Respondent name:	**Doctor** ☐
Address:	**Nurse** ☐ **Patient** ☐
Telephone No:	**Pharmacist** ☐
Email:	
Is respondent willing for the Pharmaceutical company's safety team to contact them or their doctor to discuss further? Yes ☐ No ☐	**Respondent Signature:**