Prescriber Survey to Assess Boxed Warnings Perceptions

Survey Questionnaire: Vulvar and Vaginal Atrophy

(Questions used for pre-testing condition are included at the end)

Introductory Script:

Thank you for your participation in this survey. The first few questions will focus on the condition of vulvar and vaginal atrophy in menopause, which you may also know as postmenopausal atrophic vaginitis.

**//PROGRAMMING NOTES: Display each question on its own separate screen. Do not allow participants to go back on any screen. Include soft prompts for all items. //**

**Question Type:** Single Punch

**Question Q1**

Variable Name: *Q1*

Variable Label: Q1 Familiarity with treating VVA

**Question Text:** How experienced are you with treating vulvar and vaginal atrophy?

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | Not at all experienced |
| 2 | Slightly experienced |
| 3 | Somewhat experienced |
| 4 | Experienced |
| 5 | Very experienced |
| --99 | Refused |

**Question Type:** Single Punch

**Question 2**

Variable Name: *Q2*

Variable Label: Q2 Number of patients typically seen

**Question Text:** How many patients do you typically see for treatment of vulvar and vaginal atrophy?

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | One to two patients a week, or fewer |
| 2 | Several patients a week |
| 3 | Several patients a day |
| 98 | Unsure/Don’t know |
| --99 | Refused |

**Question Type:** Single Punch

**Question Q3**

Variable Name: *Q3*

Variable Label: Q3 Bothersomeness of symptoms

**Question Text:** In general, how bothersome are symptoms of vulvar and vaginal atrophy reported by most of your patients who have the condition?

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | Not at all bothersome |
| 2 | Slightly bothersome |
| 3 | Somewhat bothersome |
| 4 | Bothersome |
| 5 | Very bothersome |
| 98 | Unsure/Don’t know |
| --99 | Refused |

**Question Type:** Single Punch

**Question Q4A**

Variable Name: *Q4A*

Variable Label: Q4A Experience prescribing vaginal inserts

**Question Text:** Which of the following is true of your prescribing vaginal inserts (e.g., Vagifem, Imvexxy) for the treatment of vulvar and vaginal atrophy?

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | I have written new prescriptions for this product |
| 2 | I have only prescribed a refill for this product |
| 3 | I have never prescribed this product |
| 98 | Unsure/don’t know |
| -99 | Refused |

**// PROGRAMMING NOTE: SKIP 4B if 4A = 2, 3, 4, or 98//**

**Question Type:** Single Punch

**Question Q4B**

Variable Name: *Q4B*

Variable Label:Q4B Frequency of prescribing vaginal inserts

**Question Text:** On average, how often do you prescribe vaginal inserts (e.g., Vagifem, Imvexxy) for the treatment of vulvar and vaginal atrophy?

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | I prescribe this product one or more times a week |
| 2 | I prescribe this product a few times a month |
| 3 | I prescribe this product a few times a year |
| 98 | Unsure/Don’t know |
| -99 | Refused |

**Question Type:** Multi-Punch

**Question Q5**

Variable Name: *Q5*

Variable Label: Q5Which treatments recommend or prescribe in a month

**Question Text:** Which of the following other treatments would you recommend or prescribe in a typical month? (Select all that apply.)

|  |  |  |
| --- | --- | --- |
| **Value** | **Value Label** | **Variable Label** |
| Q5\_1 | Over-the-counter products (e.g., personal lubricant) | Q5\_1 Typical treatment: OTC products |
| Q5\_2 | Vaginal estrogen rings (e.g., Estring, Femring) | Q5\_2 Typical treatment: Estrogen rings |
| Q5\_3 | Vaginal estrogen creams (e.g., Premarin, Estrace) | Q5\_3 Typical treatment: Estrogen creams |
| Q5\_4 | Topical estrogen gels (e.g., Estrogel, Divigel) | Q5\_4 Typical treatment: Estrogen gels |
| Q5\_5 | Oral estrogens (e.g., Premarin) | Q5\_5 Typical treatment: Oral estrogens |
| Q5\_6 | Estrogen transdermal patches (e.g., Alora, Estraderm) | Q5\_6 Typical treatment: Estrogen patch |
| Q5\_7 | Other prescription product that does not contain estrogen | Q5\_7 Typical treatment: Other prescription product w/o estrogen |
| Q5\_8 | Other (specify) | Q5\_8 Typical treatment: Other |

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | Selected |
| 0 | Not selected |

For the next few questions, we would like you to consider your patients who are postmenopausal women with vulvar and vaginal atrophy and are complaining of symptoms such as vaginal itching and discomfort or pain during intercourse. They have previously tried over-the-counter ointments with little success.

**// PROGRAMMING NOTE: [SHOW SCENARIO AT THE TOP OF THE SCREEN FOR QUESTION 6]//**

**Question Type:** Single Punch

**Question Q6**

Variable Name: *Q6*

Variable Label: Q6 Likelihood of discussing inserts

**Question Text:** How likely are you to discuss vaginal inserts, such as Vagifem or Imvexxy, as a potential option for these patients?

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | Very unlikely |
| 2 | Unlikely |
| 3 | Somewhat likely |
| 4 | Likely |
| 5 | Very likely |
| -99 | Refused |

**Question Type:** Single Punch

**Question Q7**

Variable Name: *Q7*

Variable Label: Q7 Risk assessment of vaginal inserts

**Question Text**: Which of the following statements describe your assessment of the safety of vaginal inserts used to treat vulvar and vaginal atrophy?

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | Risks are minimal for almost all patients |
| 2 | Risks are minimal for most patients, but are significant for some patients |
| 3 | Risks are significant for most patients |
| 4 | I am not familiar enough with vaginal inserts to make an assessment |
| -99 | Refused |

**Question Type:** Single Punch

**Question Q8A**

Variable Name: *Q8A*

Variable Label:Q8AAssessment of inserts vs. oral estrogen

**Question Text:** Which statement best describes your assessment of the safety of vaginal inserts compared to oral estrogen products?

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | Vaginal inserts are safer than oral estrogen products |
| 2 | Vaginal inserts are less safe than oral estrogen products |
| 3 | Vaginal inserts are no more and no less safe than oral estrogen products |
| 4 | The safety of vaginal inserts versus oral estrogen products has not been established  |
| 5 | I am not familiar enough with vaginal inserts to make an assessment |
| -99 | Refused |

**Question Type:** Single Punch

**Question Q8B**

Variable Name: *Q8B*

Variable Label: Q8B Assessment of inserts vs. transdermal estrogen

**Question Text:** Which statement best describes your assessment of the safety of vaginal inserts compared to transdermal estrogen products?

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | Vaginal inserts are safer than transdermal estrogen products |
| 2 | Vaginal inserts are less safe than transdermal estrogen products |
| 3 | Vaginal inserts are no more and no less safe than transdermal estrogen products |
| 4 | The safety of vaginal inserts versus transdermal estrogen products has not been established  |
| 5 | I am not familiar enough with vaginal inserts to make an assessment |
| -99 | Refused |

**Question Type:** Single Punch

**Question Q8C**

Variable Name: *Q8C*

Variable Label: Q8C Benefits/risks of inserts

**Question Text:** Which statement best describes your general perspective on the benefits versus risks of vaginal inserts for patients with vulvar and vaginal atrophy.

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | The benefits of vaginal inserts outweigh the risks for most patients |
| 2 | The benefits of vaginal inserts outweigh the risks for some, but not most, patients |
| 3 | The benefits of vaginal inserts outweigh the risks for very few patients |
| 4 | I am not familiar enough with vaginal inserts to make an assessment |
| -99 | Refused |

**Question Type:** Multi-Punch

**Question Q9**

Variable Name: *Q9*

Variable Label: Q9 Factors most important when choosing to prescribe vaginal inserts

**Question Text:** Which of the following factors play the most important role when deciding whether or not to prescribe vaginal inserts to a patient with vulvar and vaginal atrophy? Please choose the three factors that you consider to be most important.

**//PROGRAMMING NOTE: ALLOW PARTICIPANTS TO SELECT UP TO THREE ANSWERS//**

**[RANDOM ORDER EXCEPT FOR OTHER] [//Multi-punch//]**

|  |  |  |
| --- | --- | --- |
| **Variable Name** | **Variable Text** | **Variable Label** |
| Q9\_1 | Considerations of this patient’s ability to use the product as prescribed  | Q9\_1 Factor: Patient ability to use  |
| Q9\_2 | This patient’s understanding of and comfort with the risks of this medication | Q9\_2 Factor: Understanding and comfort with risks |
| Q9\_3 | This patient’s previous experience with treatments (over-the-counter and prescription) | Q9\_3 Factor: Patient’s previous experience |
| Q9\_4 | This patient’s medical and health context (e.g., medical history, comorbidities, family history) | Q9\_4 Factor: Medical and health context |
| Q9\_5 | Considerations of this patient’s access to the product (e.g., cost, insurance) | Q9\_5 Factor: Patient access |
| Q9\_6 | Extent, duration, and severity of this patient’s symptoms | Q9\_6 Factor: Symptoms |
| Q9\_7 | Patient’s preference for a mode of administration | Q9\_7 Factor: Patient preference for administration  |
| Q9\_8 | Potential duration of treatment use/course | Q9\_8 Factor: Duration |
| Q9\_9 | Other (please specify) | Q9\_9 Factor: Other |

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | Selected |
| 0 | Not selected |

**Question Type:** Multi-Punch

**Question Q10**

Variable Name: *Q10*

Variable Label: Q10 Top three questions from patients about using vaginal inserts

**Question Text**: What are the top three comments or questions you have you heard from patients about using vaginal inserts to treat vulvar and vaginal atrophy? (Select up to three.)

**//PROGRAMMING NOTE: ALLOW PARTICIPANTS TO SELECT UP TO THREE ANSWERS//**

 **[//Multi-punch//]**

|  |  |  |
| --- | --- | --- |
| **Variable Name** | **Variable Text** | **Variable Label** |
| Q10\_1 | Pros about vaginal inserts’ application method  | Q10\_1 Pros application method |
| Q10\_2 | Hearing positive things about how well vaginal inserts work | Q10\_2 Heard positive things |
| Q10\_3 | Whether vaginal inserts may be safer than other estrogen treatments | Q10\_3 Inserts safer than other estrogen |
| Q10\_4 | A desire to try something new | Q10\_4 Try something new |
| Q10\_5 | Cons about vaginal inserts’ application method  | Q10\_5 Cons application method |
| Q10\_6 | Concerns about insurance coverage or cost | Q10\_6 Insurance coverage/cost |
| Q10\_7 | Hearing negative things about how well vaginal inserts work  | Q10\_7 Hearing negative things |
| Q10\_8 | Concerns about using an estrogen treatment | Q10\_8 General concerns re: estrogen |
| Q10\_9 | Other (specify) | Q10\_9 Other |

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | Selected |
| 0 | Not selected |

**Question Type:** Multi-Punch

**Question Q11**

Variable Name: *Q11*

Variable Label: Q11Top three topics talk to patients about vaginal inserts

**Question Text**: What are the top three topics that you prioritize when talking to your patients about vaginal inserts as a treatment option?

**//PROGRAMMING NOTE: ALLOW PARTICIPANT TO SELECT UP TO THREE ANSWERS//**

**[RANDOM ORDER EXCEPT FOR LAST OPTION] [//Multi-punch//]**

|  |  |  |
| --- | --- | --- |
| **Variable Name** | **Variable Text** | **Variable Label** |
| Q11\_1 | How the product works | Q11\_1 Talking top 3: How product works |
| Q11\_2 | Expected benefits of the product | Q11\_2 Talking top 3: Expected benefits |
| Q11\_3 | Common side effects of the product | Q11\_3 Talking top 3: Common side effects |
| Q11\_4 | Rare but serious side effects of the product | Q11\_4 Talking top 3: Rare serious effects |
| Q11\_5 | Patient’s medical history (e.g., personal history or family history, possible co-morbidities)  | Q11\_5 Talking top 3: Medical history |
| Q11\_6 | The importance of using the product as directed | Q11\_6 Talking top 3: Importance of use as directed |
| Q11\_7 | Other (Specify) | Q11\_7 Talking top 3: Other |

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | Selected |
| 0 | Not selected |

**//PROGRAMMING NOTE: If Q11D selected, display Q11\_RISKS. OTHERWISE, PROCEED TO Q12 //**

**Question Type:** Open End Essay

**Question 11\_RISKS**

Variable Name: *Q11\_RISKS*

Variable Label:Q11\_RISKS Side effects discussed

**Question Text:** You said that you discuss rare but serious side effects of the product. What potential side effects do you discuss?

**Question Type:** Multi-Punch

**Question Q12**

Variable Name: *Q12*

Variable Label: Q12 How monitor for safety risks and side effects after prescribing vaginal inserts

**Question Text:** How do you most commonly monitor your patients for potential safety risks and side effects after prescribing vaginal inserts for vulvar and vaginal atrophy? Select all that apply.

|  |  |  |
| --- | --- | --- |
| **Variable Name** | **Value** | **Variable Label** |
| Q12\_1 | I schedule routine follow-up appointments with patients. | Q12\_1 Monitor: Follow-up appointment |
| Q12\_2 | I instruct patients to get bloodwork before follow-up appointment. | Q12\_2: Monitor: Bloodwork |
| Q12\_3 | I instruct patients to call and schedule an appointment if they experience side effects. | Q12\_3 Monitor: Appointment if side effects |
| Q12\_4 | I leave it to the patient to follow up if they feel a need to. | Q12\_4 Monitor: Leave up to patient |
| Q12\_5 | A follow-up appointment is not necessary. | Q12\_5 Monitor: Follow-up not necessary |
| Q12\_6 | Other (specify) | Q12\_6 Monitor: Other |

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | Selected |
| 0 | Not selected |

**Question Type:** Grid

**Question Q13**

Variable Name: *Q13*

Variable Label: Q13 How often look for information on vaginal inserts

**Question Text:** How often do you look for information about vaginal inserts or other products from the following sources:

**[RANDOM ORDER]**

|  |  |  |
| --- | --- | --- |
| **Variable Name** | **Variable Text** | **Variable Label** |
| Q13\_ 1 | Medical journals  | Q13\_1 Info: Medical journals |
| Q13\_2 | Medical websites or software (e.g. UpToDate, Epocrates, Medscape) | Q13\_2 Info: Medical websites or software |
| Q13\_3 | Drug company/pharmaceutical representatives or their website | Q13\_3 Info: Drug company rep or website |
| Q13\_4 | Go online/use a search engine (e.g., Google) | Q13\_4 Info: Online search |
| Q13\_5 | Professional medical societies (e.g., publications, guidelines) | Q13\_5 Info: Professional medical societies |
| Q13\_6 | Conferences | Q13\_6 Info: Conferences |
| Q13\_7 | Discussion with colleagues (e.g., in person, email) | Q13\_7 Info: Discussion w/ colleagues |
| Q13\_8 | FDA website or other FDA sources of information (e.g., email, alerts)  | Q13\_8 Info: FDA  |
| Q13\_9 | Other government agencies (e.g., NIH, CDC) | Q13\_9 Info: Other government agencies |

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | Never |
| 2 | Rarely |
| 3 | Sometimes |
| 4 | Often |

**//[SHOW QUESTION AT THE TOP OF THE SCREEN FOR QUESTION 14]//**

The next question refers to boxed warnings, commonly referred to as black box warnings, on the product labeling for Vagifem, a vaginal tablet, and other estrogen products.

**Question Type**: Multi-Punch

**Question Q14**

Variable Name: *Q14*

Variable Label: Q14 Primary role of boxed warning

**Question Text:** In your opinion, what is the primary role of a boxed warning? *Choose up to three options.*

**//Random Order, except last three**

**//PROGRAMMING NOTE: ALLOW PARTICIPANT TO UP TO SELECT THREE ANSWERS//**

|  |  |  |
| --- | --- | --- |
| **Variable Name** | **Variable Text** | **Variable Label** |
| Q14\_1 | To highlight if the product has risk of serious or life-threatening adverse effects | Q14\_1 BW Primary Role: Highlight most serious risks |
| Q14\_2 | To provide information that should be factored into a decision to prescribe the product  | Q14\_2 BW Primary Role: Provide prescribing information |
| Q14\_3 | To provide an overview of the safety profile of the product | Q14\_3 BW Primary Role: Provide safety profile overview |
| Q14\_4 | To disclose clinical trial and other product safety testing information | Q14\_4 BW Primary Role: Clinical trial and safety testing |
| Q14\_5 | To provide information that prescribers should be communicating to patients | Q14\_5 BW Primary Role: Info to communicate to patients |
| Q14\_6 | To provide information on how to safely use the product | Q14\_6 BW Primary Role: Info on how to safely use product |
| Q14\_7 | I do not see a role for them | Q14\_7 BW Primary Role: No role for BW |
| Q14\_8 | Other (specify) | Q14\_8 BW Primary Role: Other |
| Q14\_9 | Unsure/Don’t know | Q14\_9 BW Primary Role: Unsure/Don’t know |

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | Included |
| 0 | Not included |

**//PROGRAMMING NOTE: SHOW PARAGRAPH ON ITS OWN PAGE//**

The next set of questions will ask you more specifically about the boxed warning and prescribing information for Vagifem to treat vulvar and vaginal atrophy. This boxed warning appears on all prescription estrogen products.

**//PROGRAMMING NOTE: “NEXT” BUTTON TO PROCEED TO Q15//**

**Question Type**: Single Punch

**Question Q15**

Variable Name: *Q15*

Variable Label:Q15 Familiarity with BW for Vagifem and other estrogen products

**Question Text**: How would you rate your familiarity with the boxed warning information for Vagifem and other estrogen products?

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | Not at all familiar |
| 2 | Slightly familiar |
| 3 | Somewhat familiar |
| 4 | Familiar |
| 5 | Very familiar |
| -99 | Refused |

**Question Type**: Single Select Grid

**Question Q16**

Variable Name: *Q16*

Variable Label: Q16Risks recalled from vaginal insert boxed warning

**Question Text:** Which of the following risks do you recall being included in the boxed warning for vaginal inserts? Please indicate a response for each risk.

**[RANDOM ORDER EXCEPT FOR LAST OPTION]**

|  |  |  |
| --- | --- | --- |
| **Variable Name** | **Variable Text** | **Variable Label** |
| Q16\_1 | Endometrial cancer | Q16\_1 Risks: Endometrial cancer |
| Q16\_2 | Endometrial hyperplasia | Q16\_2 Risks: Endometrial hyperplasia |
| Q16\_3 | Dementia | Q16\_3 Risks: Dementia |
| Q16\_4 | Stroke | Q16\_4 Risks: Stroke |
| Q16\_5 | Deep vein thrombosis (DVT) | Q16\_5 Risks: Deep vein thrombosis |
| Q16\_6 | Breast cancer | Q16\_6 Risks: Breast cancer |
| Q16\_7 | Gallbladder disease | Q16\_7 Risks: Gallbladder disease |
| Q16\_8 | Hypercalcemia | Q16\_8 Risks: Hypercalcemia |
| Q16\_9 | Visual abnormalities | Q16\_9 Risks: Visual abnormalities |
| Q16\_10 | Elevated blood pressure | Q16\_10 Risks: Elevated blood pressure |
| Q16\_11 |  Other (specify) | Q16\_12 Risks: Other |

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | Included |
| 2 | Not included |
| 98 | Don’t know |

**//PROGRAMMING NOTE: SHOW PARAGRAPH ON ITS OWN PAGE, THEN CLICK NEXT TO VIEW BOXED WARNING//**

We would like to show you some of the boxed warning information for Vagifem, which is available in the FDA-approved prescribing information. This boxed warning information appears on the labeling for all estrogen products. Please take a few moments to review this information.

**//PROGRAMMING NOTE: SHOW THE BOXED WARNING ON ITS OWN PAGE****, CAPTURE TIME SPENT ON BOXED WARNING//**

[View boxed warning information][[1]](#footnote-2)





**//PROGRAMMING NOTE: HAVE A “NEXT” BUTTON AT THE BOTTOM OF THE BOXED WARNING PAGE TO PROCEED TO QUESTION 17//**

**Question Type:** Single Punch

**Question Q17**

Variable Name: *Q17*

Variable Label:Q17 Usefulness of BW for Vagifem

**Question Text:** How useful is the information in the boxed warning for Vagifem?

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | Not at all useful |
| 2 | Slightly useful |
| 3 | Somewhat useful |
| 4 | Useful |
| 5 | Very useful |
| -99 | Refused |

**Question Type:** Single Punch

**Question Q18**

Variable Name: *Q18*

Variable Label:Q18 Assessment of risk framing in Vagifem BW

**Question Text:** What is your assessment of the way the risks of Vagifem are framed in the boxed warning?

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | Strongly understates risk  |
| 2 | Somewhat understates risk |
| 3 | Provides appropriate assessment of risk |
| 4 | Somewhat overstates risk |
| 5 | Strongly overstates risk |
| 6 | Other (specify) |
| -99 | Refused |

**Question Type:** Single Punch

**Question Q19**

Variable Name: *Q19*

Variable Label:Q19 Assessment of benefits versus risks Post-BW

**Question Text:** Which statement best reflects your opinion on the relative benefits versus risks of vaginal inserts for patients with vulvar and vaginal atrophy.

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | The benefits of vaginal inserts outweigh the risks for most patients |
| 2 | The benefits of vaginal inserts outweigh the risks for some, but not most, patients |
| 3 | The benefits of vaginal inserts outweigh the risks for very few patients |
| 4 | I am not familiar enough with vaginal inserts to make an assessment |
| -99 | Refused |

**Question Type:** Multi-Punch

**Question Q20**

Variable Name: *Q20*

Variable Label: Q20 How improve Vagifem boxed warning

**Question Text:** What would improve the boxed warning for Vagifem, in your opinion? (Select all that apply.)

|  |  |  |
| --- | --- | --- |
| **Variable Name** | **Variable Text** | **Variable Label** |
| Q20\_1 | Nothing, the warning is fine the way it is  | Q20\_1 Improve BW: Nothing |
| Q20\_2 | Better evidence to support risk information | Q20\_2 Improve BW: Better risk info evidence |
| Q20\_3 | Decrease the amount of information given/fewer words | Q20\_3 Improve BW: Decrease amount of info/shorten |
| Q20\_4 | Simpler language | Q20\_4 Improve BW: Simpler language |
| Q20\_5 | Formatting improvements (e.g., use of boldface) | Q20\_5 Improve BW: Formatting |
| Q20\_6 | Increase the amount of information (e.g., statistics, more details) | Q20\_6 Improve BW: Increase amount of info |
| Q20\_7 | Other (Specify) | Q20\_7 Improve BW: Other (specify) |
| Q20\_8 | Make exclusive | Q20\_8 Improve BW: Unsure/Don’t know |

//Q20\_8: Make exclusive//

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | Included |
| 0 | Not included |

**Question Type:** Open-End Essay

**Question Q21**

Variable Name: *Q21*

Variable Label:Q21 Specific feedback on Vagifem BW information

**Question Text:** Please provide any specific feedback on the boxed warning information for Vagifem.

**//PROGRAMMING NOTE: SHOW SENTENCE ON ITS OWN PAGE, THEN CLICK NEXT TO VIEW Q22//**

Please now consider boxed warnings in general, not only the one you saw for Vagifem.

**Question Type:** Grid

**Question Q22**

Variable Name: *Q22*

Variable Label: Q22 Degree agree or disagree with BW statements

**Question Text:** To what degree do you agree or disagree with the following statements about boxed warnings in general (in other words, across all classes of prescription drugs)?

**[RANDOM ORDER for 1-6]**

|  |  |  |
| --- | --- | --- |
| **Variable Name** | **Variable Text** | **Variable Label** |
| Q22\_1 | Boxed warnings are very common on the products that I prescribe  | Q22\_1 Agree/Disagree: BW are very common on products I prescribe |
| Q22\_2 | Boxed warnings do not generally factor heavily into my decisions on whether to prescribe a product | Q22\_2 Agree/Disagree: BW do not generally factor heavily  |
| Q22\_3 | I think carefully before prescribing a product with a boxed warning if other treatments are available | Q22\_3 Agree/Disagree: I think carefully before prescribing BW product if others available |
| Q22\_4 | I counsel my patients differently when prescribing a product with a boxed warning | Q22\_4 Agree/Disagree: Counsel patients differently with BW |
| Q22\_5 | My patients rarely know whether a product would have a boxed warning or not | Q22\_5 Agree/Disagree: Patients rarely know if product has BW |
| Q22\_6 | My patients are worried or scared when they see boxed warnings | Q22\_6 Agree/Disagree: Patients worried/scared when they see BW |

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | Strongly disagree |
| 2 | Disagree |
| 3 | Neither agree nor disagree |
| 4 | Agree |
| 5 | Strongly agree |
| 98 | Unsure/Don’t know |

**Question Type:** Single Punch

**Question Q23**

Variable Name: *Q23*

Variable Label: Q23 General favorability of BW

**Question Text:** How favorable is your opinion of boxed warnings *in general* (across all classes of prescription drugs)?

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | Very unfavorable |
| 2 | Somewhat unfavorable |
| 3 | Neither unfavorable nor favorable |
| 4 | Somewhat favorable |
| 5 | Very favorable |
| 98 | Unsure/Don’t know |
| -99 | Refused |

**Question Type**: Open End Essay

**Question Q24**

Variable Name: *Q24*

Variable Label: Q24 Suggestions for better using BW to highlight safety info

**Question Text:** In general, what suggestions do you have on how to better use boxed warnings as a tool to highlight important safety information?

**//PRETEST ONLY//**

**//DISPLAY TEXT//**

**We would like your feedback on the survey that you completed. This will help FDA improve the survey for future use with healthcare providers.**

**Question Type**: Single Punch

**Question P1**

Variable Name: *P1*

Variable Label: P1 One session completion

**Question Text:** Were you able to complete the survey in one session?

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | Yes |
| 0 | No |

**Question Type**: Single Punch

**Question P2**

Variable Name: *P2*

Variable Label: P2 Participant Experience with Survey

**Question Text:** How would you rate your experience taking the survey?

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | Poor |
| 2 | Fair |
| 3 | Good |
| 4 | Very good |
| 5 | Excellent |
| -99 | Refused |

**Question Type**: Open End Essay

**Question P3**

Variable Name: *P3*

Variable Label: P3 Difficulty answering question

**Question Text:** Were there any questions you had difficulty answering? If yes, please explain.

**Question Type**: Open End Essay

**Question P4**

Variable Name: *P4*

**Variable Label:** P4 Other feedback

Question Text: What other suggestions of feedback about this survey would you like to share?

**//DISPLAY FOR BOTH PRETEST AND MAIN STUDY//**

Thank you for taking this survey. Your time is greatly appreciated.

1. NIH NLM (2019). LABEL: VAGIFEM- estradiol insert. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e5ad3cf6-dd96-4e64-af21-c1eee38d0b88> [↑](#footnote-ref-2)