Prescriber Survey to Assess Boxed Warnings Perceptions

Survey Questionnaire: HCV

(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 chronic hepatitis C viral infection, also known as chronic HCV.

**// *Note*: Where [drug] is indicated, respondents in the chronic HCV condition will be randomly assigned to see Harvoni, Mavyret, or Zepatier.//**

**//HIDDEN FROM PARTICIPANTS, will be used for piping only//**

**//Assign each HCV participant to one drug randomly, balancing the number assigned to each//**

**Question Type: Single Punch**

**Question DAA\_Drug**

Variable Name: *DAA\_Drug*

Variable Label**:** DAA Drug Assignment

**Question Text:** Random DAA Drug Assignment

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | Harvoni |
| 2 | Mavyret |
| 3 | Zepatier |

**//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 HCV

**Question Text:** How experienced are you with treating chronic HCV?

|  |  |
| --- | --- |
| **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 Q2**

Variable Name: *Q2*

Variable Label: Q2 Number of patients typically seen

**Question Text:** How many patients do you typically see for treatment of chronic HCV?

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | One or 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 3**

Variable Name: *Q3*

Variable Label: Q3 Importance of curing HCV

**Question Text:** In general, how important is treating chronic HCV with the goal of a curing it?

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

**Question Type:** Single Punch

**Question Q4A**

Variable Name: *Q4A*

Variable Label: Q4A Experience prescribing DAA

**Question Text:** Which of the following is true of your prescribing direct-acting antivirals (DAA) for the treatment of chronic HCV?

|  |  |
| --- | --- |
| **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 |

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

**Question Type:** Single Punch

**Question Q4B**

Variable Name: *Q4B*

Variable Label: Q4B Frequency of prescribing DAA

**Question Text:** On average, how often do you prescribe direct-acting antivirals (DAA) for treatment of chronic HCV?

|  |  |
| --- | --- |
| **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 treatments would you recommend or prescribe in a typical month (Select all that apply)?

|  |  |  |
| --- | --- | --- |
| **Variable Name** | **Value Text** | **Variable Label** |
| Q5\_1 | Direct-acting antivirals (e.g., Harvoni, Epclusa, Mavyret, Vosevi, Zepatier)  | Q5\_1 Typical treatment: DAA |
| Q5\_2 | Multi-pill regimen(s) (e.g., PEG/Riba therapy) | Q5\_2 Typical treatment: Multi pills  |
| Q5\_3 | Interferon | Q5\_3 Typical treatment: Interferon |
| Q5\_4 | Ribavirin | Q5\_4 Typical treatment: Ribavirin |
| Q5\_5 | Other (specify) | Q5\_5 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 have been newly diagnosed with chronic HCV or are exhibiting early signs and symptoms of chronic HCV (such as fatigue and mild elevations in liver enzymes).

For this section, also consider the whole class of fixed-dose combination drugs/direct-acting antivirals.

**//[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 DAA

**Question Text:** How likely are you to discuss direct-acting antivirals 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 DAA

**Question Text:** Which of the following statements describe your assessment of the safety of direct-acting antivirals used to treat HCV?

|  |  |
| --- | --- |
| **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 direct-acting antivirals to make an assessment |
| -99 | Refused |

**Question Type:** Single Punch

**Question Q8**

Variable Name: *Q8*

Variable Label: Q8 Benefits/risks of DAA

**Question Text**: Which statement best describes your general perspective on the benefits versus risks of direct-acting antivirals for patients with chronic HCV?

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

**Question Type:** Multi-Punch

**Question Q9**

Variable Name: *Q9*

Variable Label: Q9Factors most important when choosing to prescribe DAA

**Question Text:** Which of the following factors play the most important role when deciding whether or not to prescribe direct-acting antivirals to a patient with chronic HCV? 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 take the product as prescribed | Q9\_1 Factors: Patient ability to use |
| Q9\_2 | This patient’s understanding and comfort with the risks of this medication | Q9\_2 Factors: Understanding and comfort with risks |
| Q9\_3 | This patient’s previous experience with treatments | Q9\_3 Factors: Patient’s previous experience |
| Q9\_4 | This patient’s medical and health context (e.g., medical history, comorbidities) | Q9\_4 Factors: Medical and health context |
| Q9\_5 | Considerations of this patient’s access to the product (e.g., cost, insurance) | Q9\_5 Factors: Patient access |
| Q9\_6 | Extent, duration, and severity of patient’s symptoms | Q9\_6 Factors: Symptoms |
| Q9\_7 | Patient’s preference for a mode of administration | Q9\_7 Factors: Patient preference for administration |
| Q9\_8 | Potential duration of treatment use/course | Q9\_8 Factors: Duration |
| Q9\_9 | Other (please specify) | Q9\_9 Factors: Other |

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

**Question Type:** Open End Essay

**Question Q9\_ACTIONS**

Variable Name: *Q9\_ACTIONS*

Variable Label:Q9\_ACTIONS Screening Actions before Starting Treatment

**Question Text:** What screening actions, if any, would you take before starting treatment with a direct-acting antiviral for a patient with chronic HCV?

**Question Type:** Multi-Punch

**Question Q10**

Variable Name: *Q10*

Variable Label: Q10 Top three questions from patients about using DAA

**Question Text:** What are the top three comments or questions you have heard from patients about using direct-acting antivirals to treat chronic HCV? (Select up to three.)

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

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

|  |  |  |
| --- | --- | --- |
| **Variable Name** | **Variable Text** | **Variable Label** |
| Q10\_1 | Concerns about undergoing treatment if the patient is currently asymptomatic | Q10\_1 Comments top 3: Undergoing treatment if asymptomatic |
| Q10\_2 | Hearing positive things about how well direct-acting antivirals work | Q10\_2 Comments top 3: Hearing positive things |
| Q10\_3 | Concerns about specific side effects | Q10\_3 Comments top 3: Side effects |
| Q10\_4 | Concerns about insurance coverage or cost | Q10\_4 Comments top 3: Insurance coverage/cost |
| Q10\_5 | Hearing negative things about how well direct-acting antivirals work | Q10\_5 Comments top 3: Hearing negative things |
| Q10\_6 | Pros about the mode of administration | Q10\_6 Comments top 3: Pros mode of administration |
| Q10\_7 | Cons about the mode of administration | Q10\_7 Comments top 3: Cons mode of administration |
| Q10\_8 | Concerns about being able to complete treatment course | Q10\_8 Comments top 3: General concerns re: treatment |
| Q10\_9 | Other (specify) | Q10\_9 Comments top 3: Other |

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

**Question Type:** Multi-Punch

**Question Q11**

Variable Name: *Q11*

Variable Label: Q11 Top three topics talk to patients about DAA

**Question Text:** What are the top three topics that you prioritize when talking to your patients about direct-acting antivirals 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 Q11\_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 DAA

**Question Text:** How do you most commonly monitor your patients for potential safety risks and side effects after prescribing direct-acting antivirals for HCV? Select all that apply.

|  |  |  |
| --- | --- | --- |
| **Variable Name** | **Variable Text** | **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 DAA

**Question Text:** How often do you look for information about direct-acting antivirals 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 direct-acting antivirals.

**Question Type:** Multi-Punch

**Question 14**

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 the prescribing information for direct-acting antivirals to treat chronic HCV. This boxed warning appears on all prescription direct-acting antiviral 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 DAA

**Question Text:** How would you rate your familiarity with the boxed warning for direct-acting antivirals?

|  |  |
| --- | --- |
| **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: Q16 Risks recalled from DAA boxed warning

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

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

|  |  |  |
| --- | --- | --- |
| **Variable Name** | **Variable Text** | **Variable Label** |
| Q16\_1 | Hepatitis B reactivation in coinfected patients | Q16\_1 Risks: Hepatitis B |
| Q16\_2 | Bradycardia | Q16\_2 Risks: Bradycardia |
| Q16\_3 | Interaction with beta blockers | Q16\_3 Risks: Interaction with beta blockers |
| Q16\_4 | Asthenia | Q16\_4 Risks: Asthenia |
| Q16\_5 | Visual abnormalities | Q16\_5 Risks: Visual abnormalities |
| Q16\_6 | Elevated blood pressure | Q16\_6 Risks: Elevated blood pressure  |
| Q16\_7 | Stroke | Q16\_7 Risks: Stroke |
| Q16\_8 | Other (specify) | Q16\_9 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 [DAA drug], which is available in the FDA-approved prescribing information. The boxed warning information appears on the labeling for all direct-acting antivirals. Please consider [DAA drug] to serve as an example that represents the direct-acting antiviral drug class as a whole. 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)[[2]](#footnote-3)[[3]](#footnote-4)

**//DISPLAY IF DAA\_DRUG = Harvoni//**

**//DISPLAY IF DAA\_DRUG = Mavyret//**

**//DISPLAY IF DAA\_DRUG = Zepatier//**

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

**Question Type:** Single Punch

**Question 17**

Variable Name: *Q17*

Variable Label:Q17 Usefulness of BW for DAA

**Question Text:** How useful is the information in the boxed warning for [DAA drug]?

|  |  |
| --- | --- |
| **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 DAA BW

**Question Text:** What is your assessment of the way the risks of [DAA drug] are framed in the boxed warning?

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | Strongly understates risk  |
| 2 | Somewhat understates risk |
| 3 | Provides appropriate assessment of risk information |
| 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 direct-acting antivirals for patients with chronic HCV?

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

//[SHOW SCENARIO AT THE TOP OF THE SCREEN FOR QUESTION 19\_HBV]//

Imagine this scenario when answering the following question:

In prescreening, you determine that your patient with HCV has previously received treatment for an HBV infection. The patient tests positive for HBV antibodies, but has no signs of currently active infection.

**Question Type:** Single Punch

**Question Q19\_HBV**

Variable Name: *Q19\_HBV*

Variable Label: Q19\_HBV Treating patient using DAA

**Question Text:** Which of the following best describes your course of action for treating this patient?

|  |  |
| --- | --- |
| **Value** | **Value Label** |
| 1 | I would not prescribe [DAA drug] to this patient |
| 2 | I might still prescribe [DAA drug] to this patient, but would consider other options first |
| 3 | I would prescribe [DAA drug] to this patient but monitor her more carefully than other patients |
| 4 | I would refer this patient to someone else for treatment |
| 5 | Other (specify) |
| 98 | Unsure/Don’t know |
| -99 | Refused |

[PIPE ALL RESPONSES TO Q19\_HBV\_OTH]

**Question Type: Open End Essay**

**Question Q19\_HBV\_OE**

Variable Name: *Q19\_HBV\_OE*

Variable Label: Q19\_HBV\_OE Reason for treatment option

**Question Text**: You said you would take the following course of action for treating this patient:

PIPE SELECTED RESPONSE FROM Q19\_HBV]

//BOLD PIPED SELECTED RESPONSE//

Please briefly elaborate on the reason(s) for your response.

[SOFT PROMPT]

**Question Type:** Multi-Punch

**Question 20**

Variable Name: *Q20*

Variable Label: Q20 How improve DAA boxed warning

**Question Text:** What would improve the boxed warning for [DAA drug] 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 | Unsure/Don’t know | 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 DAA BW information

**Question Text:** Please provide any specific feedback on the boxed warning information for [DAA drug].

//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 [DAA drug].

**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 23**

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: HARVONI- ledipasvir and sofosbuvir tablet, film coated. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f4ec77e4-bae8-4db0-b3d5-bde09c5fa075> [↑](#footnote-ref-2)
2. NIH NLM (2020). LABEL: MAVYRET- glecaprevir and pibrentasvir tablet, film coated. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7bf99777-0401-9095-8645-16c6e907fcc0> [↑](#footnote-ref-3)
3. NIH NLM (2018). LABEL: ZEPATIER- elbasvir and grazoprevir tablet, film coated. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=164dc02a-9180-426a-b8b5-04ab39d2bbd4> [↑](#footnote-ref-4)