**Department of Health and Human Services (HHS)/ Food and Drug Administration (FDA) Biosimilars Survey**

**SURVEY QUESTIONS**

**SECTION I: Current prescribing practice**

**PROGRAMMER NOTE: For Q2 – Q4, please display blue text in blue on screen.**

Q1. In your practice, how do you most often prescribe medicines that are not controlled substances? [Single punch]

|  |  |
| --- | --- |
| Value | Label |
| 01 | Written prescriptions or orders |
| 02 | Electronic prescriptions or orders |
| 03 | Preprinted forms, prescriptions or orders |
| 04 | Verbal prescriptions or orders |
| -99 | Refused |

Q2. In your practice, what terminology do you most often use in prescribing medicine for your patients? [Single punch]

|  |  |
| --- | --- |
| Value | Label |
| 01 | The brand name of the product (e.g., Zofran) |
| 02 | The nonproprietary name of the product (e.g., ondansetron ) |
| 03 | The brand name together with the nonproprietary name (e.g., Zofran (ondansetron) |
| 04 | The nonproprietary name along with the name of the drug maker (e.g., ondansetron by Novartis) |
| 05 | Other (specify) |
| -99 | Refused |

Q3. In your practice, how do you most often identify the medicines you are prescribing to patients? [Single punch]

|  |  |
| --- | --- |
| Value | Label |
| 01 | The brand name of the product (e.g., I am treating you with Zofran) |
| 02 | The nonproprietary (generic) name of the product (e.g., I am treating you with ondansetron) |
| 03 | The brand name of the reference product regardless of whether a generic drug is prescribed (e.g., I am treating you with a generic version of Zofran) |
| 04 | The brand name together with the nonproprietary name (e.g., I am treating you with Zofran, also known as ondansetron) |
| 05 | The nonproprietary name along with the name of the drug maker (e.g., I am treating you with ondansetron by Novartis) |
| 06 | Terms related to the mechanism of action or indication of use (e.g., I am treating you with a medicine that helps prevent nausea) |
| -99 | Refused |

Q4. In your experience how do **patients**most oftenrefer to the medicines they are taking? [Single punch]

|  |  |
| --- | --- |
| Value | Label |
| 01 | The brand name of the medicine (e.g., I need a refill for Zofran) |
| 02 | The nonproprietary (generic) name of the medicine (e.g., I need a refill for ondansetron) |
| 03 | The brand name and nonproprietary name together (e.g., I need a refill for Zofran, or ondansetron) |
| 04 | The nonproprietary name along with the name of the drug maker (e.g., I need a refill for Novartis’ ondansetron) |
| 05 | Terms related to the mechanism of action or indication of use (e.g., I need a refill for my medicine for nausea) |
| 06 | **Terms related to the physical characteristics of the medication or packaging (**e.g., I need a refill for my blue and yellow pills) |
| -99 | Refused |

Q5. For **biological medicines**, please indicate how **biological medicines** are obtained and administered to your patients. Please choose all that apply. [Multi punch]

|  |  |
| --- | --- |
| Value | Label |
| 01 | I prescribe the biological medicine to patients; they pick the medicine up from a specialty pharmacy and return to a clinic for the medicine to be administered. |
| 02 | I prescribe the biological medicine to patients; they pick the medicine up from a specialty pharmacy, and administer the medicine at home. |
| 03 | I (or my staff) order biological medicines into my clinic and then administer to the patients during clinic visits. |
| 04 | I prescribe the biological medicine to patients; they pick the medicine up from a pharmacy and return to a clinic for the initial doses of the medicine to be administered. Patients may administer subsequent doses at home. |
| 05 | I prescribe the biological medicine to patients; they obtain and administer the biological medicines through other means. |
| 06 | I prescribe the biological medicine to patients; a specialty pharmacy sends it to an infusion center to be administered to patients. |
| -99 | Refused |

Q6. If you (or your staff) procure, store, and administer biological medicines in your clinic or office, how do you generally procure the biological medicines? Please choose all that apply. [Multi punch]

|  |  |
| --- | --- |
| Value | Label |
| 01 | For individual patients as the need arises |
| 02 | In bulk, to have ready for patients who are likely to present with a need for these medicines |
| 03 | A combination of bulk ordering and individual-specific ordering depending on the medicine |
| 04 | Not applicable to my practice |
| -99 | Refused |

Q7. If you (or your staff) procure, store, and administer medicines in your clinic or office, how do you order specific biological medicines for use in your clinic? Please choose all that apply. [Multi punch]

|  |  |
| --- | --- |
| Value | Label |
| 01 | National Drug Code (NDC) |
| 02 | Brand name |
| 03 | Nonproprietary name |
| 04 | Other (please specify) |
| 05 | Not sure |
| 06 | Not applicable to my practice |
| -99 | Refused |

**SECTION II: Impressions of biosimilar naming: unaided and aided questions**

**PROGRAMMER NOTE: For Q8 – Q15, pipe in appropriate information based on provider specialty. Note that the nonproprietary names should appear in parentheses after the brand names. Half of the respondents within each specialty will be randomized to receive the survey with the nonproprietary name for Junexant piped from A1 and other half the nonproprietary name for Junexant will be piped from A2.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Specialty** | **A1**  **Junexant**  **(with suffix)** | | **A2**  **Junexant**  **(without suffix)** | **B**  **Nexsymeo** | **C**  **Indication** |
| Rheumatology | | denliximab-ghvb | denliximab | denliximab-kbcn | rheumatoid arthritis |
| Dermatology | | denliximab-ghvb | denliximab | denliximab-kbcn | plaque psoriasis |
| Gastroenterology | | denliximab-ghvb | denliximab | denliximab-kbcn | adult Crohn’s Disease |
| Oncology | | alodripsim-ghvb | alodripsim | alodripsim-kbcn | treatment of neutropenia |
| Hematology | | alodripsim-ghvb | alodripsim | alodripsim-kbcn | treatment of neutropenia |
| Nephrology | | esalamin-ghvb | alodripsim | esalamin-kbcn | treatment of anemia due to chronic kidney disease (CKD) in patients on dialysis and patients not on dialysis |

Q8. Suppose Junexant ([A1 or A2: pipe in based on specialty and randomization]) is a biological product that is approved for [C: pipe in based on specialty]. Recently, a new biological product Nexsymeo ([B: pipe in based on specialty]) was introduced into the market after receiving FDA approval.

***Based only on the information presented above,*** how certain are you that the new Nexsymeo ([B: pipe in based on specialty]) product and Junexant ([A1 or A2: pipe in based on specialty and randomization]) will …? [Grid]

**PROGRAMMER NOTE: Randomize A through F, same order for Q8 and Q9.**

Q8A. Have the same active ingredient

Q8B. Have one or more of the same FDA-approved indications in common

Q8C. Have common route(s) of administration

Q8D. Have the same expected clinical performance (i.e., safety and efficacy)

Q8E. Have the same mechanism of action

Q8F. Have the same dosing

|  |  |
| --- | --- |
| Value | Label |
| 01 | Completely certain |
| 02 | Very certain |
| 03 | Somewhat certain |
| 04 | Not certain at all |
| -99 | Refused |

Q9. Assume you prescribe Junexant ([A1 or A2: pipe in based on specialty and randomization]) frequently in your practice. You research the new Nexsymeo ([B: pipe in based on specialty]) product, which is approved by the FDA as a biosimilar to Junexant for ([C: pipe in based on specialty]) . “Biosimilar” means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. A biosimilar product must also have the same strength, route of administration, and dosage form as the reference product, and its conditions of use (e.g., indications) must have been previously approved for the reference product.

In order for your patients to receive the biosimilar product, you must expressly prescribe “[B: pipe in based on specialty]” or Nexsymeo.

Considering the information above, how certain are you that the new Nexsymeo ([B: pipe in based on specialty]) product and Junexant ([A1 or A2: pipe in based on specialty and randomization]) will…? [Grid]

**PROGRAMMER NOTE: Randomize A through F, same order for Q8 and Q9.**

Q9A. Have the same active ingredient

Q9B. Have one or more of the same FDA-approved indications in common

Q9C. Have common route(s) of administration

Q9D. Have the same expected clinical performance (i.e., safety and efficacy)

Q9E. Have the same mechanism of action

Q9F. Have the same dosing

|  |  |
| --- | --- |
| Value | Label |
| 01 | Completely certain |
| 02 | Very certain |
| 03 | Somewhat certain |
| 04 | Not certain at all |
| -99 | Refused |

//NEW SCREEN//

For the following set of questions, you will be presented with a set of treatment scenarios. For each, we ask that you consider the information presented as you make your decision about which drug therapy you would prescribe. When choosing your answers, we urge you to respond as if you were actually selecting a drug for a patient.

**PROGRAMMER NOTE: For Q10-Q15, piped values should be labeled as A1: Junexant with suffix, A2: Junexant without suffix, and B: Nexsymeo**

**Use table below for Q10–Q11.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Specialty** | **A1**  **Junexant)**  **(with suffix)** | | **A2**  **Junexant**  **(without suffix)** | **B**  **Nexsymeo** | **D**  **New Patient Scenario** |
| Rheumatology | | denliximab-ghvb | denliximab | denliximab-kbcn | Your new patient with rheumatoid arthritis:   * Is symptomatic with moderately active disease * Would benefit from treatment with a TNF inhibitor |
| Dermatology | | denliximab-ghvb | denliximab | denliximab-kbcn | Your new patient has:   * Chronic and severe plaque psoriasis * Is a good candidate for systemic therapy with a TNF inhibitor |
| Gastroenterology | | denliximab-ghvb | denliximab | denliximab-kbcn | Your new adult patient with moderately active Crohn’s disease:   * Has had an inadequate response to conventional therapy * Would benefit from a TNF inhibitor |
| Oncology | | alodripsim-ghvb | alodripsim | alodripsim-kbcn | Your new patient with cancer:   * Is neutropenic following treatment with chemotherapy * She needs treatment in order to continue chemotherapy |
| Hematology | | alodripsim-ghvb | alodripsim | alodripsim-kbcn | Your new patient with cancer:   * Is neutropenic following treatment with chemotherapy * She needs treatment in order to continue chemotherapy |
| Nephrology | | esalamin-ghvb | esalamin | esalamin-kbcn | Your adult patient with end-stage renal disease requiring hemodialysis:   * Has a hemoglobin level that would be appropriate for treatment with an erythropoiesis stimulating agent |

//NEW SCREEN//

Q10. [D: pipe in based on specialty] Consider the circumstances below, and select the therapy you are more likely to prescribe. [Single punch]

|  |  |  |
| --- | --- | --- |
| Biologic: | Junexant ([A1 or A2: pipe in based on specialty and randomization]) | Nexsymeo ([B: pipe in based on specialty]) |
| Prescription history: | You have prescribed it before | Recently introduced; you have not prescribed it before |
| Formulary status: | On formulary | On formulary |
| **Method of Delivery:** | Same | |
| Indications: | Same | |

In this situation I would prescribe:

|  |  |
| --- | --- |
| Value | Label |
| 01 | Junexant ([A1 or A2: pipe in based on specialty and randomization]) |
| 02 | Nexsymeo ([B: pipe in based on specialty]) |
| -99 | Refused |

Q11. Now, again consider the **same new patient and products**, except now the **formulary** lists Nexsymeo ([B: pipe in based on specialty]), not Junexant ([A1 or A2: pipe in based on specialty and randomization]).Consider the circumstances below, and select the therapy you are more likely to prescribe. [Single punch]

|  |  |  |
| --- | --- | --- |
| Biologic: | Junexant ([A1 or A2: pipe in based on specialty and randomization]) | Nexsymeo ([B: pipe in based on specialty]) |
| Prescription history: | You have prescribed it before | Recently introduced; you have not prescribed it before |
| **Formulary status:** | NOT on formulary; higher out-of-pocket for patient | On formulary; lower out-of-pocket for patient |
| **Method of Delivery:** | Same | |
| Indications: | Same | |

In this situation, I would prescribe:

|  |  |
| --- | --- |
| Value | Label |
| 01 | Junexant ([A1 or A2: pipe in based on specialty and randomization]) |
| 02 | Nexsymeo ([B: pipe in based on specialty]) |
| -99 | Refused |

**PROGRAMMER NOTE: Use table below for Q12-Q13.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Specialty** | **A1**  **Junexant**  **(with suffix)** | **A2**  **Junexant**  **(without suffix)** | **B**  **Nexsymeo** | **E**  **Existing Patient Scenario** |
| Rheumatology | denliximab-ghvb | denliximab | denliximab-kbcn | * Has rheumatoid arthritis * Is symptomatic with moderately active disease * Has been treated with Junexant (denliximab-ghvb) previously and tolerated it well * This patient would benefit from an anti-TNF inhibitor |
| Dermatology | denliximab-ghvb | denliximab | denl.iximab-kbcn | * Has chronic and severe plaque psoriasis * Has been treated with Junexant (denliximab-ghvb) previously and tolerated it well * This patient would benefit from an anti-TNF inhibitor |
| Gastroenterology | denliximab-ghvb | denliximab | denliximab-kbcn | * Has moderately active Crohn’s disease * Has been treated with Junexant (denliximab-ghvb) previously and tolerated it well * This patient would benefit from an anti-TNF inhibitor |
| Oncology | alodripsim-ghvb | alodripsim | alodripsim-kbcn | * Isneutropenic following treatment with chemotherapy * The patient was treated with Junexant (alodripstim-ghvb)during a previous cycle of chemotherapy, and tolerated the therapy well * The patient needs treatment in order to continue chemotherapy |
| Hematology | alodripsim-ghvb | alodripsim | alodripsim-kbcn | * Isneutropenic following treatment with chemotherapy * The patient was treated with Junexant (alodripstim-ghvb)during a previous cycle of chemotherapy, and tolerated the therapy well * The patient needs treatment in order to continue chemotherapy |
| Nephrology | esalamin-ghvb | esalamin | esalamin-kbcn | * Has end-stage renal disease requiring hemodialysis * Has a hemoglobin level that would be appropriate for treatment with an erythropoiesis stimulating agent * The patient has been treated with Junexant (alodripsim-ghvb) previously and tolerated it well |

Q12. Next, please consider an **existing patient** who: [E: pipe in based on specialty] Consider the circumstances below, and select the therapy you are more likely to prescribe. [Single punch]

|  |  |  |
| --- | --- | --- |
| Biologic: | Junexant ([A1 or A2: pipe in based on specialty and randomization]) | Nexsymeo ([B: pipe in based on specialty]) |
| Prescription history: | You have prescribed it before to this patient. | Recently introduced; you have not prescribed it before to this patient |
| Formulary status: | On formulary | On formulary |
| **Method of Delivery:** | Same | |
| Indications: | Same | |

In this situation I would prescribe:

|  |  |
| --- | --- |
| Value | Label |
| 01 | Junexant ([A1 or A2: pipe in based on specialty and randomization]) |
| 02 | Nexsymeo ([B: pipe in based on specialty]) |
| -99 | Refused |

Q13. Now, consider the **same existing patient** and products, except now the **formulary** lists Nexsymeo ([B: pipe in based on specialty]), not Junexant ([A1 or A2: pipe in based on specialty and randomization]).Consider the circumstances below, and select the therapy you are more likely to prescribe. [Single punch]

|  |  |  |
| --- | --- | --- |
| Biologic: | Junexant ([A1 or A2: pipe in based on specialty and randomization]) | Nexsymeo ([B: pipe in based on specialty]) |
| Prescription history: | You have prescribed it before to this patient | Recently introduced; you have not prescribed it before to this patient |
| **Formulary status:** | NOT on formulary; higher out-of-pocket for patient | On formulary; lower out-of-pocket for patient |
| **Method of Delivery:** | Same | |
| Indications: | Same | |

In this situation I would prescribe:

|  |  |
| --- | --- |
| Value | Label |
| 01 | Junexant ([A1 or A2: pipe in based on specialty and randomization]) |
| 02 | Nexsymeo ([B: pipe in based on specialty]) |
| -99 | Refused |

**PROGRAMMER NOTE: Use table below for Q14.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Specialty** | **A1**  **Junexant**  **(with suffix)** | **A2**  **Junexant**  **(without suffix)** | **B**  **Nexsymeo** | **F**  **Junexant Presentations** | **G**  **Nexsymeo Presentation** |
| Rheumatology | denliximab-ghvb | denliximab | denliximab-kbcn | * IV infusion: Single-dose vial * Subcutaneous injection: prefilled syringe or auto-injector | * IV infusion: Single-dose vial * Subcutaneous injection: prefilled syringe |
| Dermatology | denliximab-ghvb | denliximab | denliximab-kbcn | * IV infusion: Single-dose vial * Subcutaneous injection: prefilled syringe or auto-injector | * IV infusion: Single-dose vial * Subcutaneous injection: prefilled syringe |
| Gastroenterology | denliximab-ghvb | denliximab | denliximab-kbcn | * IV infusion: Single-dose vial * Subcutaneous injection: prefilled syringe or auto-injector | * IV infusion: Single-dose vial * Subcutaneous injection: prefilled syringe |
| Oncology | alodripsim-ghvb | alodripsim | alodripsim-kbcn | * IV infusion : Single-dose vial * Subcutaneous injection: prefilled syringe or single-dose vial | * IV infusion : Single-dose vial * Subcutaneous injection: Single-dose vial |
| Hematology | alodripsim-ghvb | alodripsim | alodripsim-kbcn | * IV infusion : Single-dose vial * Subcutaneous injection: prefilled syringe | * IV infusion : Single-dose vial * Subcutaneous injection: Single-dose vial |
| Nephrology | esalamin-ghvb | esalamin | esalamin-kbcn | * IV infusion : Single-dose vial * Subcutaneous: prefilled syringe or single-dose vial | * IV infusion : Single-dose vial * Subcutaneous injection: Single-dose vial |

Q14. Now, consider the **same existing patient** and products, except that one product has fewer approved **presentations (i.e. method of delivery).** Both medications are approved for the same indications and approved for the same routes of administration. Consider the circumstances below, and select the therapy you are more likely to prescribe. [Single punch]

|  |  |  |
| --- | --- | --- |
| Biologic: | Junexant ([A1 or A2: pipe in based on specialty and randomization]) | Nexsymeo ([B: pipe in based on specialty]) |
| Prescription history: | You have prescribed it before | Recently introduced; you have not prescribed it before |
| Formulary status: | On formulary | On formulary |
| **Method of Delivery:** | [F: pipe in based on specialty] | [G: pipe in based on specialty] |
| Indications: | Same | |

In this situation I would prescribe:

|  |  |
| --- | --- |
| Value | Label |
| 01 | Junexant ([A1 or A2: pipe in based on specialty and randomization]) |
| 02 | Nexsymeo ([B: pipe in based on specialty]) |
| -99 | Refused |

**PROGRAMMER NOTE: Use table below for Q15.**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Specialty** | **A1**  **Junexant**  **(with suffix** | | **A2**  **Junexant**  **(without suffix)** | **B**  **Nexsymeo** | **H**  **Junexant Indication** | **J**  **Nexsymeo Indication** |
| Rheumatology | | denliximab-ghvb | denliximab | denliximab-kbcn | * Rheumatoid Arthritis * Juvenile Idiopathic Arthritis * Psoriatic Arthritis | * Rheumatoid Arthritis |
| Dermatology | | denliximab-ghvb | denliximab | denliximab-kbcn | * Plaque Psoriasis * Hidradenitis Suppurativa * Uveitis | * Plaque Psoriasis |
| Gastroenterology | | denliximab-ghvb | denliximab | denliximab-kbcn | * Adult Crohn’s Disease * Pediatric Crohn’s Disease * Ulcerative Colitis | * Adult Crohn’s Disease |
| Oncology | | alodripsim-ghvb | alodripsim | alodripsim-kbcn | * Treatment of neutropenia * Mobilization of stem cells | * Treatment of neutropenia |
| Hematology | | alodripsim-ghvb | alodripsim | alodripsim-kbcn | * Treatment of neutropenia * Mobilization of stem cells | * Treatment of neutropenia |
| Nephrology | | esalamin-ghvb | esalamin | esalamin-kbcn | * Treatment of anemia due to chronic kidney disease (CKD) in patients on dialysis and patients not on dialysis * Reduction of allogeneic blood transfusion in surgery patients | * Treatment of anemia due to chronic kidney disease (CKD) in patients on dialysis and patients not on dialysis |

Q15. Now, consider the **same existing patient** and products, except that one product has fewer approved **indications**. Both medications are approved for the indication your patient presents with and have the same routes of administration. Consider the circumstances below, and select the therapy you are more likely to prescribe. [Single punch]

|  |  |  |
| --- | --- | --- |
| Biologic: | Junexant ([A1 or A2: pipe in based on specialty and randomization]) | Nexsymeo ([B: pipe in based on specialty]) |
| Prescription history: | You have prescribed it before | Recently introduced; you have not prescribed it before |
| Formulary status: | On formulary | On formulary |
| **Method of Delivery:** | Same | |
| **Indications:** | [H: pipe in based on specialty] | [J: pipe in based on specialty] |

In this situation I would prescribe:

|  |  |
| --- | --- |
| Value | Label |
| 01 | Junexant ([A1 or A2: pipe in based on specialty and randomization]) |
| 02 | Nexsymeo ([B: pipe in based on specialty]) |
| -99 | Refused |

**PROGRAMMER NOTE: Use table below for Q16.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Specialty** | **A1**  **Junexant**  **(with suffix)** | **A2**  **Junexant**  **(without suffix)** | **B**  **Nexsymeo** | **K**  **Therapy type** |
| Rheumatology | denliximab-ghvb | denliximab | denliximab-kbcn | denliximab |
| Dermatology | denliximab-ghvb | denliximab | denliximab-kbcn | denliximab |
| Gastroenterology | denliximab-ghvb | denliximab | denliximab-kbcn | denliximab |
| Oncology | alodripsim-ghvb | alodripsim | alodripsim-kbcn | alodripsim |
| Hematology | alodripsim-ghvb | alodripsim | alodripsim-kbcn | alodripsim |
| Nephrology | esalamin-ghvb | esalamin | esalamin-kbcn | esalamin |

Q16. Imagine your institution or patient’s formulary recently added the biosimilar Nexsymeo ([B: pipe in based on specialty]) as a preferred product on formulary instead of Junexant ([A1 or A2: pipe in based on specialty and randomization]). For each of the following patients, indicate how likely you would be to pursue a prior authorization or formulary exception for treatment with Junexant ([A1 or A2: pipe in based on specialty and randomization]) instead of Nexsymeo ([B: pipe in based on specialty]). [Grid]

Q16A. Patients new to [A1 or A2: pipe in based on specialty and randomization].

Q16B. Patients currently treated with Junexant ([A1 or A2: pipe in based on specialty and randomization]) successfully with no tolerability issues.

Q16C. Patients currently treated with Junexant ([A1 or A2: pipe in based on specialty and randomization]) successfully with minor tolerability issues.

Q16D. Patients currently treated with Junexant ([A1 or A2: pipe in based on specialty and randomization]) successfully with moderate to major tolerability issues.

|  |  |
| --- | --- |
| Value | Label |
| 01 | Very likely |
| 02 | Likely |
| 03 | Neither likely nor unlikely |
| 04 | Unlikely |
| 05 | Very unlikely |
| -99 | Refused |

Q17. Please indicate how strongly each consideration would influence your willingness to try the new biosimilar Nexsymeo ([B: pipe in based on specialty]) for your patients. [Grid]

**[Randomize A through L; “Other” appears last]**

Q17A. Recommendations of colleagues in your field.

Q17B. Education on the type of information and analysis the FDA uses to conclude products are highly similar, including the availability of summaries that describe the analytic and clinical evidence used in the approval of this particular product.

Q17C. Confidence in specific, timely and accurate pharmacovigilance to monitor the safety of these products.

Q17D. Clarity of the labeling and package insert.

Q17E. Differences between the nonproprietary names of the biosimilar and reference products.

Q17F. The ability to identify which product is dispensed to the patient.

Q17G. Financial savings to the patient.

Q17H. Financial implications to me/my practice related to insurance reimbursement rates.

Q17I. Prior authorization (e.g. paperwork required for the patient to receive therapy).

Q17J. The patient experience with Junexant ([A1 or A2: pipe in based on specialty and randomization]).

Q17K. Patients’ interest in trying a biosimilar similar to Junexant ([A1 or A2: pipe in based on specialty and randomization).

Q17L. Institutional preference.

Q17M. Varying clinical situations.

Other; please describe what other factors would influence your decision making:

Q17M1. Factor 1:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Q17M2. Factor 2:­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Q17M3. Factor 3:­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**[Participants should be able to rate influence level for any “other” entries.]**

|  |  |
| --- | --- |
| Value | Label |
| 01 | 1 - No influence at all |
| 02 | 2 |
| 03 | 3 |
| 04 | 4 |
| 05 | 5 – Strong influence |
| -99 | Refused |

Q17BIO. Please indicate how strongly you agree or disagree with the following statement:

I would never prescribe a biosimilar. [Single Punch]

|  |  |
| --- | --- |
| Value | Label |
| 01 | Strongly agree |
| 02 | Agree |
| 03 | Neither agree nor disagree |
| 04 | Disagree |
| 05 | Strongly disagree |
| -99 | Refused |

Q18. Please indicate how strongly you agree or disagree with the following items: [Grid]

**[Randomize A through G]**

Q18A. I answered the questions as if I were actually prescribing these biologics.

Q18B. I prefer to prescribe products I have experience prescribing, rather than new products.

Q18C. I am less likely to prescribe biosimilar products than reference biologics.

Q18D. I anticipate biosimilar products will be less expensive for my patients.

Q18E. I am waiting until biosimilar products have been on the market longer before I prescribe them.

Q18F. I am more likely to prescribe biosimilar products than reference biologics.

Q18G. In general, for my patients, I specify “Dispense as Written” to ensure dispensing of the intended biological product.

|  |  |
| --- | --- |
| Value | Label |
| 01 | Strongly agree |
| 02 | Agree |
| 03 | Neither agree nor disagree |
| 04 | Disagree |
| 05 | Strongly disagree |
| -99 | Refused |

**SECTION III: Overall Impressions of Naming Scheme**

**[Randomize order of Q19, 20]**

Q19. How often is it reported to you that a patient received a different medicine than the one you had intended? [Single punch]

|  |  |
| --- | --- |
| Value | Label |
| 01 | Always |
| 02 | Frequently |
| 03 | Occasionally |
| 04 | Seldom |
| 05 | Never |
| 06 | Don’t know |
| -99 | Refused |

Q20. Suffixes incorporated in nonproprietary names of biological products… [Grid]

Q20A. Allow me to ensure my patient gets the product I intended.

Q20B. Facilitate tracking any adverse events to a specific product.

Q20C. Make prescribing burdensome.

Q20D. Make prescribing confusing.

|  |  |
| --- | --- |
| Value | Label |
| 01 | Strongly agree |
| 02 | Agree |
| 03 | Neither agree nor disagree |
| 04 | Disagree |
| 05 | Strongly disagree |
| 06 | Don’t know |
| -99 | Refused |

**SECTION IV: Impact of Biological Naming on Communication**

**PROGRAMMER NOTE: Use table below for Q21–Q23.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Specialty** | **A1**  **Junexant**  **(with suffix)** | **A2**  **Junexant**  **(without suffix)** | **B**  **Nexsymeo** | **K**  **Therapy type** |
| Rheumatology | denliximab-ghvb | denliximab | denliximab-kbcn | denliximab |
| Dermatology | denliximab-ghvb | denliximab | denliximab-kbcn | denliximab |
| Gastroenterology | denliximab-ghvb | denliximab | denliximab-kbcn | denliximab |
| Oncology | alodripsim-ghvb | alodripsim | alodripsim-kbcn | alodripsim |
| Hematology | alodripsim-ghvb | alodripsim | alodripsim-kbcn | alodripsim |
| Nephrology | esalamin-ghvb | esalamin | esalamin-kbcn | esalamin |

Q21. In your practice, what terminology would you anticipate using most often to prescribe biosimilar biological products? Select one. [Single punch]

**[Randomize A through F; G (“Other”) appears last]**

**Text in blue should appear in blue on screen. Blue text can be omitted from variable labels in data set so that we have standard labels across specialties.**

|  |  |
| --- | --- |
| Value | Label |
| 01 | The brand name of the product you want your patient to receive if the product has one (e.g., Junexant, Nexsymeo). |
| 02 | The nonproprietary name of the product including the suffix (e.g., [A1 or A2: pipe in based on specialty and randomization] or [B: pipe in based on specialty]). |
| 03 | The nonproprietary name of the product excluding the suffix (e.g., [K: pipe in based on specialty]). |
| 04 | Both the brand name, if the product has a brand name, and nonproprietary name, including suffix (e.g., Junexant ([A1 or A2: pipe in based on specialty and randomization]) or Nexsymeo ([B: pipe in based on specialty]).) |
| 05 | The drug substance name along with the name of the drug maker (e.g., “Ghyra’s [K: pipe in based on specialty] product”). |
| 06 | The brand name of the reference product (e.g., Junexant or “a biosimilar to Junexant”). |
| 07 | Other (please describe) |
| -99 | Refused |

Q22. As more biosimilar biological products are introduced, how do you anticipate that you or your staff will record the name of the prescribed medicine in the patient health record? [Single punch]

**[Randomize A through E; F (“Other”) appears last]**

**Text in blue should appear in blue on screen. Blue text can be omitted from variable labels in data set so that we have standard labels across specialties.**

|  |  |
| --- | --- |
| Value | Label |
| 01 | The brand name of the product you prescribed, if the product has one (e.g., Junexant or Nexsymeo). |
| 02 | The nonproprietary name of the product including any suffix (e.g., [A1 or A2: pipe in based on specialty and randomization] or [B: pipe in based on specialty]). |
| 03 | The nonproprietary name of the product excluding any suffix (e.g., [K: pipe in based on specialty]). |
| 04 | Both the brand name, if the product has a brand name, and nonproprietary name (e.g., Junexant ([A1 or A2: pipe in based on specialty and randomization]) or Nexsymeo ([B: pipe in based on specialty])). |
| 05 | The nonproprietary name along with the name of the drug maker (e.g., “Ghyra’s [K: pipe in based on specialty] product”). |
| 06 | Other |
| -99 | Refused |

Q23. As more biosimilar biological products are introduced, how do you anticipate that you or your staff will record the names of biological medicines administered at your office or clinic in the patient health record? [Single punch]

**[Randomize A through E; F (“Other”) and G (“Not applicable”) appear last]**

**Text in blue should appear in blue on screen. Blue text can be omitted from variable labels in data set so that we have standard labels across specialties.**

|  |  |
| --- | --- |
| Value | Label |
| 01 | The brand name of the product you prescribed, if the product has one (e.g., Junexant or Nexsymeo). |
| 02 | The nonproprietary name of the product including any suffix (e.g., [A1 or A2: pipe in based on specialty and randomization] or [B: pipe in based on specialty]). |
| 03 | The nonproprietary name of the product excluding any suffix (e.g., [K: pipe in based on specialty]). |
| 04 | Both the brand name, if the product has a brand name, and nonproprietary name (e.g., Junexant ([A1 or A2: pipe in based on specialty and randomization]) or Nexsymeo ([B: pipe in based on specialty])). |
| 05 | The nonproprietary name along with the name of the drug maker (e.g., “Ghyra’s [K: pipe in based on specialty] product”). |
| 06 | Other |
| 07 | Not applicable (Neither my staff nor I administer medicines) |
| -99 | Refused |

Q24. Have you ever prescribed a biosimilar? Examples of FDA-approved biosimilars currently on the market are Renflexis (infliximab-abda), Inflectra (infliximab-dyyb), Zarxio (filgrastim-sndz), Retacrit (epoetin alfa-epbx), and Fulphila (pegfilgrastim-jmdb). [Single punch]

|  |  |
| --- | --- |
| Value | Label |
| 01 | Yes |
| 02 | No |
| 03 | Unsure |
| -99 | Refused |

**Closing/Debrief**

Thank you for your participation in this study; we appreciate your time and effort. Your participation helps the U.S. Department of Health and Human Services and FDA learn more about how health care providers think and communicate about biosimilar drug products.

The drug names that you saw today were created for the purposes of this study and are not for real prescription drugs.