

No. 0910-0847

Expiration Date: 11/30/2020

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Your participation/nonparticipation is completely voluntary, and your responses will not have an effect on your eligibility for receipt of any FDA services. In instances where respondent identity is needed (e.g., for follow-up of non-responders), this information collection fully complies with all aspects of the Privacy Act and data will be kept private to the fullest extent allowed by law.

## WebMD Survey, HCP Drug Quality (FINAL)

### Objectives and design

*Note: This information is for reviewers and is not seen by respondents.*

**Objective:** Measure physicians' understanding of and attitudes toward drug product quality for both prescription and OTC drugs.

**Medium of data collection:** 10-minute online questionnaire. Physicians will be recruited from Medscape physician members.

**Quota:**

- 400 PCPs
- 250 specialists (50 each: cardiologists, orthopedics, rheumatologists, dermatologists, diabetologists/endocrinologists)

### Screening questions

1. What is your clinical title?
  - a. Physician
  - b. Nurse **TERMINATE**
  - c. Physician assistant **TERMINATE**
  - d. Other healthcare practitioner **TERMINATE**
  - e. Not a healthcare practitioner **TERMINATE**
  
2. What is your specialty? (Select one.)
  - a. Cardiology **"SPECIALIST"**
  - b. Dermatology **"SPECIALIST"**
  - c. Diabetes/Endocrinology **"SPECIALIST"**
  - d. Family Medicine **"PCP"**
  - e. Internal Medicine **"PCP"**
  - f. Orthopedics **"SPECIALIST"**
  - g. Rheumatology **"SPECIALIST"**
  - h. Other **TERMINATE**

3. How many years have you been in practice since your residency? (If less than one year enter 0.)

\_\_\_\_\_ years in practice since residency **TERMINATE IF <5; RANGE = 0-100**

4. What percentage of your time is devoted to direct patient care? (Please do not include research, administration, or other direct responsibilities.)

\_\_\_\_\_% of time devoted solely to direct patient care **TERMINATE IF <40%**

5. What is your age?

\_\_\_\_\_ age in years **RANGE 1-100; TERMINATE IF <26**

6. In a typical month, how many patients do you personally treat?

\_\_\_\_\_ **TERMINATE < 20**

### SET UP AS QUOTA QUESTION

#### Rx Drug Prescriptions

1. In the past 30 days, to approximately what percentage of your total patients did you write prescriptions?

\_\_\_\_\_% of total patients I wrote prescriptions for in the past 30 days **RANGE 1-100; TERMINATE IF 0**

1a. Approximately what percentage of total prescriptions written in the past 30 days were for brand-name drugs vs generic drugs?

\_\_\_\_\_% brand-name Rx **RANGE 1-100**

\_\_\_\_\_% generic Rx **RANGE 1-100**

**MUST ADD TO 100**

### SET UP AS QUOTA QUESTION

#### OTC Drug Recommendations

2. In the past 30 days, to approximately what percentage of your total patients did you recommend/prescribe any over-the-counter medication or treatment?

\_\_\_\_\_% of total patients I recommended/prescribed any over-the-counter medications or treatments in the past 30 days **RANGE 1-100; TERMINATE IF 0**

2a. Approximately what percentage of total over-the-counter medications or treatments recommended/prescribed in the past 30 days were for a brand-name vs generic?

\_\_\_\_\_% brand-name OTC medication/treatment **RANGE 1-100**

\_\_\_\_\_% generic OTC medication/treatment **RANGE 1-100**

**MUST ADD TO 100**

## Main questionnaire

**RANDOMIZE ORDER OF QUESTIONS 3/4**

### Overall Quality of Drugs

**IF Q1A BRAND-NAME > 0%**

3. In your opinion, the overall quality of prescription brand-name drugs you prescribe to your patients is...
- Excellent
  - Very Good
  - Good
  - Fair
  - Poor

**IF Q1A GENERIC > 0%**

4. In your opinion, the overall quality of prescription generic drugs you prescribe to your patients is...
- Excellent
  - Very Good
  - Good
  - Fair
  - Poor

**Prescription generic vs. prescription brand-name**

5. To what extent do you agree or disagree with the following statements about prescription generic drugs?

RANDOMIZE	Strongly Agree	Somewhat Agree	Neither Agree Nor Disagree	Somewhat Disagree	Strongly Disagree
	5	4	3	2	1
1. Compared to prescription brand-name drugs, prescription generic versions are <u>just as safe</u>					
2. Compared to prescription brand-name drugs, prescription generic versions are <u>equal in purity</u>					
3. Compared to prescription brand-name drugs, prescription generic versions are <u>just as effective</u>					
4. Compared to prescription brand-name drugs, prescription generic versions are <u>of equal quality</u>					

- 5a. How often do you write Dispense as Written (DAW) for prescription brand-name drugs when a prescription generic drug is available?
- Always
  - Often
  - Sometimes
  - Rarely
  - Never

IF 5A = A, B, OR C

5b. What are the primary reasons why you write “DAW” for prescription brand-name drugs when a prescription generic is available? (Select all that apply.)

RANDOMIZE

- a. Patients specifically request prescription brand-name drugs
- b. I do not trust prescription generic drugs
- c. Generic drugs may interact with other drugs a patient is taking
- d. I am not always aware of what generic versions are available
- e. I do it out of habit
- f. Other **ANCHOR**

IF 5A = D OR E

5c. What are the primary reasons why you do not write “DAW” for prescription brand-name drugs when a prescription generic is available? (Select all that apply.)

RANDOMIZE

- a. Patients specifically request prescription generic drugs
- b. It's cheaper for my patients
- c. Prescription generic drugs provide the same clinical benefits as their brand-name versions
- d. I trust prescription generic drugs because they are developed under the same FDA standards as brand-name drugs
- e. Other **ANCHOR**

RANDOMIZE ORDER OF QUESTIONS 6/7

IF Q2A BRAND-NAME > 0%

6. In your opinion, the overall quality of over-the-counter brand-name medications/treatments you have recommended to your patients is...
- a. Excellent
  - b. Very Good
  - c. Good
  - d. Fair
  - e. Poor

IF Q2A GENERIC > 0%

7. In your opinion, the overall quality of over-the-counter generic/store brand medications/treatments you have recommended to your patients is...
- a. Excellent
  - b. Very Good
  - c. Good
  - d. Fair
  - e. Poor

OTC generic vs. OTC brand-name

8. To what extent do you agree or disagree with the following statements about over-the-counter generic/store-brand medications/treatments?

RANDOMIZE	Strongly Agree	Somewhat Agree	Neither Agree Nor Disagree	Somewhat Disagree	Strongly Disagree
	5	4	3	2	1
1. Compared to brand-name medications, over-the-counter generic/store-brand					

versions are <u>just as safe</u>					
2. Compared to brand-name medications, over-the-counter generic/store-brand versions are <u>equal in purity</u>					
3. Compared to brand-name medications, over-the-counter generic/store-brand versions are <u>just as effective</u>					
4. Compared to brand-name medications, over-the-counter generic/store-brand versions are of <u>equal quality</u>					

**Factors indicative of quality**

9. To what extent do you agree or disagree that each item below is an indicator of drug quality?

RANDOMIZE	Strongly Agree	Somewhat Agree	Neither Agree Nor Disagree	Somewhat Disagree	Strongly Disagree
	5	4	3	2	1
1. Drug's beneficial effect					
2. Recommended or prescribed by other health care practitioners					
3. Drug's safety profile					
4. Brand-name drug					
5. Approved for sale in the U.S.					
6. Made by a pharmaceutical company I trust					
7. Higher in cost					
8. Have seen or heard an advertisement for the drug					

**Physical indicators of drug quality**

10. Which of the following are indicators of drug quality? (Select all that apply.)

RANDOMIZE

- a. The color, shape, or other similar characteristics of a drug
- b. Taste
- c. Whether pills/tablets crumble or break easily
- d. Powdery feeling pills/tablets
- e. Appropriate packaging (apart from pharmacist packaging)

- f. Whether a liquid or cream appears to have separated
- g. Whether particles are present in a bottle of liquid
- h. Other **ANCHOR**
- i. Not sure **EXCLUSIVE ANCHOR**

**PROGRAMMER—NO BACK BUTTON ON THIS QUESTION**

**Aided Awareness—FDA**

11. Which, if any, of the following are functions of the FDA in terms of regulating drug quality? (Select all that apply.)

**RANDOMIZE**

- a. Oversee the research, development, manufacture, and marketing of drugs in the U.S.
- b. Evaluate and approve new drugs before they can be sold
- c. Make certain that all drugs marketed in the U.S.—brand and generic, prescription and over-the-counter—are safe and effective and that their health benefits outweigh known risks
- d. Monitor truth in advertising for prescription drugs
- e. Monitor the use of marketed drugs for unexpected health risks
- f. Remove a drug from market if unexpected risks are detected after a drug is already approved
- g. Manufacture drugs
- h. Set prices for drugs
- i. Prevent unapproved drugs from being imported to the U.S.
- j. Test drugs
- k. Work with other organizations, such as the United States Pharmacopeia (USP), to set quality standards for drugs
- l. None of the above **EXCLUSIVE ANCHOR**
- m. Not sure **EXCLUSIVE ANCHOR**

**Quality of drugs imported to US**

12. Do you believe drugs manufactured outside the U.S. and sold in the U.S. adhere to strict manufacturing standards and regulations required by the FDA?
- a. Yes
  - b. No
  - c. Not sure

**Quality of drugs manufactured outside of US**

13. Compared to drugs manufactured within the U.S., do you think those manufactured outside the U.S. for sale inside the U.S. are...?
- a. Much higher quality
  - b. Higher quality
  - c. About the same quality
  - d. Lower quality
  - e. Much lower quality
  - f. Not sure

**IF Q13 = D OR E**

**Quality of drugs manufactured outside the US**

14. Why do you believe that drugs manufactured outside the U.S. for sale inside the U.S. are of poor quality or poorer quality than drugs manufactured in the U.S.? (Select all that apply.)

**RANDOMIZE**

Drugs manufactured outside the U.S....

- a. ...are not strong enough
- b. ...cause more side effects
- c. ...are not as pure or could be contaminated
- d. ...use inferior active ingredients
- e. ...crumble, break, or chip more easily

- f. ...have an inferior appearance (shape, color, etc.)
- g. ...have a bad reputation
- h. ...may be from places that experience health and sanitation problems
- i. Other (please specify: \_\_\_\_\_) **ANCHOR AT BOTTOM DON'T FORCE ANSWER; IF LEFT BLANK CODE AS "Other"**
- j. None of the above **EXCLUSIVE ANCHOR**
- k. Not sure **EXCLUSIVE ANCHOR**

**Drug Shortage**

15. Are drugs that are sold in the U.S. ever in short supply?

- a. Yes
- b. No
- c. Not sure

**Drug Shortage**

16. Have your patients experienced any difficulty in filling prescription(s) due to drug shortage (not just a brief pharmacy delay for reordering)?

- a. Yes
- b. No
- c. Not sure

**Reasons for shortage**

17. What are possible reasons for drug shortages? (Select all that apply.)

**RANDOMIZE**

- a. Aging manufacturing facilities or manufacturing equipment
- b. Quality/manufacturing problems (e.g., failure to produce the correct strength)
- c. Production delays at the manufacturer
- d. Safety problems (e.g., contamination/lack of purity)
- e. Delays companies have experienced receiving raw materials and components from suppliers
- f. Natural disaster (hurricane, earthquake, etc.)
- g. Discontinuation of drug by manufacturer
- h. FDA preventing sale of the drug from one or more manufacturers until required quality levels are met
- i. Not sure **ANCHOR EXCLUSIVE**
- j. None of the above **ANCHOR EXCLUSIVE**

**EACH RESPONDENT RECEIVES Q18 OR Q18A. RANDOMIZE SELECTION. ALLOW QUESTION TO BE SKIPPED IF RESPONDENT DOES NOT WANT TO ANSWER.**

**Impact of shortage on quality of drug**

18. There are times when the FDA may take steps to maintain safety and quality standards for a drug, which can cause a supply shortage. This may be viewed as a tradeoff between constant availability of drugs on one side and quality and safety of drugs on the other. Please use the scale below to indicate where you feel that the FDA should stand on this tradeoff. The scale ranges from zero on one end, which indicates "constant availability" and ten on the other end, which indicates "quality and safety." You can choose any number on the scale to represent your opinion.

<b>Constant Availability</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>Quality and Safety</b>
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18a. There are times when the FDA may take steps to maintain safety and quality standards for a drug, which can cause a supply shortage. This may be viewed as a tradeoff between quality and safety of drugs on one side and constant availability on the other. Please use the scale below to indicate where you feel that the FDA should stand on this tradeoff. The scale ranges from zero on one end, which indicates "quality and safety" and ten on the other end, which indicates "constant availability." You can choose any number on the scale to represent your opinion.





23. In what state or U.S. territory do you practice? *Select one from the dropdown menu*

PROVIDE DROP-DOWN MENU WITH THE 50 STATES, DISTRICT OF COLUMBIA, PUERTO RICO, AND "OTHER U.S. COMMONWEALTH, TERRITORY, OR PROTECTORATE"

**PROGRAM INTO REGION VARIABLES BELOW**

- a. Northeast (ME, NH, VT, MA, CT, RI)
- b. Mid-Atlantic (WV, VA, DE, MD, DC, NC, PA, NJ, NY)
- c. Great Lakes (OH, MI, IN, IL, WI, MN)
- d. Southeast (SC, GA, FL, AL, MS, LA, TN, KY)
- e. South Central (TX, OK, AR)
- f. Southwest (AZ, UT, CO, NM, NV)
- g. North Central (IA, MO, KS, NE, SD, ND)
- h. Northwest (MT, WY, ID, OR, WA)
- i. West (CA, AK, HI)
- j. U.S. commonwealth, territory, or protectorate