Verification Program Guidance Policies

Protecting the Public Health:

Helping Consumers Find Information About Verified Online Pharmacies that Sell Affordable Medications

Rev. April 30, 2017

Note: Verification Program policies provide applicants and members additional information regarding compliance with Verification Program Standards and Guide.

PharmacyChecker Verification Program Guidance Policies

16-01 Pharmacist Consultation

Pharmacist Consultation

PharmacyChecker Verification Program	
Policy No: 16-01	**Version No:** 1.0
Date Written: May 2016	**Date Revised:** N/A
Effective Date: September 4, 2016	**Replaces Version No:** N/A

PURPOSE:

This policy identifies the requirements that PharmacyChecker (PC) Verification Program members ("Members") must meet in order to comply with PharmacyChecker Verification Program Standards related to patient counseling by a pharmacist.

SCOPE:

This policy applies to all Members that market, sell, process and / or dispense, prescription medications. It identifies the practice standards that Members must meet pertaining to patient counseling by a pharmacist.

RESPONSIBILITY:

Members are responsible for ensuring their website clearly provides information regarding pharmacist consultation, including a phone number a patient may use to request pharmacist consultation.

The Pharmacist-in-Charge, pharmacist manager, or equivalent name for the lead pharmacist of a pharmacy, ("PIC") is responsible to ensure that patient(s) have access to a pharmacist for consultation, the pharmacist performing the counseling is competent, the pharmacy's Standard Operating Procedures (SOPs) cover patient counseling and documentation requirements.

REQUIREMENTS:

1. Members must ensure that patients have access to a competent and licensed pharmacist in a timely manner but not to exceed 72 hours.

2. Members must ensure that patients have telephone access to connect with a pharmacist for consultation; if live chat or a messaging service is used, the Member must have a process for ensuring timely receipt of the message by the pharmacist.

3. Members must ensure that patients can leave messages at all times, including after hours.

4. The PIC is responsible to ensure that its website and others that are Members and take orders filled by the PIC, explicitly states the hours that pharmacist consultation is available, which, at a minimum, must be available during normal business hours.

5. A Member's SOP must include the requirements of the pharmacist related to patient consultation. These duties, include but are not limited to:

a. Making appropriate recommendations regarding medication therapy management and adherence;
b. Obtaining a medication profile, allergy and pertinent medical history from the patient seeking consultation;
c. Evaluating the patient's medication profile, in conjunction with applicable allergies and disease states, in order to determine appropriate interventions and/or referrals;
d. Ensuring the patient understands the counseling points explained;
e. Establishing contact with the patient's provider in the event a referral or intervention in therapy is needed;
f. Performing a full review of the information obtained from the patient looking for issues pertaining to non-compliance, inappropriate therapies or prescribing practices; over/underutilization, and interactions with other pharmaceuticals, allergies, disease-states, or supplements; and
g. Recording pertinent information related to the information obtained from the patient and the counseling performed into the patient's profile or the pharmacy's counseling log.

6. The pharmacist performing patient counseling must be licensed and able to perform all requirements under this policy, in addition to the requirements in their own country, state, or relevant jurisdiction.

7. The pharmacist performing patient counseling must be able to competently, clearly, and concisely deliver sound advice within their scope of practice. If communication issues arise, due to language differences, or the consulting pharmacist is unable to help the patient directly, the Members must have a process to refer the patient to another licensed pharmacist or appropriate healthcare professional.

8. The PIC must ensure competency of the pharmacist performing counseling. Documentation of competency assessment for each pharmacist must be kept on file.

9. The Member's SOP must include the competency standards assessed, frequency of assessment and methods used to evaluate competency of each pharmacist providing patient counseling.

10. Member websites must:
    a. clearly provide information regarding pharmacist consultation; and
    b. provide a phone number a patient may use to request pharmacist consultation.

11. Member pharmacies must provide PharmacyChecker with SOP for patient counseling, the pharmacy's counseling log, and related pharmacist competency assessment documentation upon request.

ATTACHMENTS:

N/A

HISTORY:

Version Number	Date Effective	Description of Change
1.0		New SOP

Temperature Sensitive Medications: Shipping Requirements

PharmacyChecker Verification Program	
Policy No: 16-03	**Version No:** 1.0
Date Written: 2010	**Date Revised:** May 2016
Effective Date: July 21, 2016	**Replaces Version No:** 10-008 (revised Jan. 2011)

PURPOSE:

This policy outlines the requirements for PharmacyChecker (PC) Verification Program members ("Members") regarding compliance with PharmacyChecker Verification Program Standards related to ensuring that the cold chain supply is maintained throughout the shipping process when dispensing temperature sensitive medications.

SCOPE:

This policy applies to all Members that dispense temperature sensitive products.

RESPONSIBILITY:

The Pharmacist-in-Charge, pharmacist manager, or equivalent name for the lead pharmacist of a pharmacy, ("PIC") is responsible for compliance with PharmacyChecker Verification Program Standards and Pharmacy Standards Agreement.

REFERENCES:

United States Pharmacopeia (USP) Chapter <1079>, Good Storage & Shipping Practices, https://pharmacy.ks.gov/docs/default-source/default-document-library/ups-36-good-storage-and-shipping-practices.pdf

Health Canada, Guidelines for Temperature Control of Drug Products during Storage and Transportation (GUI-0069), http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/gui-0069-eng.php

MHRA – Refrigerated Products: What Pharmacists Need to Know, https://www.woolcool.com/wp-content/uploads/2014/07/MHRA-Refrigerated-medicinal-products-what-pharmacists-need-to-know.pdf

DEFINITIONS:

Cold Chain Supply: the transportation of temperature sensitive products along a supply chain through thermal and refrigerated packaging methods and the logistical planning to protect the integrity of these shipments.

Temperature indicator: a device that monitors temperatures during shipping and storage and provides visual evidence of exposure to unacceptable temperature levels, protecting product quality throughout the entire shipping and handling process.

GENERAL INFORMATION:

- The manufacturer's labelling of many medications, including insulin, contains optimal storage conditions between 2ºC and 8ºC.
- Medications must be shipped and stored in a manner that ensures the products will be maintained within an acceptable temperature range as defined in the approved labelling and supported by stability data.
- Packaging and shipping method may not risk exposure to temperatures outside a medication's recommended storage conditions.
- The manufacturer's storage requirements must be maintained through all stages of the medication distribution process, including shipping and storage by the patient upon receipt of the product.
- The shipping process and containers must be designed to prevent damage and maintain the integrity and quality of the medication(s) until receipt and storage by the patient.

REQUIRMENTS:

1. Members shipping temperature sensitive medications shall develop a Standard Operating Procedure (SOP) for packaging and shipping such medications.

2. Members may use more than one method depending on the product(s). The method used must not deviate from the manufacturers' labelling.
3. The SOP must include:

    a. a list of temperature sensitive medications dispensed/shipped;

    b. the required temperature, packaging and shipping method for each medication; and

    c. corrective actions and documentation requirements for temperature excursions outside predetermined temperature conditions.

4. The manufacturer's labelling on the storage and shipping needs of each medication must be adhered to. In the absence of manufacturer's labelling, information from peer reviewed journal articles or other reputable sources must be utilized to develop the SOP.

5. Selection of a shipping container and/or box will be based on factors such as duration of transit, the size of the shipment and the ambient or outside temperatures experienced are important in deciding what type of packaging is required. Within a shipping container, the packaging configuration, which provides the primary means of environmental control for the medication, must ensure that the medication remains within the acceptable temperature range.

6. The SOP must also take into account the nature of the medication, local conditions, modes of transport and any seasonal variations experienced, as well as describe any special handling precautions.

7. The SOP must include information regarding cold packs placed in shipping containers used to transport medications, including:

    a. the type, size and number of packs should correspond to the shipping duration and temperature needed;
    b. the location of the packs should ensure that the entire shipment of the product is maintained within the labelled storage conditions; and
    c. adequate barrier materials should be used to prevent contact between the packs and the products, if the packs are at a temperature outside the range acceptable for product storage.

8. The shipping container with medications requiring refrigeration must contain a temperature indicator with clear directions to the recipient for the evaluation of monitoring indicators and steps to take in the event of an excursion.
9. The exterior of the shipping container must be properly labeled to alert the patient to open and refrigerate the contents immediately upon receipt. The label must be securely affixed and indelible.

    Example labeling includes:

10. Packaging and shipping method must be qualified to ensure that appropriate conditions are maintained under probable extremes of ambient temperature and should also account for possible unforeseen delays which may occur in shipping/transportation (for example, shipment delays at international mail facilities). Validation that the shipping method retains the required storage conditions and will not deviate during the shipping process may be available from the commercial courier. Alternatively, Members may perform its own validation process to ensure that packing and shipping method retains the cold chain supply.

11. The PIC shall document the source of all information used in developing the SOP, such as manufacturer recommendation, journal articles, studies to demonstrate adequacy of the packing/shipping method, validation and trial shipping data.

ATTACHMENTS: N/A

HISTORY:

Version Number	Date Effective	Description of Change
1.0		New SOP

Maximum Three Months' Supply Dispensed Internationally

PharmacyChecker Verification Program	
Policy No: 16-04	**Version No:** 3.0
Date Written: June 17, 2016	**Date Revised:** October 5, 2016
Effective Date: November 30, 2016	**Replaces Version No:** 16-04 version 2.0

PURPOSE:

This policy outlines the requirements for PharmacyChecker (PC) Verification Program members ("Members") regarding compliance with PharmacyChecker Verification Program Standards (the "Standards") related to ensuring that medications dispensed internationally do not exceed a three months' supply, unless medically necessary or an exception as defined by this policy is met.

SCOPE:

This policy applies to all Members that market, sell, process and / or dispense medications internationally. This policy outlines requirements for the website, pharmacy, and pharmacist(s) related to our standards that limit the international dispensing of medication to a three months' supply, unless medically necessary or an exception as defined by this policy is met. The policy does not affect domestic dispensing.

RESPONSIBILITY:

The Pharmacist-in-Charge, pharmacist manager, or equivalent name for the lead pharmacist of a pharmacy, ("PIC") is responsible for compliance with the Standards as they apply to dispensing pharmacies.

Members must ensure that online pharmacies do not exceed marketing limitation and clearly provide pertinent information and required disclaimers regarding these medications, as outlined below.

Members participating in the PC Listing Program must ensure that listings comply with this policy as well as PC Listing Program Policy 14-002: *Price Submission Guidelines for Popular Medications.*

DEFINITIONS:

Days' Supply: the number of days that the supply of dispensed medication will last. For the purposes of this policy, the days' supply is calculated based on the recommended daily dose / administration schedule as noted in the manufacturer package insert. The pharmacist must use professional judgement in processing / dispensing prescriptions outside the recommended dose / administration schedule and the reason for doing so shall be documented.

Medically necessary: a decision by the prescriber, exercising prudent clinical judgment, that the care warrants the patient to require a greater than a three months' supply of medication at a time for the purpose of treating an illness, injury, disease or its symptoms. The prescriber's decision must be:

a. in accordance with the generally accepted standards of medical practice; and
b. clinically appropriate for the patient's illness, injury or disease.

REQUIREMENTS:

Members may not market, process and / or dispense a supply exceeding a three months' supply maximum for erectile dysfunction medications, such as Viagra, Cialis, under any circumstances. **Members found to be marketing and / or dispensing greater than a three months' supply of erectile dysfunction medications are subject to immediate discipline, up to and including termination from the Program.**

Online Pharmacy Members:

1. Members processing and/ or referring prescription orders to other pharmacies must ensure that the online pharmacy has an SOP regarding a three months' maximum supply dispensed internationally. The SOP must:
    a. prohibit exceeding a three months' supply maximum for erectile dysfunction medications, such as Viagra, Cialis, and Levitra under any circumstances;
    b. include the requirements, as defined by this policy, for exceeding a three months' supply based on manufacturer packaging;
    c. include the requirements, as defined in this policy, for exceeding a three months' supply if medically necessary;
    d. include a definition of medically necessary, as defined in this policy; and
    e. clearly delineate the responsibilities between the online pharmacy and the dispensing pharmacy regarding requirements and roles for processing and dispensing prescriptions internationally, in accordance with this policy.

2. If the agreement between Members requires the online pharmacy to process the prescription order prior to international dispensing by another pharmacy, the Member must ensure that no prescription with a quantity exceeding a three months' supply is transmitted to another pharmacy for dispensing; unless
    a. Based on the manufacturer packaging of the medication:
        i. The medication will be dispensed in the sealed manufacturer package of #100 tablets / capsules;
        ii. The medication will be dispensed with a combination of smaller sealed manufacturer packages and the pharmacist calculates the quantity as close to the maximum three months' supply as possible based on package size
        iii. The medication is only available in one package size that exceeds a three months' supply and the medication will be dispensed in the sealed manufacturer package.

OR

    b. It is medically necessary, as defined above, to exceed a three months' supply demonstrated by:
        i. the prescriber was contacted; and
        ii. the prescriber indicates a medically necessary reason to exceed a three months' supply; and
        iii. the pharmacist documents this information on the prescription or within the patient's medication profile.

Dispensing Pharmacy Members:

1. The PIC of the dispensing pharmacy must ensure that the pharmacy has an SOP regarding the 90-day maximum supply dispensed internationally.

2. The SOP must:
    a. prohibit exceeding a three months' supply maximum for lifestyle medications, such as Viagra, Cialis, under any circumstances;
    b. include the requirements, as defined by this policy, for exceeding a three months' supply based on manufacturer packaging
    c. include the requirements, as defined in this policy, for exceeding a three months' supply if medically necessary;
    d. include a definition of medically necessary, as defined in this policy; and

    e. clearly delineate the responsibilities between the online pharmacy and the dispensing pharmacy regarding requirements and roles for processing and dispensing prescriptions internationally, in accordance with this policy.

3. The pharmacist must ensure that no prescription with a quantity exceeding a three months' supply is dispensed internationally; unless
    a. Based on the manufacturer packaging of the medication:
        i. The medication will be dispensed in the sealed manufacturer package(s) of #100 tablets / capsules; or
        ii. The medication will be dispensed with a combination of smaller sealed manufacturer packages and the pharmacist calculates the quantity as close to the maximum three months' supply as possible based on package size;
        iii. The medication is only available in one package size that exceeds a three months' supply and the medication will be dispensed in the sealed manufacturer package.

    OR

    b. It is medically necessary, as defined above, to exceed a three months' supply demonstrated by:
        iv. the prescriber was contacted; and
        v. the prescriber indicates a medically necessary reason to exceed a three months' supply; and
        vi. the pharmacist documents this information on the prescription or within the patient's medication profile.

ATTACHMENTS:

N/A

HISTORY:

Version Number	Date Effective	Description of Change
1.0		New SOP
2.0		Updated to include exception for U.S. and Canadian pharmacy dispensing a three months' supply internationally with sealed manufacturer bottle(s) of #100 tablets / capsules (except for erectile dysfunction medications).
3.0		90-day changed to three months throughout document Exceptions for exceeding a three months' supply updated to include options for dispensing sealed manufacturer packages of medication: • sealed manufacturer packaging of #100 tablets / capsules • a combination of smaller sealed manufacturer packages calculating the quantity as close to the maximum three months' supply as possible based on package size; and • smallest available manufacturer sealed packaging when the medication is not available in smaller package sizes and the available package exceeds a three months' supply

Marketing/Dispensing Indian Pharmaceutical Products Internationally

PharmacyChecker Verification Program	
Policy No: 16-05	**Version No:** 1.0
Date Written: August 2016	**Date Revised:** N/A
Effective Date: April 10, 2017	**Replaces Version No:** 12-002 and strikes 4.9.3 of PharmacyChecker Inspection Program

PURPOSE:

This policy amends and outlines the requirements for PharmacyChecker (PC) Verification Program members ("Members") regarding compliance with PharmacyChecker Verification Program Standards and Agreement related to dispensing Indian pharmaceutical products internationally, as outlined below. Indian pharmaceutical products that fall outside of these parameters may not be marketed, processed and / or dispensed internationally by Members.

SCOPE:

This policy applies to Members that market, process and / or dispense Indian pharmaceutical products internationally.

RESPONSIBILITY:

The Pharmacist-in-Charge, pharmacist manager, or equivalent name for the lead pharmacist of a pharmacy, ("PIC") is responsible for compliance with PC standards and policies as they apply to dispensing pharmacies.

Members that market, process and / or dispense Indian pharmaceutical products internationally are responsible for compliance with the requirements outlined below.

RATIONAL:

PC requires Members to sell prescription drugs manufactured under current Good Manufacturing Practices (GMP), and provide a safe international mail-order pharmacy service. PC Policy Marketing / Dispensing Indian Pharmaceutical Products Internationally is based on:

1) a 2012 report that suggests a higher incidence of substandard drugs sold in India by smaller Indian drug manufacturers compared to the largest Indian manufacturers, specifically those whose products are known to meet exceedingly high international standards;

2) PC's understanding that products manufactured in plants with approval by the U.S. Food and Drug Administration, United Kingdom Medicines and Healthcare Products Regulatory Agency, Australian Therapeutics Goods Agency, European Medicines Agency, and/or equivalent drug regulatory authorities are more reliable than those without such approvals; and

3) PC's understanding that ethically promoted global pharmaceutical company products marketed through their branded divisions are the highest quality products available for sale in India.

DEFINITIONS:

Indian Pharmaceutical Product: products approved for sale in Indian pharmacies.

Ethically promoted pharmaceutical products: pharmaceutical products approved for sale in India that have been manufactured by First-Tier Indian manufacturers (defined below) and that are marketed under a brand name directly promoted through the company's branded division.

First-tier Indian manufacturer: a pharmaceutical company based in India that:

- has a global presence in at least one of the following markets: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland South Africa and United Kingdom, United States; **and** products approved for sale in at least one of the aforementioned countries or

- is registered with a drug regulatory authority of one of the following: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland South Africa and United Kingdom, United States.

Global pharmaceutical company: for the purposes of this policy, is a pharmaceutical company that is based in Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland South Africa, United Kingdom, United States , that has products approved for sale in the aforementioned countries **and** sells pharmaceutical products internationally to one or more of the aforementioned countries.

REQUIREMENTS:

1. Members marketing, processing and / or dispensing pharmaceuticals approved for sale in India must ensure the products are:
    a. Ethically promoted pharmaceutical products manufactured by first-tier Indian manufacturers and global pharmaceutical companies, **and/or**

    b. Products manufactured in plants registered with regulatory authorities of one of the following: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland South Africa, United Kingdom, and United States.

2. The PIC is responsible for:
    a. confirming the pedigree of all medications the pharmacy dispenses;

b. maintaining a list that *at a minimum* must include:

i. manufacturers confirmed by the pharmacy to be first Tier Indian manufacturers;
ii. name of each pharmaceutical confirmed by the pharmacy to be ethically promoted; and
iii. wholesalers confirmed by the pharmacy to be trusted sources of first Tier Indian manufacturer's ethically promoted products

c. developing and maintaining an SOP for purchasing and dispensing Indian pharmaceuticals in accordance with this policy; and

d. ensuring staff are trained on the SOPs for purchasing and dispensing Indian pharmaceuticals and documenting the training.

3. The SOP must be reviewed and updated periodically to reflect the addition or deletion of manufacturer(s) or product(s).

ATTACHMENTS:

Appendix I: Indian Pharmaceutical Products

HISTORY:

Version Number	Date Effective	Description of Change
1.0		New SOP- amends and replaces Policy 12-02 and strikes 4.9.3 from the PharmacyChecker Inspection Program 4.9.3 Products manufactured in plants inspected for cGMP by PharmacyChecker or a third-party inspector acceptable to PharmacyChecker. Lists the countries that acceded to the EU prior to 2002. Adds guidance for determining global pharmaceutical company, First-Tier Indian Manufacturers and ethically promoted products.

Appendix I: Indian Pharmaceutical Products

The following table can be used to determine whether a pharmaceutical product approved for sale in India is compliant (meaning one that is an ethically promoted pharmaceutical by First-Tier Manufacturers and global pharmaceutical companies).

Manufacturer			Yes	No
1.0	Is the manufacturer a global pharmaceutical company?	Go to 1.1		
1.1	Does the manufacturer have a global presence in at least one of the following top tier countries Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland South Africa, United Kingdom or United States?	If Yes, go to 1.2 If No, go to 2.0		
1.2	Does the manufacturer have products approved for sale in at least one of the following top tier countries Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland South Africa, United Kingdom or United States?	If Yes, go to 1.3 If No, go to 2.0		
1.3	Are the products approved for sale in 1.2 manufactured in plants registered with the U.S. Food and Drug Administration, Canadian Therapeutic Products Directorate, United Kingdom Medicines and Healthcare Products Regulatory Agency, Australian Therapeutics Goods Agency, European Medicines Agency, and/or other equivalent agencies, subject to PC's approval.	If Yes, the manufacturer meets standard 4.9 as a global manufacturer go to 3.0 If No, go to 2.0		
2.0	Is the manufacturer a First-Tier Indian Manufacturer?	Go to 2.1		
2.1	Is the Indian manufacturing plant registered with regulatory authorities of one of the following: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland South Africa, United Kingdom, and United States?	If Yes, the manufacturer meets standard 4.9 as a First-Tier Indian manufacturer, go to 3.0 If No, go to 2.2		
2.2	Does the Indian Manufacturing plant have global presence in at least one of the following top tier countries Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland South Africa, United Kingdom or United States?	If Yes go to 2.3 If No, the manufacturer does **NOT** meet standard 4.9 as a First-Tier First Tier Indian manufacturer		

2.3	Does the Indian manufacturer have products approved for sale in at least one of the following top tier countries Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland South Africa, United Kingdom or United States?	If Yes, the manufacturer meets standard 4.9 as a First-Tier Indian manufacturer, go to 2.0 If No, the manufacturer does **NOT** meet standard 4.9 as a First-Tier First Tier Indian manufacturer		
Pharmaceutical Product			**Yes**	**No**
3.0	Is the medication manufactured in a plant registered with regulatory authorities of one of the following: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland South Africa, United Kingdom, and United States?	If Yes, the medication meets standard 4.9 If No, go to 3.1		
3.1	Is the medication ethically promoted through the First-Tier Indian manufacturer's branded division?	Go to 3.2		
3.2	Does the First-Tier Indian manufacturer market the medication under a brand name?	If Yes, the medication is a branded-generic, go to 3.3 If No, the medication does not meet standard 4.9		
3.3	Is the 'branded generic' marketed through the branded division of the First-Tier Indian manufacturer?	If Yes, the medication meets standard 4.9 If No, the medication does not meet standard 4.9		