ORGANIZATION OF AMERICAN STATES

INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION

cicad

GROUP OF EXPERTS ON PHARMACEUTICAL PRODUCTS

Guide for health professionals concerning counterfeit drugs

Bahamas - Brasil

Lima, Peru

GENERAL SECRETARIAT OF THE ORGANIZATION OF AMERICAN STATES, WASHINGTON, D.C. 20006

TEMPLATE CHECKLIST FOR PROCUREMENT ENTITIES

1. Name and address of applicant/supplier(s)
2. Name and address of "Marketing Authorization Holder"
3. Name of pharmaceutical
4. Name and address of manufacturer of pharmaceutical
5. Country of original manufacture and export
6. DRA registration number of the product (or applicable registration number)
7. Product specifications:
    a. Product International Nonproprietary Name
    b. NDC or DIN number
    c. Formulation
    d. Strength
    e. Package size and primary container
    f. Therapeutic class (list all applicable)
    g. Therapeutic code (if applicable)
    h. Domestic (or institutional ID number)
    i. Listing of all active ingredients
    j. Therapeutic indication(s)
    k. Route of Administration

8. Notarized copies of the following must be presented:
    a. Official labeling and package insert for product
    b. Registration/licensure certificate for each supplier (or from applicable authority)
    c. DRA registration certificate for the product (or from applicable authority)
    d. Import certificate (if applicable)
9. All other applicable domestic/international requirements deemed necessary

Template Checklist for Drug Regulatory Authorities

Manufacturers & Distributors

1. Name and address of applicant/supplier(s)
2. Name and address of "Marketing Authorization Holder"
3. Name of pharmaceutical
4. Name and address of manufacturer of pharmaceutical
5. Country of original manufacture and export
6. Product specifications:
    a. Product International Nonproprietary Name
    b. NDC or DIN number
    c. Formulation & Strength
    d. Route of Administration
    e. Package size and primary container
    f. Therapeutic class (list all applicable) and code
    g. Domestic (or institutional ID number)
    h. Listing of all active ingredients
    i. Therapeutic indication(s)

7. Notarized copies of the following must be presented:
    a. Official labeling and package insert, with official product monograph
    b. WHO-type certificate from the country of origin for the product
    c. Proof of current GMP certification (or accepted equivalent) for the manufacturer
    d. Proof of current GSP & GTDP certification (or accepted equivalent) for manufacturer and each supplier
    e. Domestic business license (where applicable)

8. Pedigree records are accessible and in good order for all pharmaceuticals
9. Estimate of amount of the product to be repackaged (if applicable)
10. Relevant authorization for export/import of bulk API.
11. All other applicable domestic/international requirements deemed necessary

Template Checklist for Drug Regulatory Authorities

Pharmacy Facility

1. Name and address of facility
2. Name and address of applicant representing the facility
3. Position of person representing the facility
4. Type(s) of business/practice to be conducted within the facility and its grounds
5. Listing of pharmacy personnel and registration/licensure numbers
6. Inspection process should ensure that:
    a. Storage and supply conditions meet all current GSP standards
    b. Trade and distribution processes meet all current GTDP standards
    c. All concerns noted at the previous inspection have been addressed
    d. All pharmaceuticals in the facility have current DRA registration certificates
    e. All pharmaceuticals present in the facility correspond to the products on record
    f. All mandatory records are accessible and in good order
    g. Institutional processes exist for the reporting of adverse pharmaceutical events
    h. Institutional processes exist for the reporting of suspected counterfeit pharmaceuticals
    i. Pedigree records exist for all pharmaceuticals on the premises
    j. Mechanisms exist for patient feedback relative to their pharmaceutical products and care
    k. All domestic/international licenses are current relative to the stated scope of practice of the facility.
7. All other applicable domestic/international requirements deemed necessary

Template Checklist for Incident Reporting by Health Professionals Concerning Counterfeit Pharmaceuticals to DRA's

1. Name of pharmaceutical
2. Name and address of manufacturer of pharmaceutical
3. Name and address of applicant/supplier(s)
4. DRA registration number of the product (or applicable registration number)
5. Name and address of facility where product was made/distributed/dispensed
6. Name and address of patient (if applicable)
7. Product specifications:
    a. Product International Nonproprietary Name
    b. NDC or DIN number
    c. Formulation & Route of administration
    d. Strength
    e. Package size and primary container
    f. Therapeutic class (list all applicable)
    g. Therapeutic code (if applicable)
    h. Domestic (or institutional ID number)
    i. Listing of all active ingredients
    j. Therapeutic indication(s)
    k. Lot and/or batch number

8. Indication for which the product is used for in this case
9. Specific nature of complaint with product
10. List all documented adverse effects or physical abnormalities of product
11. List all undocumented reports of adverse effects or physical abnormalities of product
12. Strength, regimen, route of administration, and duration of treatment
13. If regimen was modified or discontinued, what effect was seen on the adverse effects?
14. If regimen was reintroduced, what effect was seen on the adverse effects?
15. Have you experienced any other difficulties with this product? If yes, give details.

Template Checklist for Patient-Education by Health Professionals Concerning Suspected Counterfeit Pharmaceuticals

NB. This information has been adapted from guidelines developed by Bryan A. Liang, MD, PhD, JD of the Institute of Health Law Studies, California Western School of Law and the San Diego Center for Patient Safety.[19] This information is meant only as a template for areas that can be covered by the health professional during patient counseling or education sessions. The dialogue listed is intended as a guide, and is not intended as a definitive detailing of patient counseling.

"If your physician has prescribed a medication that you have never taken before, request samples from your physician. This will allow you to compare the appearance, taste, texture, and reaction later to medications you receive later. It is important to note that manufacturer samples are usually only available for brand medications and not generics. You can save the sample's packaging for comparison later."

"If you are using the Internet to purchase medicines, please ensure that the Web site is a certified site. In this jurisdiction, the regulatory body that certifies Internet pharmacies is……. **OR** …..there is no authority to certify Internet pharmacies, so you may need to check for international certification like the VIPPS program in the USA."

" A good way to compare the prescription medicine you receive with what it is supposed to look like, is by taking pictures of the original manufacturer's drug and the packaging. You may also find pictures of these products in the Physicians Desk Reference available at your local library, or online in various credible sites. You will need to look for differences in paper quality, printing characteristics (is it the same size, raised print, embossed, etc.), color, and fonts. Pharmaceutical companies are very strict about the characteristics on their product and packaging, so any noticeable differences may be an indication that your product may not be genuine."

“Please note that if you are prescribed or dispensed a generic product, it may differ in shape or color and still be a safe and effective product. If you have any questions on the identification of medications, please feel free to ask me... **OR**… talk to your pharmacist.”

“Take note of the prescription drug’s taste and any associated feeling once you take it, especially if it feels different than usual. For example, if injecting a medication, is it supposed to burn? Is there anything unusual in your body’s reaction compared to when you took it before? Remember that counterfeit drugs can contain no active ingredient, not enough, or even too much of it. So if your drugs do not seem to have the same taste, or if you feel different than usual, immediately write down your symptoms and contact your doctor and pharmacist.”

“Do you feel that you are benefiting from the medication? Is your condition improving, stabilizing, or do you feel worse now that you are being treated with this drug? What did your physician or pharmacist tell you about how you should expect to feel while being treated, and when you should expect to begin feeling relief or improvement? If you should be feeling better by now, but are not, maybe we should evaluate the product you are taking.”

“If you find strong indications that the medicine you have been taking may be a counterfeit pharmaceutical, immediately remove it from your medicine cabinet. Distinctly mark the packaging so you will not mistakenly take it again. You can mark it with a red pen, or put tape around the top of the drug container so that it will be unavailable to you or others in your family. Take the medications to your local law enforcement officials and contact our local Drug Regulatory Authority for more information. In our jurisdiction, the local DRA is …… and is located……..”

“In our jurisdiction, the website for our local DRA is ……..and the phone contact is…..”

“Before you contact the local DRA office you will need to have information related to how you got the counterfeit medication and how long you have been taking it. One of the key issues is where you purchased the medication. Did you buy it from a website, a mail order facility, or

from a local pharmacy? When did you purchase the medication? Do you still have the packaging? How long have you been taking the counterfeit drugs? These are all questions that you will be asked in order to process your complaint."

"If you need to take this medicine routinely, you will have to contact your physician or pharmacist to arrange for a new supply so that you can resume your treatment."

Template Form – Incident/Product Report for General Public

1. What is the name of the medicine that you are taking? If there are more than one names on your product packaging, list all of them.

2. Have you ever taken this medication before? If so, was it the same brand or generic that you are taking now?

3. What condition are you taking this medication for?

4. What is the name of the prescribing physician or health professional?

5. What is the name of the healthcare facility where you were treated?

6. Where (or who) did you obtain the medication?

7. What does your medication look like?

8. Describe how it made you feel after taking it?

9. Have you noticed anything different about how the medication looks, feels or tastes?

10. Have you noticed anything different about how the packaging looks or feels?