nhra BAHRAIN
الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

مكتب الرئيس التنفيذي
Chief Executive Office

مملكة البحرين
Kingdom of Bahrain

Circular (41) 2020

To all Hospitals, pharmaceutical companies and agents

Subject: Procedures for importing non-registered medicines and pharmaceuticals products

Reference to the Resolution No. (32) Of 2020 Issuing regulation for medicines and pharmaceutical products registration system and determination of their prices and announcing them, please be informed of the following new regulations regarding Governmental and private hospitals' and agents' procedures to import non-registered medicines and pharmaceutical products**:**

First: Governmental and private hospitals' Procedures for importing non-registered medicines and pharmaceutical products:

A- Import conditions:

1- Obtaining the authority's permission to import non-registered medicines and pharmaceutical products before issuing the purchase order.

2- The required medicine or pharmaceutical product is of importance and there is no registered alternative available in the Kingdom.

3- The medicines or pharmaceutical products are registered with the Gulf Health Council or with one of the countries of the Gulf Cooperation Council for the Arab Gulf States.

4- The medicines or pharmaceutical products are identified with the authority or registered with one of the following authorities:

A) (FDA) - US Food and Drug Administration.
B) (HEALTH CANADA)
C) (EMA) - European Medicines Authority or a Western European country.
D) (SWISSMEDIC)
E) (TGA) - Australian Medicines Administration.
F) (Pmda) - Japanese Ministry of Health.
G) (MHRA) - British Medicines and Health Products Authority.

5- The medicine or pharmaceutical products are marketed in the country of origin.

6- The requesting party must commit to issuing the purchase order for registered medicines and pharmaceutical products from one of its agents approved by the authority without considering the price difference with the non-registered substitute or the product that will be supplied from other than its agent, with the exception of innovative medicines.

7- The requesting party must verify that there is no registered substitute for the required product with its agents, and if there is no registered alternative for the product, the Authority must be notified.

8- The manufacturing company must be registered with the authority or registered centrally in the Gulf health Council except for the inability to obtain the product from registered companies.

9 - Quantities are requested by the requesting party for enough period of time, provided that they are not sold or loaned without the knowledge of the authority.

10- The outer packages of medicines and pharmaceutical products should contain the trade name, scientific name, strength, storage conditions, batch number, pharmaceutical form, production and expiry date, and the name and address of the manufacturer.

11- To transport and preserve the medicines and pharmaceuticals products in containers according to the conditions of transport and storage recommended by the manufacturer.

12- Some medicines and pharmaceutical products for the treatment of rare and emergency cases and tumors that have no registered alternative are excluded from the requirements referred to in (3), (4) and (5) of this clause, according to the list of emergency medicines attached to this decision or based on Board approval.

B- Import permit requirements:

Those wishing to import non-registered medicines and pharmaceuticals products must apply to the office, by e-mail, accompanied by the following documents:

1- Application form with all its data.

2- A copy of the Medicines and Pharmaceutical product Certificate (CPP) or the registration certificate of the medicine or product issued by one of the countries or authorities referred to in (4) of Clause (A) of the first paragraph of this Article.

3- A copy of the good manufacturing practice (GMP) certificate of the manufacturer, provided it is issued from the country of origin or one of the countries referred to in (4) of Clause (A) of the first paragraph of this Article.

Second: Agents' Procedures for importing non-registered medicines and pharmaceutical products:

A- Import conditions:

Agents of medicines and pharmaceutical companies that have submitted the registration files may request importation until the registration of the medicine and pharmaceutical product is completed, provided that the conditions from (1) to (4) stipulated in Clause (A) of the first paragraph of this Article are fulfilled.

B- Import permit requirements:

For agents who wish to import non-registered medicines or pharmaceutical products must apply to the office, by e-mail, accompanied by the following documents:

1- Application form with all its data.

2- A copy of the Medicines and Pharmaceutical Product Certificate (CPP) or the product registration certificate issued by one of the countries or-authorities referred to in (4) of Clause (A) of the first paragraph of this Article.

3- A copy of the good manufacturing practice (GMP) certificate of the manufacturer, provided it is issued from the country of origin or one of the countries referred to in (4) of Clause (a) of the first paragraph of this Article.

In the event of requesting medicines and pharmaceutical preparations for the treatment of rare and emergency cases and tumors that do not have a registered alternative and do not meet the requirements referred to in (3), (4) and (5) in item (A), please send a letter to the authority to obtain the Chairman of the Council's approval to permit for importation.

Address your requests with the complete requirements as the above, checklist and application form filled appropriately, to the designated PPR department staff.

Dr. Mariam Athbi Al Jalahma
Chief Executive officer

Attached resolution (32), checklist and application form.