Biotechnological Drugs in the Dominican Republic

General Directorate of Drugs, Food and Medical Devices of the Ministry of Public Health and Social Assistance

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Junio de 2016
The Ministry of Public Health – MPH-, through the General Directorate of Drugs, Food and Medical Devices –DIGEMAPS- (spanish acronym), is responsible for the implementation of the provisions of the General Health Law 42-01, the Regulation on Drugs, Decree 246 -06, and all regulations related to products, establishments and persons authorized within the pharmaceutical sector.
The primary objective is to ensure the quality, safety and efficacy of all products, through the regulation of the sector.

This regulation also extends to raw materials, excipients, materials used for the preparation, manufacture and packaging, plus all necessary measures to develop health surveillance.
The **General Directorate of Drugs, Food and Medical Devices** has been created by decree No. 82-15, issued on April 6, 2015…

… this directorate consolidates the former General Directorate of Drug and Pharmacies and the former Department of Food of the General Directorate of Environmental Health.

✓ Also, the need to re-structuring for the compliance given in the regulation, control and monitoring of drugs, medical devices, food, beverages, cosmetics, hygiene (care) products, technologies and materials for human use.
Pharmaceutical product whose active ingredient is made from a living organism whose genetic structure has been modified through technology, through techniques such as recombinant DNA, antibody-based methods, etc. These drugs can be recombinant proteins, monoclonal antibodies, vectors to transport genetic material, vaccines, etc.
An innovative biotechnological drug is one that has been authorized by the health authority on the basis of a full registration dossier and the indication or indications for use were authorized on the basis of full quality, efficacy and safety data according standards of international guidelines published by the reference entities (FDA, EMA, ICH, WHO)
A biotechnological drug similar in terms of quality, safety and efficiency to a previously authorized innovative biotechnological drug. These products are known in other jurisdictions as "biosimilars"
Biotechnological products in the Dominican Republic:

- Promote development and access of biotechnological drugs through a fair and balanced regulatory framework ensures that more citizens have the possibility of benefiting from such therapies.

- The pharmaceutical market for these products is valued with a significant potential growth in the Dominican Republic.

Biotechnological products represent a significant advance in the cost effectiveness of the treatment of chronic diseases in developing countries.
Now the Dominican Republic is in the process of formalizing a specific regulation for the registration of biotechnological drugs.

To date, the regulation is made on the basis criteria of the general principles established in the existing legal and general framework of drugs.
The Ministry of Public Health and Social Assistance through the DIGEMAPS has to drawing up the list of innovative biotechnological drugs reference.

Criteria for choosing the biotechnology drug reference:

- The innovative biotechnological drug reference must be authorized in the Dominican Republic and the same must have been marketed for at least five (5) years.
Criteria for choosing the biotechnology drug reference:

- b) The innovative biotechnological drug reference must have been authorized on the basis of comprehensive data of quality, safety and efficacy.

- c) The same innovative biotechnological drug should be used throughout the development process of the not innovative biotechnological drug during all stages of the exercise of comparability and to demonstrate the similarity in terms of quality, safety and efficacy.
In case the innovative biotechnological drug reference not be authorized in the Dominican Republic, the Ministry of Public Health and Social Assistance, through the DIGEMAPS, can choose the same, on the basis that it has authorizations from regulatory authority concerned strict by WHO

- Has submitted a full record dossier
- Possible demonstration of similarity
General requirements:

a) Description and detailed assessment of the methods used by the manufacturer.

b) Details of related quality control and origin of the raw material used for production process and controls in that process, as well as an extensive characterization for product development and quality control, consistency and robustness of production between batches and stability of the active ingredient and the finished product.
Biotechnological products in the Dominican Republic:

Requirements for sanitary registration of innovative and non-innovative biotechnological drugs

c) The authorities of the MPH will follow international guidelines published by the Food and Drug Administration of the United States of America (FDA), European Medicines Agency (EMA), International Conference on Harmonization force (ICH) and / or World Health Organization (WHO).

d) Innovative and non-innovative biotechnological drugs must submit their own program of risk management and pharmacovigilance plan.
Biotechnological products in the Dominican Republic:

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e) It is understood that the marketing and use of non-innovative biotechnological drugs should not involve as acceptable practice the generic or automatic replacement with innovative biotechnological drug and/or interchangeability without the consent of the prescribing physician to avoid immunogenicity and/or other potential adverse reactions.
Quality requirements

✓ For the active ingredient
✓ For the finished product

Innovative biotechnological drugs, must submit:

a) Non-clinical studies.
b) Clinical trials in phase I, II and III.
c) Risk management and pharmacovigilance plans (post-marketing).
Biotechnological products in the Dominican Republic:

In addition to the above, they must submit:

a) Results for the comparability exercise
b) Comparative studies of quality attributes
c) Comparative non-clinical studies
d) Comparative clinical studies with the reference product, preferably of equivalence
e) Letter of approval of the Scientific Ethics Committee, endorsed by the Regulatory Agency
f) Risk Management and Pharmacovigilance plans

Requirements for sanitary registration of innovative and non-innovative biotechnological drugs

Non-innovative biotechnological drug
The type and number of studies depend on the characteristics of the reference product and the therapeutic indications that are requesting, considering the current International Guidelines published by the FDA, EMA, ICH and/or the WHO.

Requirements for sanitary registration of innovative and non-innovative biotechnological drugs

Non-innovative biotechnological drug
If it is observed significant differences in quality studies, nonclinical and/or clinical, it is probably that the product does not meet the requirements of a non-innovative biotechnological drug and consequently require further information nonclinical and clinical, in order to support the application for authorization in accordance with the provisions of the regulation.
Biotechnological products in the Dominican Republic:

- Extrapolation of indications.

- All therapeutic indications applied for in the register, both for innovative biotechnological drug and for not innovative one, must be demonstrated in reports of clinical studies.

- For non innovative biotechnological drugs is possible the extrapolation of indications, provided they comply with the provisions of the current International Guidelines published.
Innovative and non-innovative biotechnological drugs must comply with the labeling requirements and paper insert according to current legislation.

Unlike generic pharmaceuticals products, the applicant sanitary registration of a non-innovative biotechnological drug cannot use the innovative biotechnological drug monograph (reference) in full as his own product.

Should not declare claims of bioequivalence.
Biotechnological products in the Dominican Republic:

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http://www.drogasyfarmacias.gob.do/
http://www.sespas.gov.do/

Thank you for your attention!!!