Technical Sub Committee's Implementation for Drug Technical file review

The Technical Committee (TC) of Drugs is defined by the **Article 54 of the Pharmacy Profession Law 367/1994**. Its main activity is to provide Market Authorization (MA) for drugs.

The TC bylaw or internal regulation issued in 2012 clarifies its mission, structure, working and meeting procedure and describes its duties.

According to the Article 4 of the bylaw, the TC may refer to subcommittees or external experts to review a part of a medicine's technical file. While the number of generic drugs coming from Non Reference countries was increasing, the MoPH had the urge to better organize the file's review and to reinforce the evaluation before the grant of a MA.

To do so, a **Ministerial Decision #1634/1/2013** was issued to seek for experts in drug registration selected among specialists and academicians from different Lebanese universities to study and evaluate Module 3 and Module 5 of drug CTD file.

Experts in Pharmacology, Pharmacokinetics, Pharmacotechnology, Analytical and Organic chemistry were selected and recruited after submission of their CVs to MoPH.

In 2014, two sub committees (SC) were formed and started officially to evaluate, review files and submit a technical reports to the TC. While the 2 sub committees act as consultants, the TC is the decision maker regarding the grant of MA.

Moreover, other activities were attributed to the SC. In fact, to improve the review and the evaluation of Module 3 and Module 5 of the Drug Technical file, the SC experts drafted the following 4 Guides:

- Guideline for the Quality Module 3- Part S - Drug Substance- 2017
- Guideline for the Quality Module 3- Part P - Finished Product- 2017
- Guideline for Bioequivalence - Module 5- 2017
- Guidelines for Bioequivalence Biowaivers: Criteria, Requirements and checklist.

These Guidelines were intended to provide guidance and requirements for the importers of drugs to well prepare the technical file to be submitted to the MOPH Technical Committee of Drugs and to optimize the review by the subcommittees. These guidelines are based on ICH standards and are useful for the applicants of Generic Drug Technical file. Two editions were published in 2015 and in 2017 based respectively on **DG Decision #1343/2/2015 and on DG Decision # 344/2/2017**

Furthermore, and to make sure that the already registered medicines were conform to the standards set by the MoPH, a reevaluation process of those medicines has been put in place along with **Ministerial Decision #293/1/2015**, **Memorendum 114/2016 and Ministerial Decision #538/1/2017**. Priorities have been set, and the reevaluation process started with Generics coming from non-reference countries. In addition, drugs for reevaluation were categorized based on the importance of their therapeutic uses such as Antineoplastic and Immunomodulating agents as well as the Generic drugs purchased by the MOPH

The importers have to submit the drug technical file for reevaluation as if they were applying for a new medicine.

Several technical training workshops have been delivered to the SC experts on the file review methodology since their recruitment in order to verify the efficacy of the evaluation and the method of writing reports.