GGM Recommendations in 2009 and updates in 2019

Recommendation	Addressed	Implemented
Registration		
• Specify a time-frame for an application to be studied by the committee. There is a need for faster registration processing.	Agenda and MoM of technical committee are published	Yes
• Develop a clearly written document for the public explaining how registration decisions are taken by the committee.	Guidelines/SOPs developed	Yes
• Develop written guidelines to be followed by the registration committee in the registration process.	Guidelines/SOPs developed	Yes
• Ensure that formal appeals are submitted to a different regulatory body	No	
• Widely announce to the public that all the registration forms and requirements are already available on the website	Done	Yes
• Enforce a re-registration process of medicines every 3 to 5 years. In Lebanon, medicines are registered for life.	Yes	Yes every 5 years
• Develop a conflict of interests form to be signed by the members of the registration committee.	Developed	Yes
• Provide technical support in terms of access to international information and access to data in order to check the data provided by medicine importers.	Yes For more details, kindly check the attached brief about Sub-committees role in reviewing and evaluation registration files	All members of the technical committee has access to international information via different sources, i.e MedScape

		Sub-committees were formed from experts from academia to give advice on drugs from non-reference countries and to evaluate generic files; mainly module 3 and 5
Control of medicine promotion		
• Develop a more detailed law for medicine promotion. The existing law is explained in five lines.	Partially	Many ministerial decrees were issued in this regard
• Write standard operating procedures for the control of medicine promotion based on the newly developed law.	General guidelines were developed and posted based on the code developed	Partially Implemented
• Develop a code of ethics for all medicine promotion activities to the public and to professionals to be enforced by the Ministry and the orders of pharmacists an physicians.	Code of ethics is developed	Partially Implemented
• Form an official committee inside the Ministry of Health and involve other relevant parties such as medical societies and academia to approve promotional material and take action against unethical promotional practices by pharmaceutical companies and individuals.	Developed by a ministerial decree	No
Inspection		
• Centralize the process and introduce a reporting system which is the responsibility of one party to ensure better coordination.	Yes	Yes

• Introduce capacity building activities for the inspectors.	Yes	Yes supported by WHO and LU
• Better equip the inspector teams with cars and computers.	No	
• Provide legal protection to inspectors as some inspection operations can be dangerous.	Yes	Ministerial decree to ministry of interior to provide support when needed
• Follow-up on the inspection results through the courts and enforce severe sanctions in cases of violation, particularly in cases of medicine smuggling and counterfeiting.	Yes	Yes
• Introduce new standards for GMP for local manufacturers and inspection activities that target manufacturers in the country.	New guidelines were developed in 2009 and in 2018 will undergo another round of updating	Yes
Selection of Medication		
• Re-activate the selection committee	Yes	Yes
• Update the essential medicines list and make it widely available to all by nationwide distribution of hard copies and placing it on the Ministry of Health website.	Updated in 2010 Now in the process of updating before end of 2018	Yes At PHC level
• Introduce written criteria for the selection of the committee members.	No	
• Develop written criteria for the selection of medicines to be added to or removed from the essential medicines list. Include the use of evidence-based and cost-effectiveness information in the selection process.	Yes	Based on WHO criteria in addition to some requirements based on the Lebanese context
• Publicize the essential medicines list widely within the private sector to encourage its	Yes	Partially done at the PHC

use among practitioners. The gap between the public and the private sector needs to be bridged in order to coordinate this.		level only not in the private sector
Procurement at the MOH level		
• Consider the impact of external influences on the procurement process.	Yes Mainly funding limitations and debt	
• Develop standards for the medicines needed and quantities required based on real needs bearing in mind quality.	Yes	Yes
• Introduce a computerized system for all the steps involved in procurement, starting from announcing the tender or the bid up till procurement is complete.	No	
• Include generics with established quality in the process.	Yes	Yes
• Announce the tender in all newspapers and on the website of the Ministry of Health with the tender list of medicines. Give enough time between the announcement and the deadline for application.	Yes	In 3 newspapers and on website
• Announce the results to the public with justifications.	No	No
Distribution		
• Develop a better coding system for marking medications that are distributed by the Ministry of Health to ensure that it cannot be tampered with.	Partially	Not coding system but a sentence to be added on the outer box and the box is permanently marked
• Introduce security management and install an alarm system and cameras inside the central medicines warehouse.	Yes	Yes

• Link all points of distribution to each other for easy traceability of medicine stock and a faster ordering system between all levels of distribution and the central medicines warehouse.	Bar code project	Pilot phase started
• Post the list of medicines available without charge from the Ministry of Health on the Ministry of Health website.	Yes	Yes
• Ensure the supply of medicines in a practical manner and put a system in place to ensure continuous medicines supply. This can only be guaranteed with proper policy-based budget planning, revision of the current time-consumption, procurement practices and enforcement of Ministry of Health therapeutic guidelines in medicine dispensing.	Yes	Yes
• Involve the media in order to announce the processes of selection, procurement and distribution to the public, since these are sensitive issues that directly affect patients.	No	
Clinical Trials Regulations		
• Legal provision requiring the regulation of CT	Ministerial decrees and memos	Yes
• Written guidelines on principles of GCP	Yes	We follow the international GCP
• Written and publicly available guidelines on submission of application to MOH to conduct CT	Yes	Yes
• Documented policy or procedure for submission of CT applications to Independent IRBs	Yes	Yes
• Requirements for the manufacturing, importation, exportation and use of investigational products	No	
• Formal Review committee in the MOH responsible for reviewing applications and CT results	Yes	Relevant to importation of IMP Does not review results
• CT inspection system	No	
• Publicly available list/database of all approved and rejected CT applications-Registry	Yes	Pilot just started