REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

Quality Assurance of Pharmaceutical Products Program Implementation

ESA

18 December 2013

Presented by: Dr. Rita Karam

Outline

REPUBLIC OF LEBANON
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- Introduction
- Program Main Objectives
- Program Action Plan
- Program Activities
- Conclusion

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Introduction

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Ensuring and providing high quality health services for all citizens at the lowest possible cost

- Issuing a new resolution 1686/1 dated 10/23/2012 for the establishment of a new program entitled **Quality Assurance of Pharmaceutical Products (QAPP).**

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Program Main Objectives

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- Strengthen the implementation of Quality Standards relating to the Safety of Pharmaceutical Products
- Ensure that all practices related to drugs such as manufacturing, registration, importation, storage, distribution and dispensing are compliant with the International Quality Standards and predetermined specifications
- Raise awareness and training among the actors involved in the registration of drugs

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Program Action Plan

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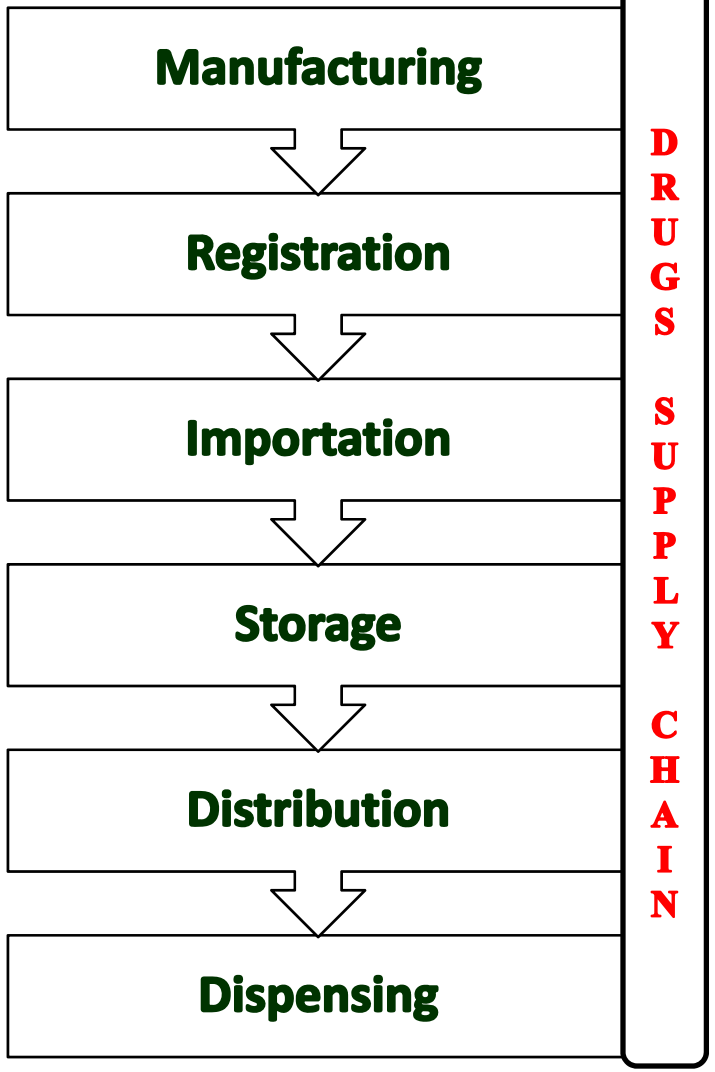
WHO – ANSM – EMA – FDA

- New Classification of Post Marketing Variations Type I and II for Imported and Locally Manufactured Drugs
- Regulatory Guidelines for Biosimilar Medicinal Products in Lebanon
- Manual of SOPs for Pharmacy Service and Pharmacy Departments
- Guidelines on Good Storage and Distribution Practices of Pharmaceutical Products (GSDP)



QAPP Program Activities - 2013

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Project # 1

New Classification of Post Marketing Variations Type I and II for Imported and Locally Manufactured Drugs (Law # 530 - Decree # 571)

Detected Gaps	Activities Done by the QAPP	Trainings	Regulation
Gaps related to the Classification of Post Marketing Variations of Drugs	• Reviewing the post marketing changes • Preparing a new classification of post-marketing variations • Updating relevant documents required for each new variation • New classification technically and structurally inspired by several International Guidelines mainly WHO guidelines	Two training workshops were organized in 2013 in collaboration with experts from ANSM	• Resolution #1638/2013 formed a special committee to propose amendments to the Decree 571/2008 concerning the new classification of the post-marketing changes • Awaiting for the committee approval and an update of legal texts

QAPP Program Activities - 2013

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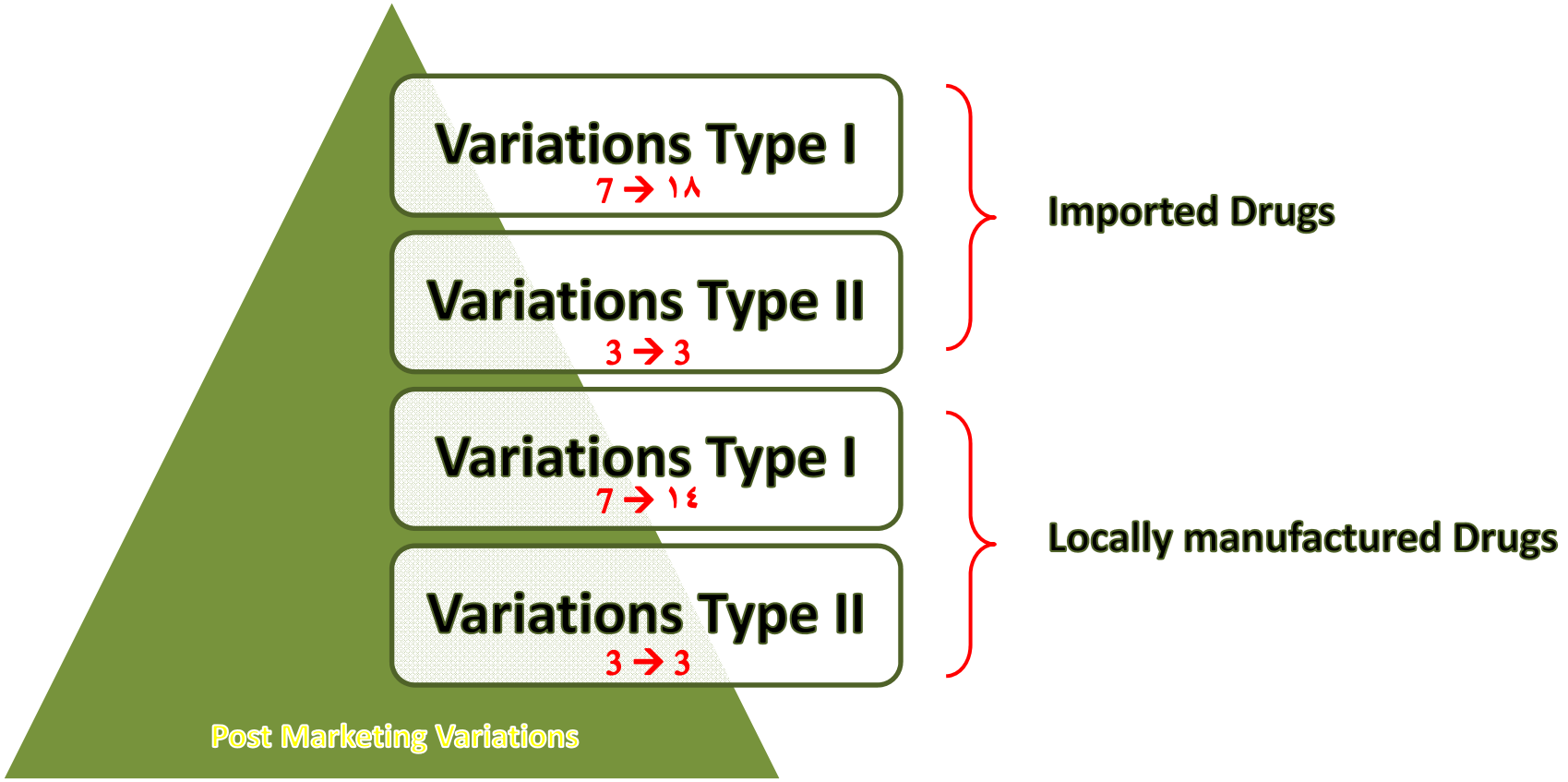
Project # 1: Modifications



Based on WHO recommendations and guidelines

QAPP Program Activities - 2013

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Project # 2

Regulatory Guidelines for the Registration of Biosimilar Medicinal Products in Lebanon

Detected Gaps	Activities Done by the QAPP	Regulation
▪ Biopharmaceuticals and Biosimilar medicinal Products are drugs prepared by Biotechnological processes. ▪ In order to assure the biosafety and efficacy of Biosimilar drugs, the MOPH decided to develop Requirements and Guidance for Registration of Biosimilar drugs.	▪ Guidelines and Requirements were drafted for Registration of Biosimilar medicinal products which follows the EMA guidelines, WHO and ICH Guidance on Similar Biological Products in collaboration with *ansm* (Format CTD).	▪ Resolution#1638/2013 formed a special committee to propose amendments to the Decree 571/2008 concerning the Regulatory Guidelines for Biosimilar medicinal products in Lebanon ▪ Awaiting for the committee approval and an update of legal texts

QAPP Program Activities - 2013

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Project # 2: Guidelines for Biosimilar Medicinal Products

Proposed Requirements and Guidance for the registration of Biosimilar medicinal products based on international CTD format

Requirements according to CTD format

Module 1 Administrative information	Module 2 Overview of M3, M4, M5	Module 3 Quality	Module 4 Safety	Module 5 Clinical	Pharmacovigilance and RMP Plan

QAPP Program Activities - 2013

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Project # 3

Manuals of SOPs for Pharmacy Service and Pharmacy Departments

Detected Gaps	Activities Done by the QAPP	Regulation
SOPs were missing. They are the most important components of a Quality Manual as they provide sufficient information to carry out the work concerned and to ensure the **Quality of Service** in the Pharmacy Departments	• Two Manuals of SOPs, for the Import Export Department and for Pharmacy Service were drafted • Flow charts were drawn to visualize a process and to represent the essential elements of a given procedure	• Resolution #1635/2013 was issued to adopt the SOPs Manual • The two Manuals are published already on moph website

QAPP Program Activities - 2013

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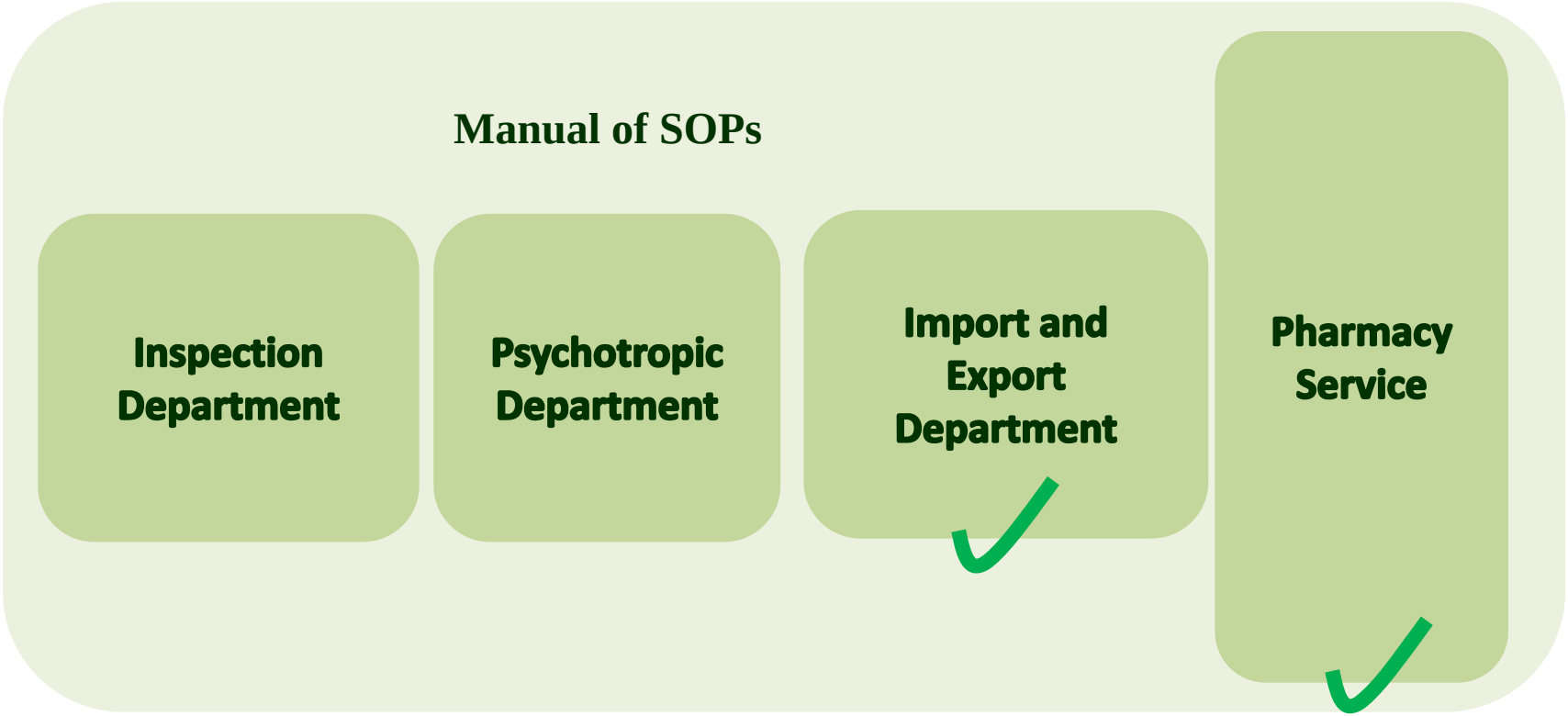
Project # 3: Manual of SOPs



QAPP Program Activities - 2013

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Project # 4

Guidelines on Good Storage and Distribution Practices of Pharmaceutical Products (GSDP)

Detected Gaps	Activities Done by the QAPP	Regulation
Need to ensure the Quality and Identity of drugs during the whole distribution process and to avoid the introduction of counterfeits products into the marketplace via the distribution chain	• Guidelines were drafted according to the Guidelines and Instructions of the WHO and ISO 9001:2008 for Quality Management System • Feedback was taken from the OPL, LPIA and the LAPI before the publishing of the Guidelines • The comments and remarks were taking into consideration	• Resolution #1637/2013 was issued by the Minister of Health to adopt the GSDP Manual • The final version is published now on the MOPH website

QAPP Program Activities - 2013

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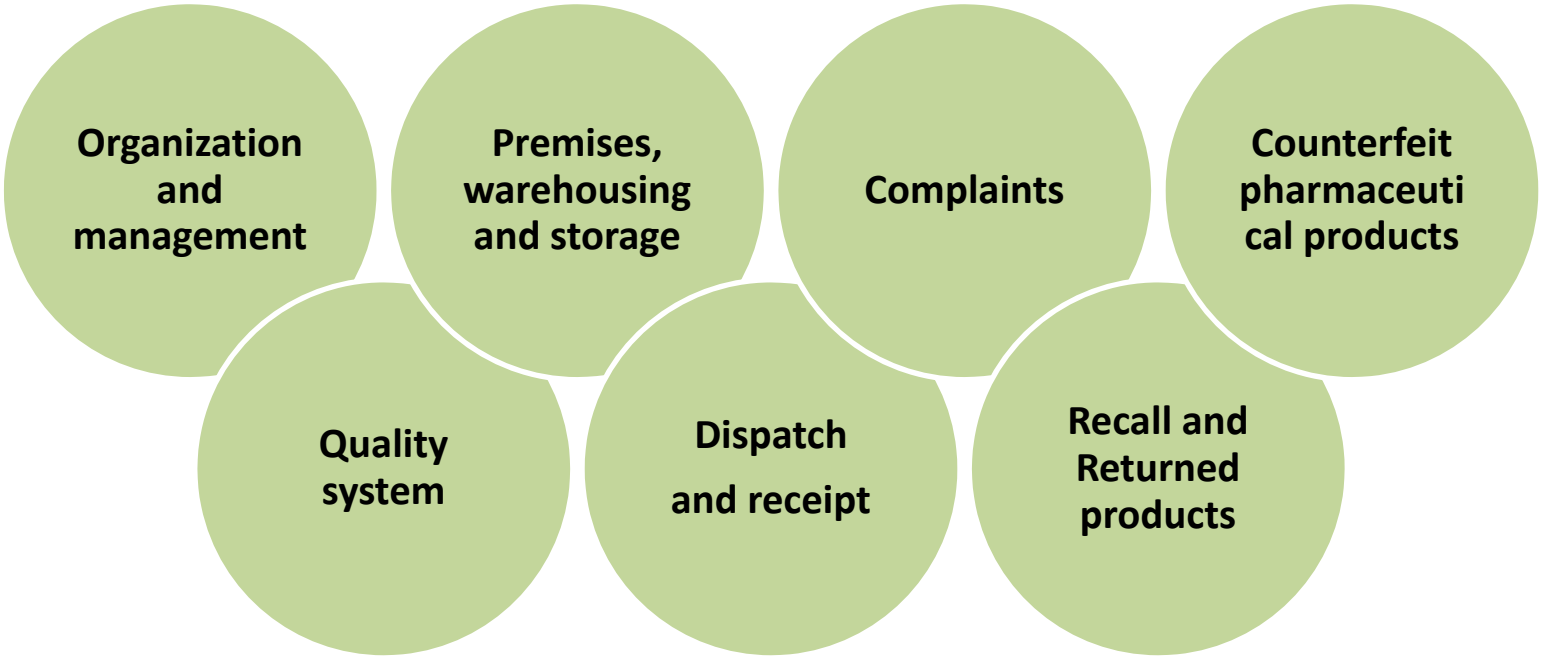
Project # 4: Content of GSDP



GSDP Chapters

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Conclusion

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Next Steps of the **Quality Assurance of Pharmaceutical Products Program**

Projects currently under development

- Project #3: document 2 Manuals of SOPs for Psychotropic drugs and Inspection Departments
- Two subcommittees of Experts to study and to evaluate Module 3 (Quality) and Module 5 (Bioequivalence) of the Drug Registration Technical File.

Future Projects

- Drafting Guidelines for Good Pharmacovigilance Practices (GPVP)
- Project #4: Implementation of Other Articles of the Resolution #1637/2013 related to the Guidelines for Good Distribution and Storage Practices (GDSP)

Project under development

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Establish 2 subcommittees of experts to study and to evaluate Module 3 (Quality) and Module 5 (Bioequivalence) of the Drug Registration Technical File

Detected Gaps	Regulation
Need to evaluate the drugs technical files submitted for registration.	Resolution #1634/2013 to seek for experts in drug registration selected among specialists and professionals from different universities to study and evaluate Module 3 and Module 5 of drug CTD file.

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Future Projects

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Pharmacovigilance Committee for Examination and Evaluation of ADR

Detected Gaps	Regulation
Early detection of unknown Adverse Drug Reactions (ADR) Detection of increases in frequency of known Adverse Drug Reactions	Resolution #1636/2013 to form a PV Special Committee: • Collect data related to ADR • Review and evaluate ADR data • Communicate with PV centers of other countries. • Draft reports to the Drug Technical Committee

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Future Projects

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Project # 4: Guidelines on Good Storage and Distribution Practices of Pharmaceutical Products (GSDP)

Other Articles of the Resolution #1637/2013: Guidelines on Good Storage and Distribution Practices of Pharmaceutical Products (GSDP)
Training on GSDP Guidelines for the MOPH inspectors and the pharmacists of the MOPH affiliated drug distribution centers
Implementation of the Guidelines by the pharmaceutical institutions in 2014
Monitoring the implementation of the GSDP by the Inspection Department and First Assessment of the pharmaceutical institutions by a Special Committee
Certification for Pharmaceutical Institutions who applied GSDP Guidelines by the Minister of Public Health

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Thank you!