



EFFECTIVE USE OF PHARMACOPOEIAS

23 Septembre 2022

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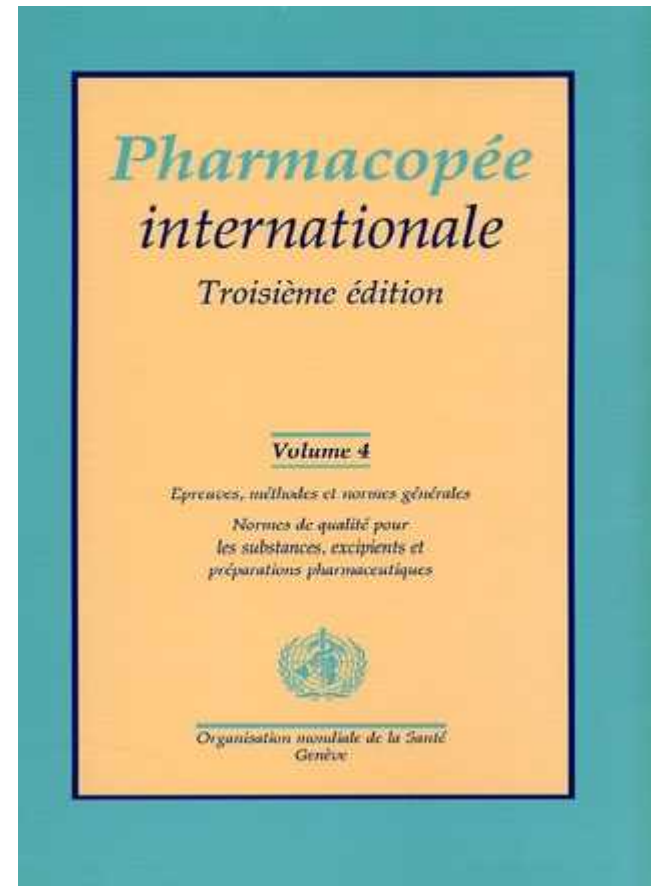
GENERAL ASPECTS (1)

- Pharmacopoeias are collective and official collections of prescriptions on the quality of medicines
- They contain binding rules, which have force of law to apply to all medicines.
- They are periodically revised by a scientific commission, published by each country or a group of countries and WHO
- They serve as a legal and binding standards for specifications, preparations, quality control tests and others characteristics of medicinal products.

GENERAL ASPECTS (3)

Around the World : national and international Pharmacopoeias:

- ✓ International Pharmacopoeia,
- ✓ European Pharmacopoeia,
- ✓ African Pharmacopoeia,
- ✓ American Pharmacopoeia,
- ✓ Indian Pharmacopoeia,
- ✓ French Pharmacopoeia,
- ✓ Japanese Pharmacopoeia,
- ✓ Chinese Pharmacopoeia,
- ✓ Others...



GENERAL ASPECTS (4)

❖ Coexistence of an increasing number of pharmacopoeias, due in particular to lot of pharmaceutical activities of emerging countries, has increased the complexity of analytical and regulatory landscape and poses growing problems of harmonization.

▪ Harmonizing these documents is not so easy, mainly because authorization procedures are different and their evolution over time has not been identical in countries and regions.

▪ However, efforts are also being made to harmonize pharmacopoeial prescriptions globally.

EFFECTIVE USE OF PHARMACOPOEIAS (1)

What are Pharmacopoeias used for?

❖ Industrial processes and formulations of pharmaceutical products,

❖ Marketing authorization process in the different countries and regions

Pharmacopoeias are undeniable support for:

❖ Analytical development and quality control process

❖ Surveillance of national and international markets,

❖ Regulatory affairs for products intended for national and international markets



EFFECTIVE USE OF PHARMACOPOEIAS (2)

Effective use of pharmacopoeias requires:

❖ To develop knowledge of general texts and specific monographs as any preparation must comply with specific monograph

Users must work to provide regularly updated pharmacopoeias they use

To know pharmacopoeias organization, operations and missions in order to get the best out of them for activities

To Know where and how to view information from different pharmacopoeias, online or otherwise

EFFECTIVE USE OF PHARMACOPOEIAS (3)

ADVANTAGES OF EFFECTIVE USE OF PHARMACOPEA:

- ❖ Essential support for the sustainability of pharmaceutical industry and systems because
- ❖ They represent reference tools, a regulatory and legal basis for industries and pharmaceutical health professionals
- ❖ Regular update in the whole pharmaceutical system
- ❖ For professionals, establish uniform general conditions in terms of quality, so
- ❖ All populations have access to good medicines
- ❖ Instruments to use against falsified and substandard medicines

Ultimately, they are instruments to protect public health
Protect public health

IN SUMMERY

- ❑ A good knowledge of the characteristics of pharmacopoeias, their mode of operation, their common points and their specificities, is therefore essential to allow international development of medicines and consequently permits free movement and free exchange of medicines between countries and regions;
- ❑ All professionals must constantly update their knowledge;
- ❑ It is important to keep informed of developments through pharmacopoeias for an efficient, sustainable, robust pharmaceutical system at the service of health in the world.

MERCI!

