



Federal Agency for Medicines and Health Products (FAMHP)

Practical implications of changes within the herbals regulatory environment:

01. Legal background

Unit Homeo - Phyto



Public health problem statement

Herbal Health Care

- has gained popularity and validity in recent years
- herbals have been recognized as a medically legitimate form of treatment and prevention.

Regulatory environment has opened up:

- > pharmaceutical manufacturers identified the herbal health care market as a growing industry
- > high potential.

Scientific validation of herbal remedies -> impact upon consumer demand.

People concerned about:

- aging and related illness
 - side-effects of conventional medicines
- > have embraced NATURAL self-care which may lead to longer, healthier lives.

Public health problem statement

More than before, natural remedies are used to treat the common “problems” of daily living:

- indigestion,
- sleeplessness,
- common cold, ...

A lot of the used preparations are of herbal origin.

ASSOCIATED RISKS:

- The general public => herbal (natural) = safe
- Extrapolation of non-applicable data between preparations due to the matrix effect
- People do not mention the use thereof to their doctors which may lead to interactions or complications (in relation to other treatments)

Public health problem statement

MATRIX EFFECT

- Nature is “well built” => buffer for harmful effects
- Herbal preparations are a complex mixture of substances.
- Complexity may contribute to efficacy and safety
- Complexity may also explain possible side effects and interactions
- Toxicity may appear/disappear after e.g. extraction
- Efficacy may increase/decrease after e.g. extraction
- Care needed when extrapolating data : herbals used as such or used after processing.

PROBLEM: effects seen when used in tradition are used as a basis for developing concentrated extracts that no longer respect the traditional matrix.

FAMHP and (Traditional)HMP

Challenge/mission of the Federal Agency for Medicines and Health Products (FAMHP):

The FAMHP ensures, from development to use, the

- quality
- safety
- efficacy

of medicines for human and veterinary use

- including homeopathic medicines
- herbal medicines
- pharmacy made and officinal preparations
- medical devices and accessories
- raw materials for the preparation and production of medicines.

⇒ **What about Herbal Medicinal Products (HMP)?**

FAMHP and (T)HMP

Fields of competency of the FAHMP:

Registration/marketing authorization: evaluation of new requests for registration or marketing authorization of a medicine or changes thereof.

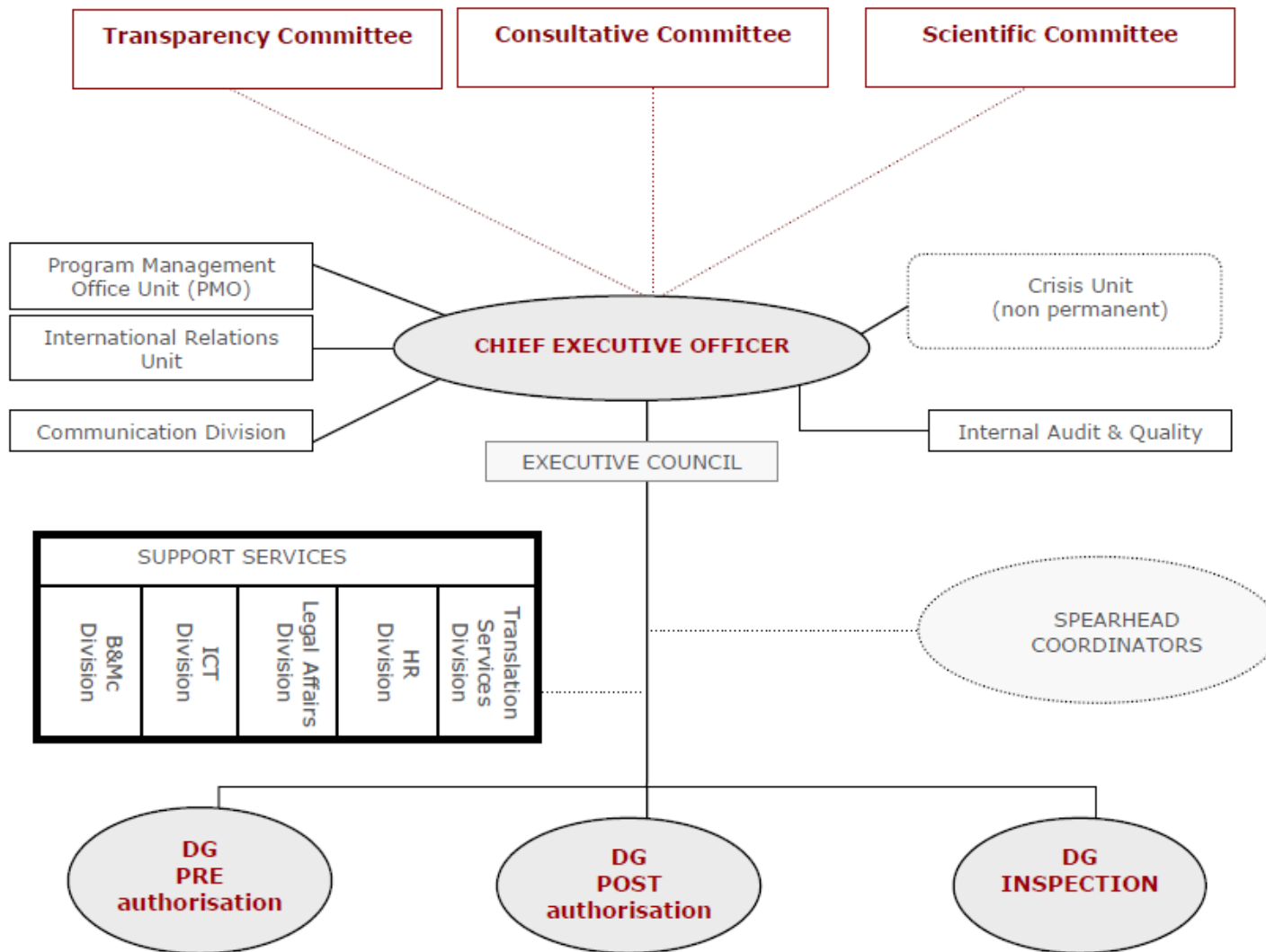
Vigilance: supervise the adverse effects due to the use of medicines or health products by collecting information which is evaluated and, if necessary, measures are taken.

Production/distribution: grant authorizations and check that medicines and health products are conform current regulations concerning manufacture, distribution, delivery, imports/exports.

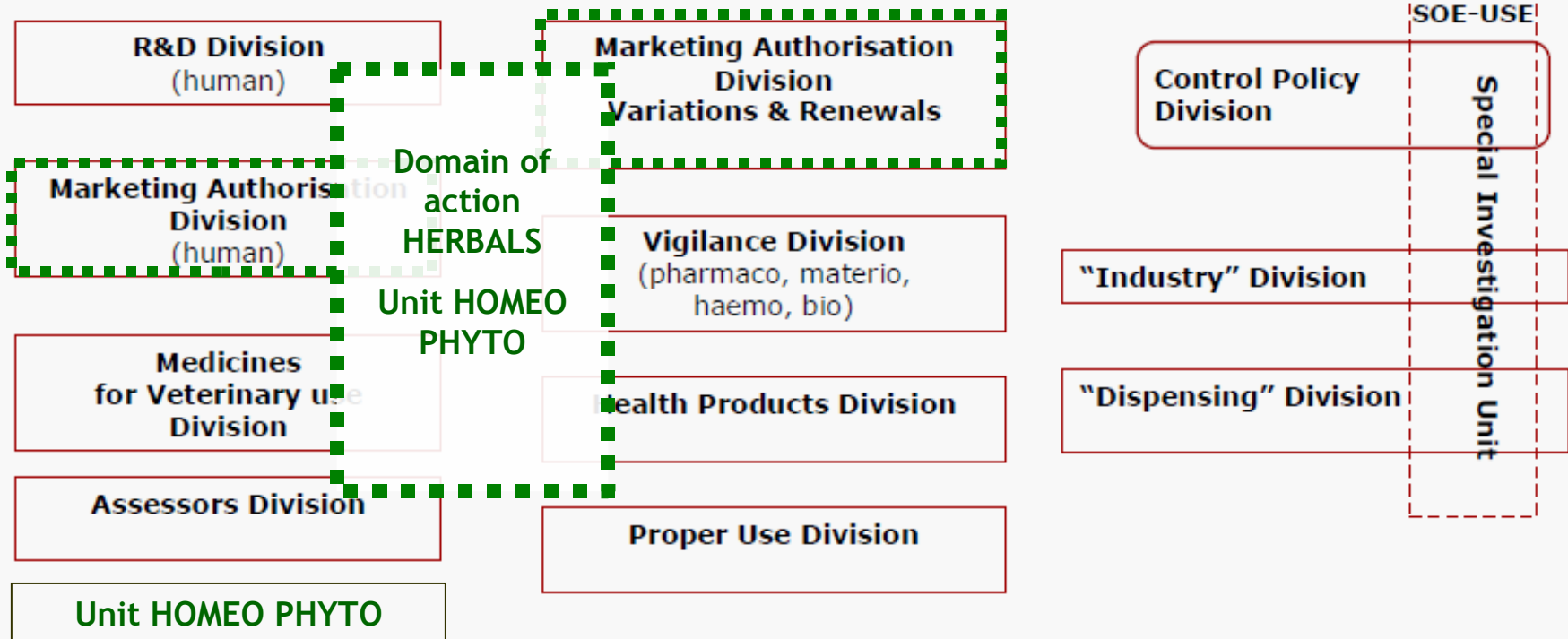
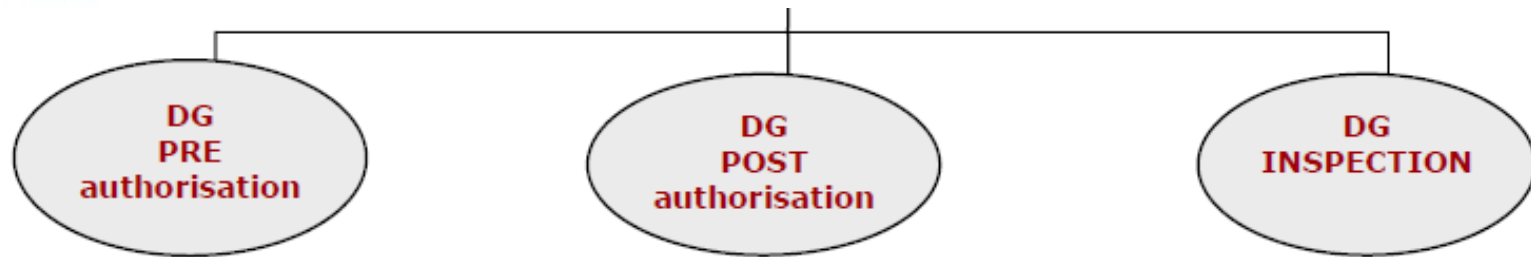
Proper use: see to it that patients have relevant information so that medicines and health products are used rationally and safely.

⇒ **What about HMP?**

FAMHP : organigram



FAMHP : organigram



What about Medicinal Products (MP)?

Definitions from European Directive 2001/83/EC (=> Belgian legislation RD 14/12/2006 and Law 25/03/1964):

Medicinal product (MP):

Definition consists of 2 parts

- (a) presentation
- (b) function

(a) any substance or combination of substances presented as having properties for

- treating
- preventing

disease in human beings

= MP by PRESENTATION

-> intended use?

What about MP?

Definitions from European Directive 2001/83/EC (=> Belgian legislation RD 14/12/2006 and Law 25/03/1964):

Medicinal product:

b) any substance or combination of substances which may be used in or administered to human beings either with a view to

- restoring
- correcting
- modifying

physiological functions by exerting a pharmacological, immunological or metabolic action

- making a medical diagnosis.

= MP by FUNCTION

FAMHP/wvt

What about HMP?

Definitions from European Directive 2001/83/EC (=> Belgian legislation RD 14/12/2006 and Law 25/03/1964):

Herbal substances:

All mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried, form, but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances.

Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author).

Herbal preparations:

Preparations obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation.

These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.

What about THMP?

Traditional herbal medicinal products (THMP)

= medicinal products containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations => **herbal medicinal products (HMP)**

IF

- (g) they have indications exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment;
- (b) they are exclusively for administration in accordance with a specified strength and posology;

What about THMP?

(c) they are an oral, external and/or inhalation preparation;

(d) the period of traditional use has elapsed;
the medicinal product (corresponding product) has been in medicinal use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the Community

“medicinal use”

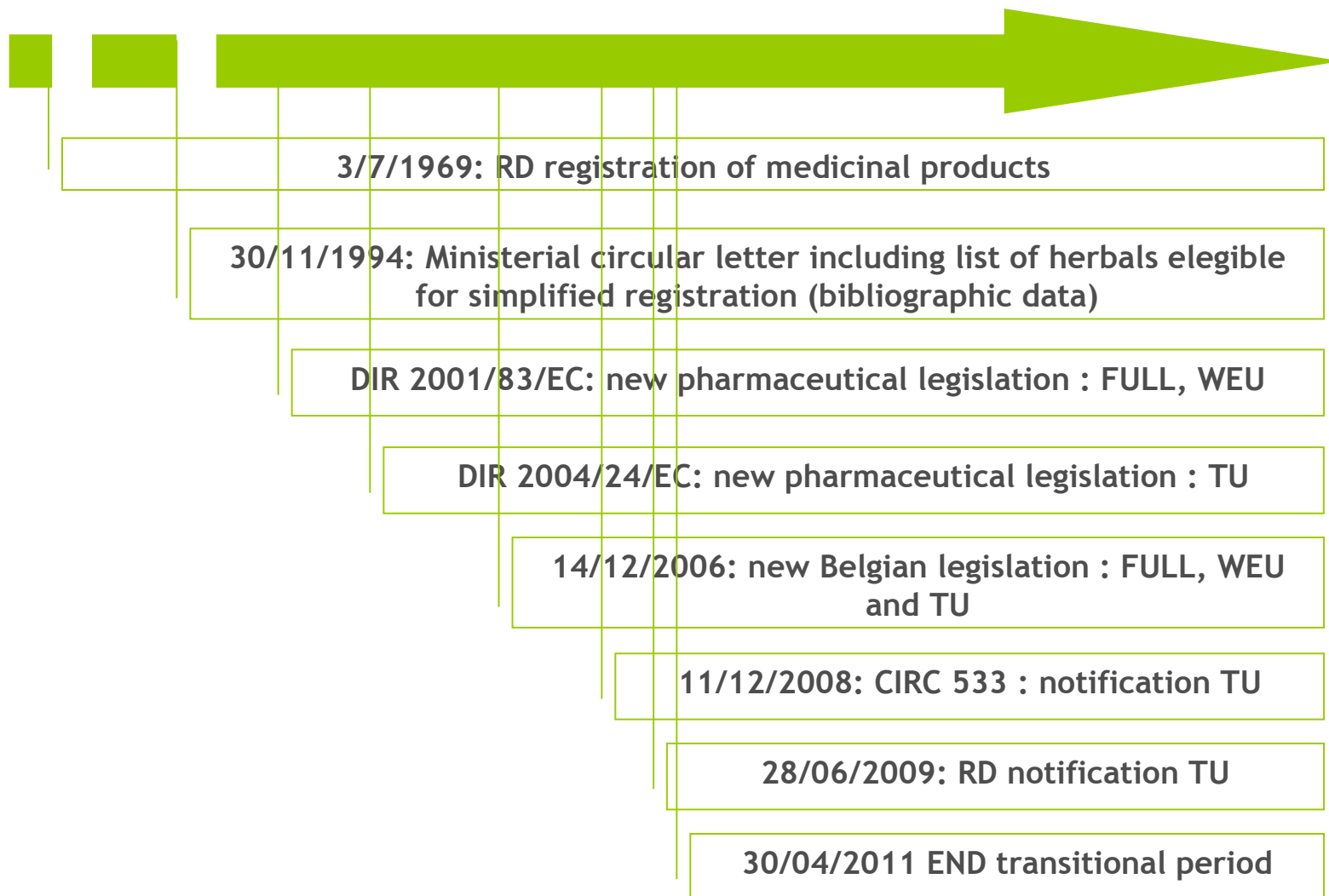
does not exclusively mean “use as an authorised medicinal product”
proof of medicinal use may be submitted even in the absence of a marketing authorisation

(e) the data on the traditional use of the medicinal product are sufficient;

the product proves not to be harmful when used as specified
the pharmacological effects or efficacy of the medicinal product are plausible on the basis of longstanding use and experience.

-> Can contain vitamins & minerals with ancillary action

What about Belgium?



Borderline?

Natural products ranges used in self care often include herbs, herbal materials, herbal preparations and finished herbal products that are administered in view of treating or preventing disease

- ⇒ for a lot of these preparations : **NO borderline**
- ⇒ CLEARLY Medicinal Product
- ⇒ Intended use?

In case of doubt about status:

=> Mixed Commission : will decide about status based on gathered information (presentation, composition,...)

Borderline?

Case-by-case evaluation:

taking account of all the characteristics of the product, in particular:

- ⇒ its composition
- ⇒ its pharmacological, immunological or metabolic properties, to the extent to which they can be established in the present state of scientific knowledge
- ⇒ the manner in which it is used
- ⇒ the extent of its distribution
- ⇒ its familiarity to consumers
- ⇒ the risks which its use may entail