Unlicensed Medicines
Scope & Definitions

V'Iain Fenton-May

Member of Ph Eur Commission
Chair PHP Working Party
Vice Chair British Pharmacopoiea
Chair Unlicensed Medicines Expert Group BP
Former Quality Controller to Welsh Hospitals

eahp
european association of hospital pharmacists

Disclosure

I have no financial interest in any of the points under discussion

eahp
european association of hospital pharmacists

Topics to be covered

- Historical Background
- Current & Future Position of Unlicensed Medicines
- Definitions & Scope

From ancient times until relatively recently medicines were made manually

By an apothecary

Preparing the medicines himself by hand

From starting materials he had

- Gathered
- Prepared
- Purchased
- Stored in the pharmacy

Everything under direct control

Prior to 1968 (in the UK) anyone could make, in their back garden, any product and advertise it for any use !

However mass manufacture and potent medicines lead to mistakes with large scale consequences that politicians could not ignore

Legislation has now led us to the point that most Medicines are made by the

Pharmaceutical industry

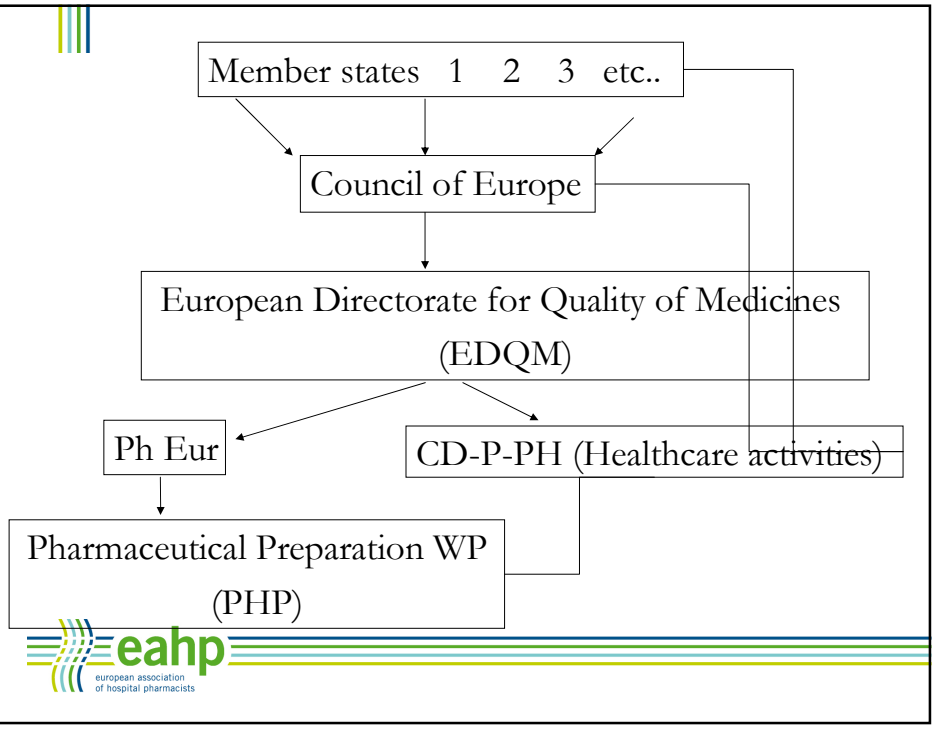
which is under strict Regulatory control needing

Manufacturer's licence and product licence

Good Manufacturing Practice principles

Unlicensed Medicines are now **not understood** and **feared** by Politicians, Legislators (and many of our 'Clinical Colleagues')

There are now moves to control those products. Most Member States have some methods but there is a move for a Europe wide agreement on standards.



Scope

The **PHP WP** of the PH Eur to define the extent to which the Ph Eur applies to unlicensed Medicines

The **CD-P-PH** will define the process standards that will apply across Europe. This may be through Legislation or an Advisory letter.

eahp european association of hospital pharmacists

A **Major** issue, when defining standards is the **definitions** used.

eahp european association of hospital pharmacists

- Medicinal products are produced by pharmacist and others via different routes
  - Manufacturing
  - Preparation/Compounding
  - Extemporaneous preparation
  - Magistral Preparations
  - Preparation at the bedside

- Manufacture
  - Defined by
    - Size of operation (based on local discussions)
    - Indirect line to patient. (clinical responsibility passed to another pharmacist)
    - Transfer between legal entities

- Preparation
  - Defined by
    - Line responsibility to the patient
    - Small batch size (less than Manufacture)
    - Primarily for use within ones own legal entity

    NB the Pharmaceutical Inspectors have suggested that 'Manufacture' be reserved for Licensed products

Extemporaneous products

[including reconstitution in a pharmacy]

- Defined by
  - Dispensing according to a prescription for an individual patient
  - Some anticipation of the prescription can be allowed BUT a batch preparation is not allowed

Magistral preparation: Any medicinal product prepared in a pharmacy in accordance with a medical prescription for an individual patient.

Officinal preparation: Any medicinal product which is prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the patients served by the pharmacy in question

- Preparation at the bedside
  - The medicine is prepared according to the SPC outside the pharmacy in a legitimate clinical area.

- The controls applied to each type of preparation are dependent on the level of production
  - Manufacturing
    - GMP
  - Preparation
    - Appropriate level of GMP [GMP(H), GPP]
  - Extemporaneous preparation
    - Good Pharmacy Practice
  - Preparation at the bedside
    - Good Nursing Practice

Is the scope of what can be made as an unlicensed medicine restricted in any way ?

Unlicensed Medicines British Pharmacopeia

SCOPE This general monograph applies to those dosage forms that are routinely manufactured or prepared as unlicensed medicines and are usually presented as conventional-release formulations. These include:

Capsules — Liquids for Cutaneous Application — Ear Drops and Lotions — Eye Drops — Preparations for Irrigation — Nasal Preparations — Oral Liquids — Oral Powders — Parenteral Preparations — Rectal Preparations — Tablets — Topical Semi-solid Preparations — Vaginal Preparations