Activities of the EDQM: Benefits for public health and the protection of patients throughout the continent and beyond

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Activities of the EDQM

Legal basis: a 1964 Convention that is still effectively responding to public health needs.

A single point of access to a set of activities for the protection of public health in Europe and beyond.

Activities of the EDQM

- Quality of medicines and substances for pharmaceutical use (European Pharmacopoeia);
- Programmes for the market surveillance of medicinal products (OMCL network);
- Fighting the counterfeiting/falsifying of medical products;
- Pharmaceutical practices & pharmaceutical care;
- Activities in the field of blood transfusion and organ transplantation;
- Consumer health protection.

→ A single secretariat for all these activities: the EDQM.

Pharmaceuticals and pharmaceutical care

This activity began because of a study, which revealed that:

- worldwide, 50% of all medicines are inappropriately prescribed or dispensed;
- 50% of all patients fail to take their medicines properly.

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Activities in the areas of blood transfusion and transplantation

- Productive international collaboration
- Promotion of strong principles such as non-commercialisation of donations
- Worldwide scientific recognition
- 60 years of CoE activities in the area of blood transfusion
- Expertise used to alert states to new risks and help them respond

Consumer Health Protection

The aim: to establish common policies concerning:

- the quality and safety of cosmetics and
- packaging for food.
- A network of official cosmetics control laboratories (OCCL) was set up in 2010; it is open to European Pharmacopoeia member states and observers.

Impact of activities of the EDQM

The EDQM contributes to:

- protecting public health,
- promoting animal welfare,
- optimising the use of its member states' resources,

..... its activities have an impact that extends well beyond Europe

Quality of Medicinal Products and Starting Materials in Europe: Role of the European Pharmacopoeia

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Role of a Pharmacopoeia

- A compilation of common standards for the quality of medicines and their ingredients
- Harmonization of these quality criteria
- Essential basis for the free movement of medicines within a legal/political entity

European Pharmacopoeia

- 1963:
  - Initial discussions on medicines within the Common Market
  - 1st decision:
    The need for common standards
- 1964:
  - Creation of a European Pharmacopoeia
    (Partial Agreement of the Council of Europe)
    Founder states: Benelux, DE, FR, IT + CH and UK

European Pharmacopoeia

- A programme centred on the quality of medicines and scientific progress,
- After 50 years of activity:
  - from the 1st Edition to the 8th Edition,
  - from 120 to over 2500 common, mandatory quality standards;
  - from 8 founder states to 37 member states today, with the EU as its 38th member.
- → Its influence now extends far beyond Europe.

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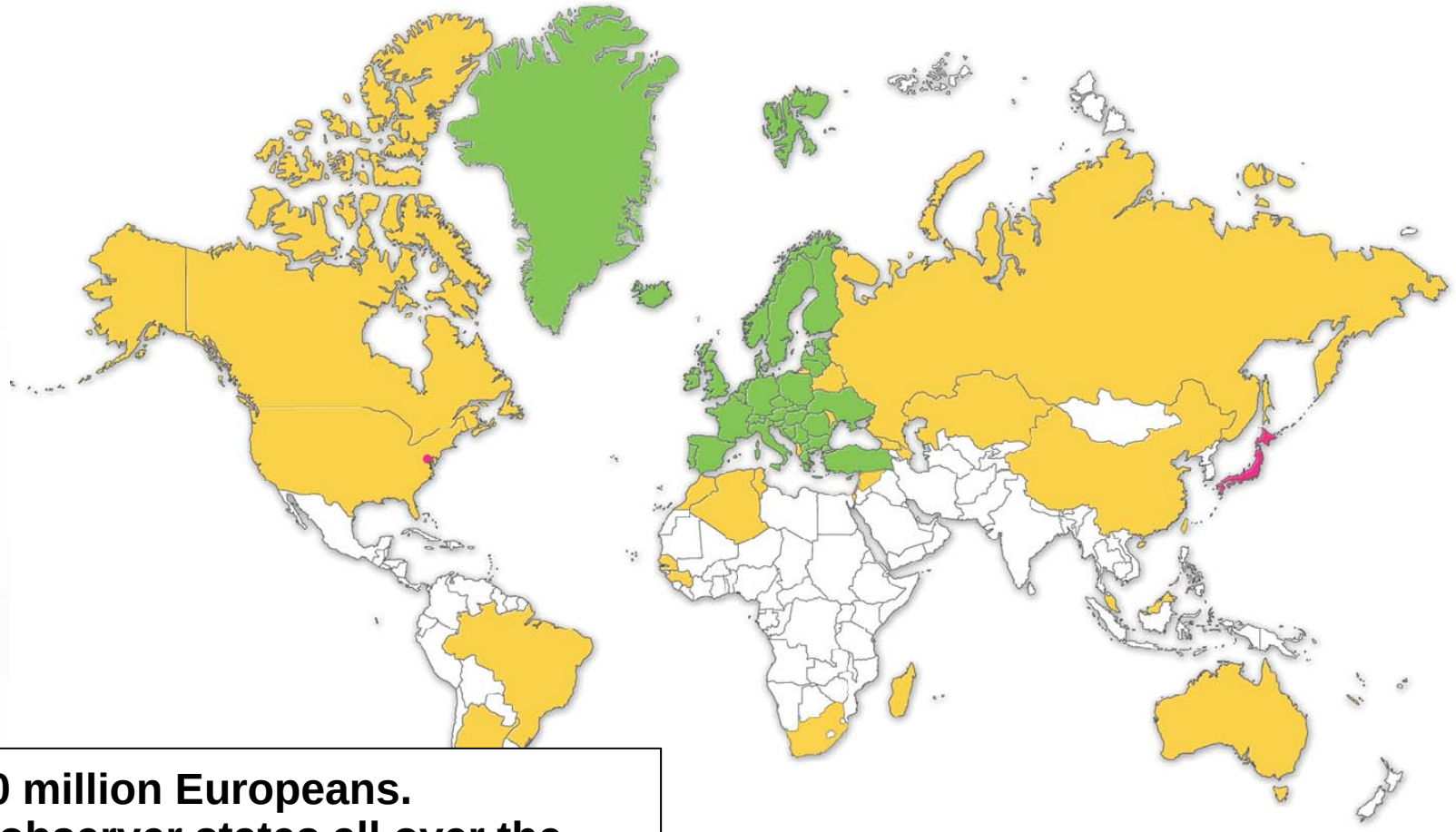
Influence of the European Pharmacopoeia



640 million Europeans.
25 observer states all over the world, as well as the WHO and the Taiwan Food and Drug Administration (TFDA)

Legally Binding Reference

- The Ph. Eur. is legally binding in all the signatory states of the Convention.
- As an example in the EU:
- Directive 2003/63/EC of the Commission amending Directive 2001/83/EC
  - The monographs of the European Pharmacopoeia shall be applicable to all substances, preparations and pharmaceutical forms appearing in it.
  - For other substances, each member state can require compliance with its own pharmacopoeia.

Ph. Eur. Organisational chart

Ph. Eur. Commission

Composition:

- 28 EU member states
- European Commission
- 9 non-EU member states
- 27 observers:

  8 European countries, 17 non-European countries,
  Taiwan Food and Drug Administration (TFDA)
  World Health Organization (WHO)

Presidium:
chair
2 vice-chairs
Ph. Eur. secretariat

Meetings of the presidium + Chairs of groups of experts

Groups of experts

Contributors:

- National Pharmacopoeia Authorities
- Competent authorities
- Industries
- OMCL Network

Strengths of the Ph. Eur.

- Composition of the COM: member states
  - Guarantees acceptability of monographs
- Composition of the groups of experts: a mixture of experts from competent authorities, universities, industry
  - Guarantees a high scientific standard
- Close collaboration with the national and European licensing authorities
  - Up to date with regulatory developments
  - Allows regular re-adjustment of quality criteria

Strengths of the Ph. Eur. (2)

- Collaboration at the international level
- Permanent re-evaluation of monographs
  - Via the certification procedure (CEP)
  - Via feed-back from licensing authorities foreseen in the EU pharmaceutical legislation
- Flexibility of texts whilst guaranteeing quality: ultimately the Ph. Eur. prevails

Contributions of the Ph. Eur. to the quality of medicines

- Thanks to all its strengths, the Ph. Eur. guarantees:
  - A high standard of quality
  - Predictability for pharmaceutical manufacturers
  - Effective test methods to be used by official medicines control laboratories
- Ultimately: medicines that are safe for use by patients

Challenges for the future

- Strengthen the position of the Ph. Eur. in a globalised world
  - Ph. Eur. to act as reference for the quality of medicinal substances
- Effect of globalisation:
  - Increase in the number of pharmaceutical players
  - Need to guarantee a global quality that takes into account different manufacturing processes
- Guarantee quality in the face of a growing demand for generic medicines
- Adapt to technical and scientific progress
- Adapt to changes in legislation

Thank you for your attention

European Directorate for the Quality of Medicines & HealthCare (EDQM)

Workshop for journalists

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