# The Availability of Homeopathic Medicinal Products (HMPs) in Europe

## with reference to the Matrix Report

A presentation to the European Parliament CAM Interest Group 1 July 2015

By Stephen Gordon General Secretary

European Central Council of Homeopaths

EUROCAM

EUROPEAN CENTRAL COUNCIL OF HOMEOPATHS

EccH

EST 1990

# The Availability of HMPs in Europe

- Homeopathic Medicinal Products are defined in EU Directive 2001/83/EC as products "prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States"132.
- ECHAMP (European Coalition on Homeopathic and Anthroposophic Medicinal Products) estimated the total sales (at ex-factory prices) of homeopathic products in 2010 to be EUR 1,035bn = ~ 1% of the EU pharmaceutical market
-

EUROCAM

EUROPEAN CENTRAL COUNCIL OF HOMEOPATHS
EccH
EST 1990

# The Availability of HMPs in Europe

**ECCH Report 2005: The availability and quality of HMPs in Europe**

- "A recent investigation by ECCH into the situation in each country has revealed wide variation between Member States in progressing the implementation of EU directives, in how they are being implemented and in the registration costs being levied on manufacturers and distributers."
- "We have the strong impression that there is a lack of understanding of the nature of homeopathic pharmacy on the part of some officials within European institutions and within some individual national medicines authorities."

EUROCAM

EUROPEAN CENTRAL COUNCIL OF HOMEOPATHS
EccH
EST 1990

# The Availability of HMPs in Europe

**2010 ECH and ECCH Joint Position Paper on The Availability, Quality and Safety of Homeopathic Medicinal Products in Europe Revised edition 2010**

- Homeopathy is by definition a medicine based therapy that relies on an individualised prescription of a homeopathic medicinal product for each patient and their condition.
- Consequently a wide variety of homeopathic medicinal products of high quality in a full range of potencies are needed by practitioners in order to undertake successful homeopathic treatment.
- The recent significant and ongoing decline in the availability of the full range of homeopathic medicinal products in a growing number of European countries, despite the considerable efforts of producers of homeopathic medicinal products, has now created a serious situation that needs to be addressed.

EUROCAM

EUROPEAN CENTRAL COUNCIL OF HOMEOPATHS
EccH
EST 1990

# The Availability of HMPs in Europe

**2012 ECHAMP Report:** The Availability of Homeopathic and Anthroposophic Medicinal Products in the EU

The report showed:

- modest to high demand for HAMPs in at least two thirds of the EU Member States, while –

At the same time, there is a lack of comprehensive information on the regulatory status of the products in the Member States.

**The progress of enforcement of the relevant articles of Directive 2001/83/EC1 is far from complete, and this both seriously limits present availability and raises a question mark over sustained future availability of the products.**

EUROCAM

EUROPEAN CENTRAL COUNCIL OF HOMEOPATHS
EccH
EST 1990

# The Availability of HMPs in Europe

**2012 ECHAMP Report:** The Availability of Homeopathic and Anthroposophic Medicinal Products in the EU

**The following main deficits and needs were identified:**

- i. The burden for the establishment and maintenance of registrations and marketing authorisations is disproportionate to the purpose of simplified registration and presents a permanent threat to the whole lifecycle of the thousands of homeopathic stocks which are needed by homeopathic prescribers. Mutual recognition/decentralised procedures require an effort that is also disproportionate to this area.
- ii. The assessment policy for applications for registrations according to Article 14 of the Directive is far from harmonised, increasing the administrative burden for applicants.
- iii. The lack of implementation and execution of adequate rules following Article 16.2 represents a threat to the clearly visible demand for OTC- and self-medication across the Member States. A more harmonised approach is also needed.

EUROCAM

EUROPEAN CENTRAL COUNCIL OF HOMEOPATHS
EccH
EST 1990

# The Availability of HMPs in Europe

- In terms of medicinal products for human use, the Directorate General for Health and Consumers (DG SANCO) has responsibility for guaranteeing the highest possible level of public health and to secure the availability of medicinal products to citizens across the European Union, based on the principle that the placing on the market of medicinal products is made subject to the granting of a marketing authorisation by the competent authorities.

EUROCAM

EUROPEAN CENTRAL COUNCIL OF HOMEOPATHS
EccH
EST 1990

# The Availability of HMPs in Europe

**The Matrix Insight Report: Commissioned by DG SANTE 2010 finalised 2012 published 2014**

- focuses on the authorisation procedures for medicinal products, a principal area of EU competence
- availability to patients of medicinal products in a pharmacy setting.
- availability of active substances rather than limited availability of individual products that constitutes a public health risk.
- the study investigates the problem drivers and examines the effectiveness of existing European legislative provisions in addressing these problems, making recommendations where relevant.

EUROCAM

EUROPEAN CENTRAL COUNCIL OF HOMEOPATHS
EccH
EST 1990

# The Availability of HMPs in Europe

- **The Matrix Insight Report** includes six in-depth case studies exploring particular issues relating to the availability and authorisation of medicinal products, one of which, Case Study 6, focuses on herbal, homeopathic and anthroposophic medicinal products
- the case study looks at the availability of the products as medicinal products for human use,
- the report establishes that national medical traditions differ with regard to how these product groups are perceived;
- **there are availability problems across the EU linked to the differences in national approaches as well as ineffective or inconsistent application of European provisions.**

EUROCAM

EUROPEAN CENTRAL COUNCIL OF HOMEOPATHS
EccH
EST 1990

# The Availability of HMPs in Europe

- ..the implementation of existing EU provisions concerning these products could be further improved.
- Given the demand for such products, there appears to be a need for further action in this area, which, according to consulted stakeholders, should focus on ensuring that the process of authorisation of herbal medicinal products and HAMPs is more consistent, both with the text of the existing provisions and between Member States.

EUROCAM

EUROPEAN CENTRAL COUNCIL OF HOMEOPATHS
ECCH
EST 1990

# The Availability of HMPs in Europe

**The Heads of Medicines** Agencies brings together representatives of all European medicines agencies.

Because, unlike herbal products, HMPs are not covered by the European Medicines Agency, it has a specific working group on HMPS, the Homeopathic Medicinal Products Working Group (HMPWG)

In 2014 the Chair of the HMA management Group wrote to Andrea Rys of DG SANTE

- welcoming the Matrix report and its different case studies
- **stating the findings endorsed its own 2007 Task Force report on the problems of availability for all medicinal products**

EUROCAM

EUROPEAN CENTRAL COUNCIL OF HOMEOPATHS
EccH
EST 1990

# The Matrix Report: DG SANTE's response

- 'Regarding homeopathic products, it is acknowledged that there are generally no major issues regarding availability of homeopathic medicinal products for specific symptoms and that products can usually be delivered through order.'

EUROCAM

EUROPEAN CENTRAL COUNCIL OF HOMEOPATHS
EccH
EST 1990

# Our recommendations

DG SANTE

- takes the findings of the Matrix Insight Report more seriously
- takes into account the reports of ECCH, ECH and ECHAMP
- accepts it is not necessarily change to legislation that is needed

but better application of what already exists

- that it should 'encourage' Member States MAs to be more consistent in applying minimal requirements and costs appropriate to HMPs, based on the practice MS MAs where availability is high e.g. UK, Germany ,Ireland
- it should support the work of the HMA's HMPWG which is providing a set of guidance documents to facilitate MS MAAs

EUROCAM

EUROPEAN CENTRAL COUNCIL OF HOMEOPATHS
EccH
EST 1990

# Why full availability of HMPs across the EU is essential

- 25% of EU citizens use HMPs or access homeopathic treatment
- 10s of thousands of MDs and practitioners use them to treat patients
- they provide an important alternative to antibiotics,
- They provide an important alternative in veterinary medicine and the animal food industry
- Homeopathy provides an alternative and complement to conventional care and has a potentially important role to play in treating an aging population with multi-morbidity and the associated risks of conventional drug polypharmacy.

EUROCAM

EUROPEAN CENTRAL COUNCIL OF HOMEOPATHS
EccH
EST 1990

# The Matrix Report: DG SANTE's response

- 'Regarding homeopathic products, it is acknowledged that there are generally no major issues regarding availability of homeopathic medicinal products for specific symptoms and that products can usually be delivered through order.'

EUROCAM

EUROPEAN CENTRAL COUNCIL OF HOMEOPATHS
EccH
EST 1990