Chinese Medicines Products and the European Union Regulatory Framework – an Update

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With reference to the publication policy of the European Medicines Agency (EMA) I do not speak on behalf of the Committee on Herbal Medicinal Products (HMPC) or the EMA.

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Traditional medicines all over the world
European Union

Political union of 28 Member States

about 500 Mio inhabitants

24 official languages
Pharmaceutical Legislation in the EU

- CD 2001/83 (**“Basic”** regulation on medicinal products) amended by
  - CD 2003/63 (Annex I, CTD criteria)
  - CD 2004/24 (**Traditional herbal medicinal products**)
Pharmaceutical Legislation in the EU
Definitions

Medicinal product

Herbal medicinal product
Traditional herbal medicinal product
(longstanding tradition, plausibility)

Herbal substance (Eur. Ph. “Herbal drug”)
Herbal preparation (Eur. Ph. “Herbal drug preparation”)
Key Institutions

**European Commission**
European Parliament
Regulatory framework, law
Directives, Regulations

**National authorities**
Assessment
Marketing authorisation
DCP, MRP, national

**European Pharmacopeia**
Quality standards
General
Herbal drugs/preparations

**EMA**
Coordination
Guidance
Centralised procedure

Diagram illustrating the interactions between key institutions.
Tasks

**EMA**

HMPC monographs
Safety + Efficacy

**Standards**

**European Pharmacopeia**

Eur. Ph. monographs
Quality

**National authorities or EMA (centralised)**
Product applications
Assessment
Licensing
Access to the Market – Options and Concepts

• Marketing authorisation
  full application (e.g. new medicinal products)
  well-established use

• Registration
  traditional use
Specific Concepts – Well-established use

- More than 10 years accepted medicinal use in the EU based on a marketing authorization
- Quantitative substantiation of use of the substance
- Degree of scientific interest in the use of the substance
- Coherence of bibliographic scientific data, scientific assessments and published scientific literature
- HMPC monographs: at least one controlled clinical trial of good quality
Specific Concepts – Traditional Use

Registration of traditional herbal medicinal products applicable to *traditional* herbal medicinal products

**Article 16c 1 (c)**

> 30 years of medicinal use within the EU or

> 15 years in and > 15 years outside the EU

**Deviations** may be decided by the Herbal Medicinal Products Committee (HMPC, EMA) if requested by a Member State
Specific Concepts – Traditional Use

- **Indication(s) appropriate** – minor diseases
- **Without the supervision** of a medical practitioner for diagnosis, prescription or monitoring of treatment
- Only **oral, external** and **inhalation**
- **Sufficient data** on traditional use
- **Pharmacological effects / efficacy plausible** on the basis of long-standing use and experience
Marketing Authorisation

Pharmacovigilance

Registration

- Consumer information; labeling; advertising
  - Efficacy
    - new trials  bibliographic  traditional use
  - Safety
    - new tests  bibliographic  expert report bibliographic new tests

- Quality Control
  - Good Manufacturing Practices
  - Good Agricultural and Collection Practices

new  well-established  traditional
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HMPC and Development of European Union Monographs

HMPC and guests at the presidency meeting 2015
European Medicines Agency - EMA

- Central European Authority with specified tasks
- Committees and Working Parties
- Coordination of National Competent Authorities
- Documents (www.ema.europa.eu)
Committees at EMA

CHMP  Committee on Medicinal Products for Human Use

COMP  Committee on Orphan Medicinal Products

PDCO  Paediatric Committee

HMPC  Committee on Herbal Medicinal Products

CAT   Committee on Advanced Therapies

CVMP  Committee on Medicinal Products for Veterinary Use

PRAC  Pharmacovigilance Risk Assessment Committee

COMPOSITION:
- 1 member per Member State
- 1 member each from Norway and Iceland
- Up to 5 co-opted Members
- Alternate Members, Observers (e.g. EDQM)
EU Legal Framework and Different Traditions


THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the opinion of the European Economic and Social Committee (*)

Acting in accordance with the procedure referred to in Article 251 of the Treaty (†).

and an acceptable level of safety and are not eligible for marketing authorisation. To maintain these products on the market, the Member States have enacted differing procedures and provisions. The differences that currently exist between the regulatory systems in the Member States may give rise to arbitrary discrimination and distort competition between manufacturers of these products. This is likely to have an impact on the protection of the health of the public because the necessary guarantees of quality, safety and efficacy are not always provided at present.

(4) Having regard to the characteristics of these herbal medicinal products due to their long tradition, it is desirable that the simplified registration procedure for herbal medicinal products. However, this simplified procedure should be use
HMPC – Elaboration of Harmonised Standards

European Union Monographs on safety and efficacy
Guidance documents
Documents developed by the HMPC

- **HMPC-Monographs** on efficacy and safety – recommendation to Member States
- **List Entries** – published by EC, binding to Member States
- **Public Statements** – specific information (e.g. no release of a monograph, safety of specific constituents)
- **Revisions** – every 5 years, sustainability of the system
- **Guidelines** – recommendations to national competent authorities and applicants, consensus on harmonized assessment
- **Reflection Paper, Questions & Answers** – regulatory perspectives on selected topics
HMPC - Achievements

- Monographs: 140
- List Entries: 13
- Revisions: 16
- Public Statements: 13
- Guidance: about 30

www.ema.europa.eu
Standards made public

Agendas
Meeting reports
Minutes

Monographs
Assessment reports
References
Comments

Guidelines

www.ema.europa.eu
Therapeutic Areas of Traditional Herbal Medicinal Products
(reference: www.ema.europa.eu)

- Cough and cold: 287
- Mental stress & mood disorders: 231
- Gastrointestinal disorders: 215
- Urinary tract and gynaecology disorders: 181
- Sleep disorders & temporary insomnia: 171
- Pain and inflammation: 114
- Skin disorders & minor wounds: 80
- Mouth and throat disorders: 72
- Fatigue & weakness: 66
- Venous circulatory disorders: 48
- Loss of appetite: 23
- Constipation: 9
- Eye discomfort: 3
Monographs – Request for Data

Call for scientific data for use in HMPC assessment work on Paeonieae radix
Submission period: 15 February 2014 - 15 May 2014

The HMPC invites all interested parties such as pharmaceutical industry associations, healthcare professional groups, learned societies, consumer and patients’ associations, governmental institutions as well as EU and EEA/EFTA Member States to submit any scientific data, which may be used in the assessment of Paeonieae radix as part of the establishment of Community herbal monographs and/or Community list entries.

Scientific contributions should be sent:
By post
European Medicines Agency
7 Westferry Circus
Canary Wharf
UK-London E14 4WB
Attn.: HMPC secretariat
or by email
hmpc.secretariat@ema.europa.eu

If an interested party intends to send scientific contributions in response to several calls for scientific data, response should be sent separately to each call. A list of all scientific contributions and their references should be enclosed. The name and contact details of the interested party providing the scientific contributions is required. Unpublished data may be included. However, the consent of the data owner is a necessary requirement. The owner of the data will be given the opportunity to review the assessment report to remove any confidential data. The HMPC will consider such submissions on a case-by-case basis. Submitting parties are bound to obey existing copyrights. Contributions should also take duly into account the rights of interested parties, as the documentation provided will be used for the development of Community list entries and Community herbal monographs. Such development is

Community herbal monograph on Ginkgo biloba L., folium
Draft

28 January 2014
EMA/HMPC/211/07/2012
Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on Ginkgo biloba L., folium

Discussion in Working Party on Community monographs and Community list (MLWP) May, Sep, Nov 2012
Adaptation by Committee on Herbal Medicinal Products (HMPC) for release for consultation 28 January 2014
End of consultation (deadline for comments). Comments should be provided using this template 15 June 2014
to hmpc@communityhealthtopics.europa.eu
Rediscussion in Working Party on Community monographs and Community list (MLWP) May, Sep, Nov 2012
Adaptation by Committees on Herbal Medicinal Products (HMPC)

Keywords: Herbal medicinal products; HMPC; Community herbal monographs; well-established medicinal use; traditional use; Ginkgo biloba L., folium; Ginkgo biloba leaf
Monographs – Options for Input of Data

• Call for data before start of the work
• Public consultation after finalisation of a draft monograph
• Support by interested parties
• Scientifically based and justified input with supporting documentation is welcome
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Traditional medicine from non-European countries in Europe

• May be available in pharmacies
• May be available in herbalist shops
• May be applied in specialized hospitals

• May be offered via internet
• May be sold with different classification

Need for harmonisation
HMPC Work Program 2012 - 2015

High
– Regulatory guidance for non-European interested parties – 2012

Initiate pilot projects for herbal substances with a non-European traditional background. **Identify central questions or obstacles** and provide specific information in conjunction with a training for assessors.

High
HMPC – Activities towards non-European traditional medicines

2014  Question & Answers (… non-European …)
2013  Pilot Project on Monographs for herbal substances from traditional medicines of non-European Origin
2012  HMPC Assessors Training on non-European Traditional Medicines
2011  HMPC delegation in Beijing (seminar, meetings with authorities)
Questions & Answers Document

25 March 2014
EMA/HMPC/402684/2013
Committee on Herbal Medicinal Products (HMPC)

Questions & Answers on the EU framework for (traditional) herbal medicinal products, including those from a ‘non-European’ tradition

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Experiences

- No sufficient data to support well-established use
- No sufficient data to support tradition of 15 + 15 years
- No sufficient data on posology
- No sufficient data on safety and plausibility

✔ Future task: search for strategies and solutions
From non-European countries to Europe

• Access to the European market for finished medicinal products according to European legislation fulfilling requirements traditional, (well-established use), new product

• Procedures for finished medicinal products national procedure decentralised/ mutual recognition procedure centralised procedure
Examples of Two Successful Applications for Traditional Herbal Medicinal Products

- Professional strategies include
  Early scientific advice (national or European level)
  Resources
  Sound data and adequate documentation

- Successful applications
  Traditional herbal medicinal products
Conclusions

1. HMPC has developed harmonised European standards for the Member States of the European Union.

2. The European legal framework offers options for (traditional) herbal medicinal products from non-European countries.

3. HMPC has followed different approaches to strive for harmonised assessment of (traditional) herbal medicinal products from non-European countries.

4. Scientific advise is offered and professional applications are welcome.

5. Communication amongst regulators at global level is developing.
Thank you very much for your attention!

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