



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Herbal summaries for the public

Involvement of PCOs in preparation of herbal summaries

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An agency of the European Union





Overview

- Role of the Committee on Herbal Medicinal Products (HMPC)
- Herbal summary for the general public
- Involvement of PCOs in preparation of summaries



Role of the Committee on Herbal Medicinal Products (HMPC)

- Most herbal medicines are authorised at national level in EU
- HMPC established in 2004 following new legislation (Directive 2004/24/EC) which introduced simplified registration procedure for traditional herbal medicines in EU Member States
- HMPC activities aim at assisting harmonisation on use of herbal medicines by preparing scientific opinions on herbal medicines (monographs):
 - a unique set of information on a herbal preparation (its therapeutic uses and a set of recommended safe conditions of use) that MS will be able to refer to when evaluating marketing applications for herbal medicines



Herbal summaries for the public

- Key considerations when drafting the template for herbal summaries:
 - Authorisation process for herbal medicines
 - Summary of HMPC conclusions and NOT authorised use
 - Need to refer patients/public to the NCAs and PL for further information
 - Extent of data available varies -> optional sections
- Experience used from writing other documents for general public (EPAR summaries, summaries of orphan designation, etc.) in terms of:
 - Structure
 - Content
 - Style
- Basis for the summary: adopted monograph and HMPC assessment report



Herbal summaries for the public - template

English name of herbal substance/preparation

latin name

This is a summary of the scientific conclusions reached by the Committee on Herbal Medicinal Products (HMPC) on the medicinal uses of <X>. The HMPC conclusions are taken into account by EU Member States when evaluating applications for the licensing of herbal medicines containing <X>.

This summary is not intended to provide practical advice on how to use medicines containing <X>. For practical information, patients should read the package leaflet that comes with the medicine.

*Description of herbal substance,
how is obtained and how is
available as medicine*

- **What is <X>?**
- **What are the HMPC conclusions on its medicinal uses?**
- **<How does <X> work as a medicine?>**
- **What evidence supports the use of <X> medicines?**
- **What are the risks associated with <X> medicines?**

*Description of recommended
indication and condition of use*

*Brief description of data
assessed by HMPC*

*List side effects and
contraindications*



Herbal summaries for the public – template (contd.)

- **How are <X> medicines approved in the EU?**

Any applications for the licensing of medicines containing <X> have to be submitted to the national authorities responsible for medicinal products, which will assess the application for the herbal medicine and take into account the scientific conclusions of the HMPC.

Information on the use and licensing of <X> medicines in EU Member States should be obtained from the relevant national authorities.

- **Other information about <X> medicines**

Further information on the HMPC assessment of <X> medicines, including details of the Committee's conclusions, can be found under the tab 'All documents' on the Agency's website: ema.europa.eu/Find_medicine/Herbal_medicines_for_human_use. For more information about treatment with <X> medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.



Herbal summaries for the public

How to find them on the EMA website:

<http://www.ema.europa.eu/ema/>



Involvement of PCOs in preparation of summaries

- In the past, PCO representatives highlighted the need for more information on herbal medicines adapted to the general public, and expressed interest in being involved in the preparation of this information
- Involvement of patients and consumers in preparation of herbal summaries is very much welcomed by HMPC
- Opportunity to provide a unique perspective
- Built on positive experience on EPAR summaries

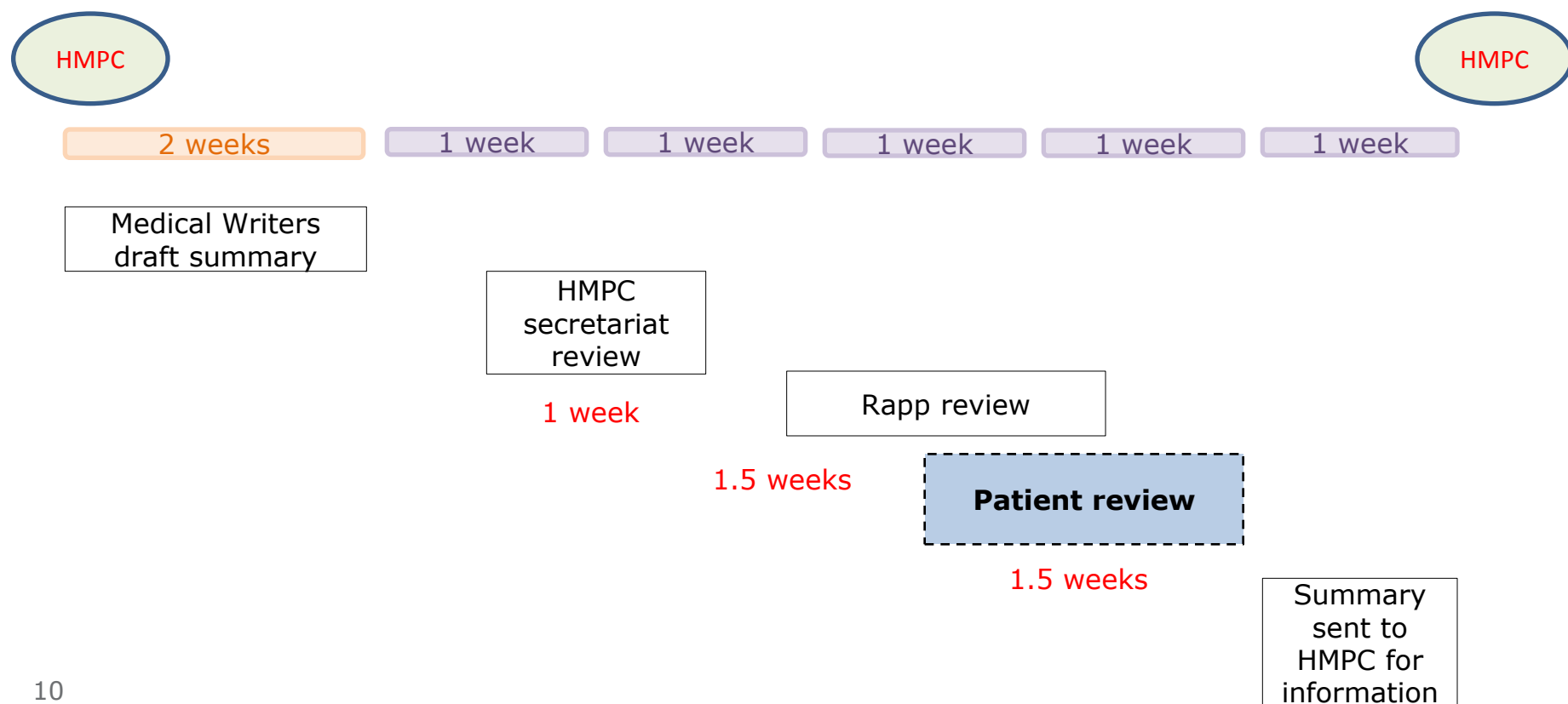


Next steps

- Around 30 herbal summaries to be prepared per year (and translated in all EU languages)
- Discussion on how to best involve PCOs:
 - ‘call for expression of interest’ for eligible patients with interest/expertise in herbal medicines?



Timelines





Thank you!