HERBAL MEDICINAL PRODUCTS COMMITTEE (HPMC)

(slides from EMA, Herbal Committee, and me)

Rob Camp

May 2017, Budapest

EURORDIS.ORG

What is the Committee on Herbal Medicinal Products (HMPC)?

HMPC Chair:
Marisa Delbo (IT)

What is the Committee on Herbal Medicinal Products (HMPC)?

- The HMPC is one of seven committees at the European Medicines Agency (EMA). It is responsible for carrying tasks concerning the authorisation and the simplified registration of herbal medicinal products (HMP).
- The members and alternates of the HMPC are nominated by EU Member States and are chosen based on their qualifications and expertise...
- The members of the HMPC are appointed for a renewable period of three years*. The chair and vice-chair are elected from its members for a term of three years, which may be renewed once.

What is the Committee on Herbal Medicinal Products (HMPC)? *cont'd*

The HMPC is composed of:

- one **chair** plus one **vice-chair**, who is also a HMPC member, both elected by serving HMPC members.
- one **member** and an alternate nominated by each of the 28 **EU** Member States.
- one **member** and an alternate nominated by the **EEA-EFTA** states Iceland and Norway (Liechtenstein did not nominate a member).
- up to five **co-opted members**, chosen among experts nominated by Member States or the Agency to gain additional expertise in a particular scientific area. These are elected by the HMPC members.

What is the Committee on Herbal Medicinal Products (HMPC)? *cont'd*

- The HMPC **meets every other month** for 1 day at the premises of the EMA in London (except in August) (see HMPC Meeting dates)*.
- HMPC meetings are not public.

What is the competence of the HMPC?

- Establish **European Union herbal monographs**
  - compiling and assessing scientific data on herbal substances, preparations and combinations
  - with a focus on the safety and efficacy
  - Monographs can be used by applicants as application reference material.
- Establish a draft `**European Union list** of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products'.

What is raspberry leaf?

Raspberry leaf is the common name for the leaf of the plant *Rubus idaeus* L.

The HMPC conclusions only cover raspberry leaf preparations which are obtained by drying and reducing the leaves into tiny pieces or as dry extracts. Dry extracts are obtained by putting the plant material in a solvent to dissolve it and form a liquid extract. This is then evaporated to obtain a dry extract.

Herbal medicines containing raspberry leaf preparations are usually available as herbal tea to be drunk, as infusions to be applied (as drops?) to the inside of the mouth and in solid forms (pills) to be swallowed.

Raspberry leaf preparations may also be found in combination with other herbal substances. These combinations are not covered here.

What are the HMPC conclusions on the medicinal uses of raspberry leaf?

The HMPC has concluded that, on the basis of "long-standing use", these raspberry leaf preparations can be used for

a) relief of minor spasms associated with menstrual periods,

Rob Camp 9/5/17 20:19
Deleted:)

Rob Camp 9/5/17 20:19
Deleted: the leaves and

Rob Camp 9/5/17 20:20
Deleted: compounds

Rob Camp 9/5/17 20:20
Deleted: The solvent

Rob Camp 9/5/17 20:21
Deleted: lining

Rob Camp 9/5/17 20:21
Deleted: in some herbal medicines

Rob Camp 9/5/17 20:21
Deleted: in this summary

Rob Camp 9/5/17 20:22
Deleted: its

Rob Camp 9/5/17 20:22
Deleted: its

Rob Camp 9/5/17 20:23
Formatted: Numbered + Level: 1 + Numbering Style: a, b, c, … + Start at: 1 + Alignment: Left + Aligned at: 0,63 cm + Indent at: 1,27 cm

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 Facsimile +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

b) treatment of mild mouth or throat inflammation, and

c) treatment of mild diarrhoea.

Raspberry leaf medicines should only be used in adults. When taking the medicine for diarrhoea, a

Rob Camp 9/5/17 20:23
Deleted: for

Rob Camp 9/5/17 20:23

What is the competence of the HMPC? *cont'd*

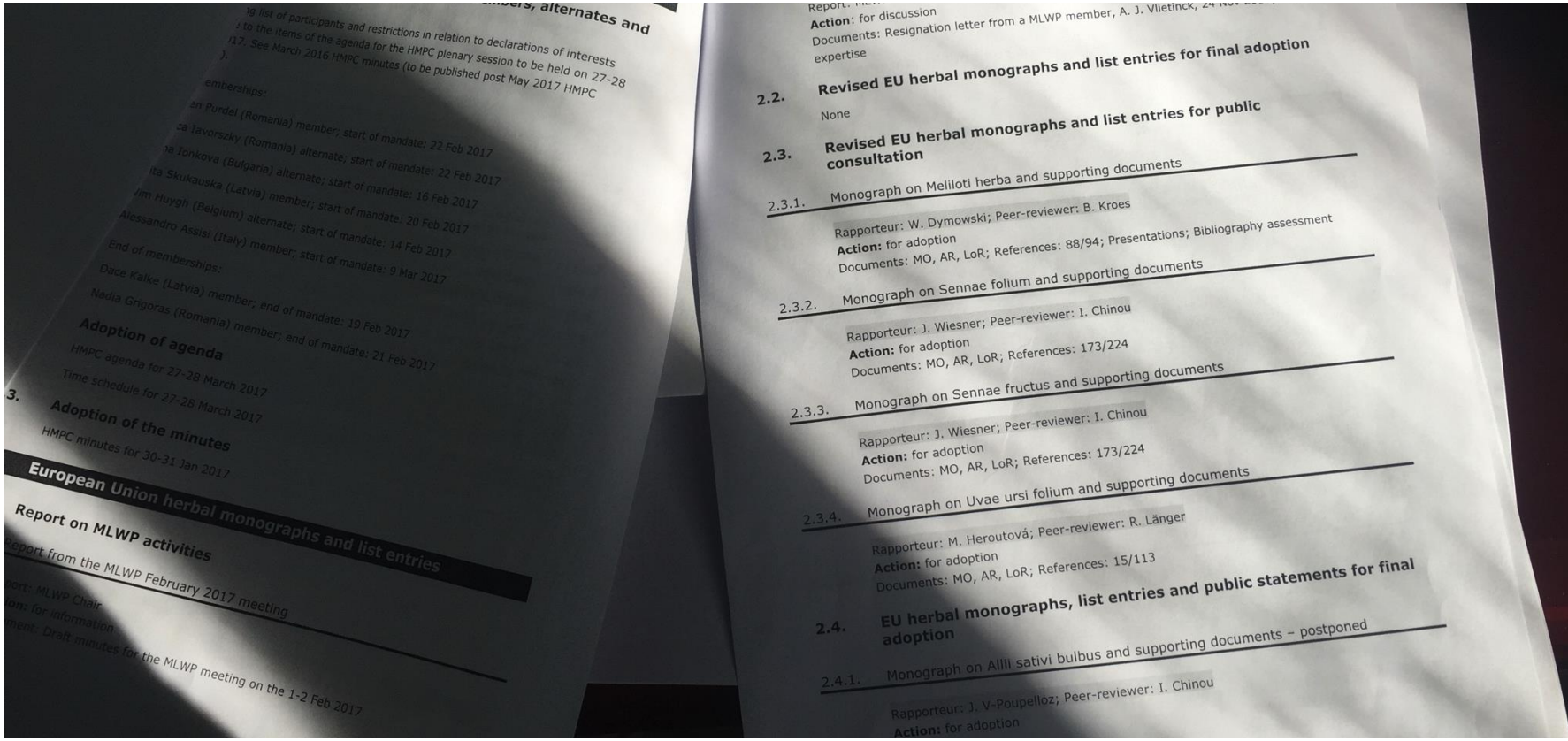
- Adopt scientific opinions on matters referred by Member States to the HMPC in relation to a THMP:
  - the adequacy of the evidence of its long-standing use.
  - the evidence of traditional use for this THMP amounts to less than 15 years in the EU.

  Such opinions are not legally binding to these Member States.
- Adopt scientific and regulatory guidance for the purpose of facilitating the fulfilment of the above-mentioned competence or for the purpose of enhancing the European harmonisation process in the field across the Member States.

What is the role of a HMPC member/alternate?

- HMPC members present their position to the committee and **take part in adoption** of various draft and final HMPC documents. HMPC members aim to adopt HMPC documents **by consensus**; otherwise a vote take place.
- **HMPC members are encouraged to take an active role as Rapporteurs to prepare the draft HMPC position for topics either in procedures involving the HMPC only or in procedures where cross-committees coordination is required.**
- HMPC members participate **orally** during discussions and **in writing** by exchanging written comments between meetings.

Agenda for March meeting – 12 pages



What are the main documents adopted by the HMPC?

- The HMPC adopts the following types of documents:

  1. European Union **herbal monographs** (and supporting documents) and list entries.
  2. Scientific guidelines and other forms of scientific guidance (e.g. reflection paper, Questions & Answers).
  3. Scientific positions on questions arising as part of a referral procedure.
  4. Scientific positions on questions arising as part of a cross-committee coordination procedure (e.g. CHMP scientific advice on a HMP).
  5. Regulatory guidance (e.g. regulatory interpretation of legal provisions) and procedural documents (e.g. templates).


CARRER D'ASTÚRIES
FARMACIA GUERRA
GUERRA

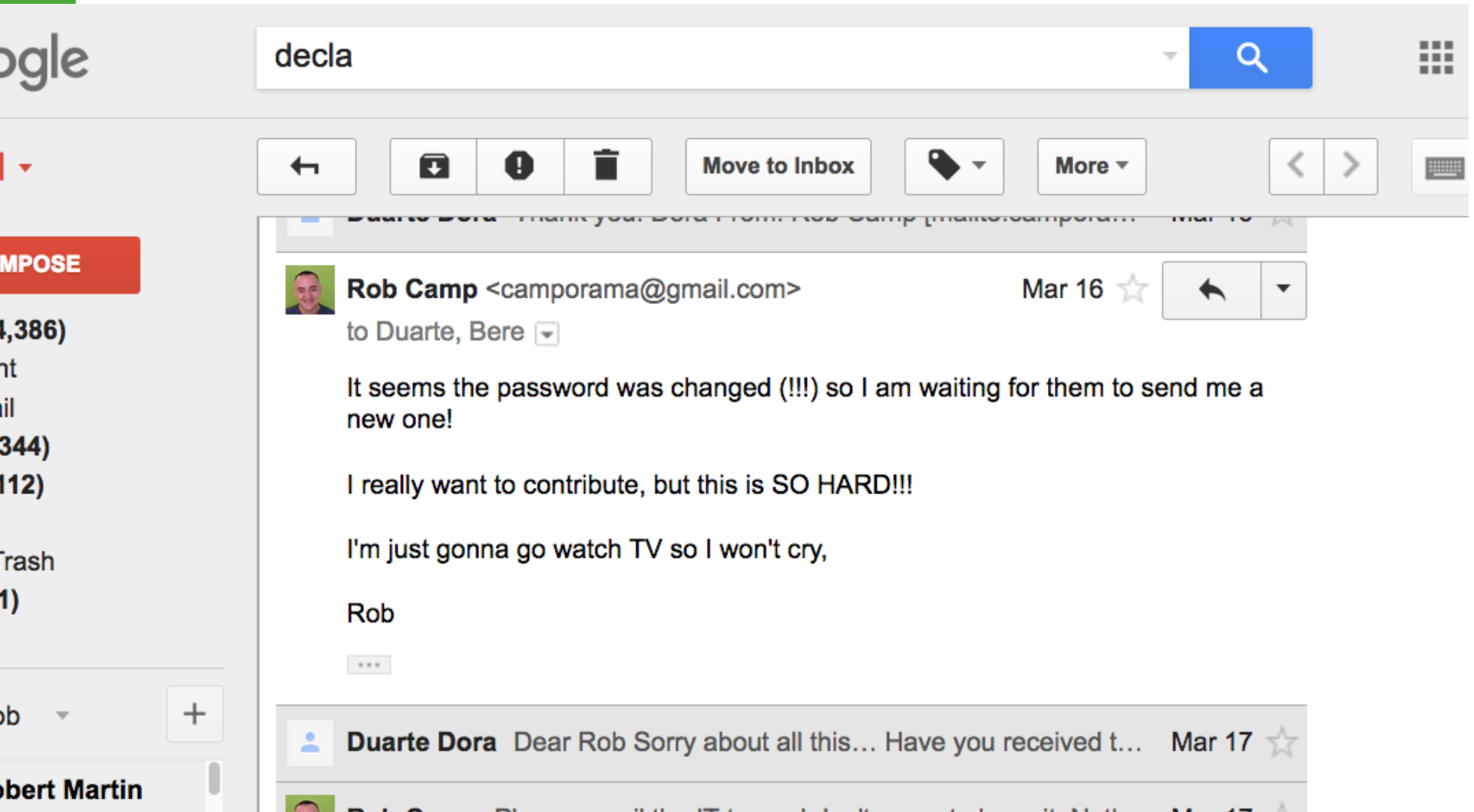

FARMÀCIA SALUD
Farmàcies de Guàrdia
¡CUÍDATE CORAZÓN!
Medición Riesgo Cardiovascular
10€
DEA
BETER
taxfree


L'Ase Blanc
HERBOLARI ARTESÀ
EN TRASPÀS
DIETA ACTIVA
13

Can national experts attend the HMPC meetings?

- **Yes** national experts can attend, but there are specific requirements.
- In order for national experts to be allowed to participate in EMA activities, they need to be nominated by the NCA and registered in the EMA Experts database.
- **For this, they have to complete an electronic Declaration of Interest form and a Confidentiality Undertaking and provide an up-to-date electronic CV*.**
- Following receipt of the documents, the Agency assesses the information to determine the level of involvement in EMA activities.
- The EMA may either grant full participation, grant restricted participation or exclude the experts from meeting participation as appropriate.

DoI form – instructions for the form is 17 pages. It took me approx 3 weeks to figure it out, turn it in, have it rejected, re-do it, etc



How are the Table of Decisions (ToD) and the Minutes prepared?

- During the HMPC meeting, members of the HMPC secretariat record the main points of **the discussions and their outcome***.
- After preparation by the secretariat, the ToD is circulated internally to relevant colleagues and to the HMPC Chair for review, prior to circulating to all HMPC members for comments.

How does the HMPC form an opinion?

- When an adoption takes places, the Chair asks the HMPC members a specific question, e.g. if they are positive for the adoption of a given document.
- The results are recorded by the **HMPC secretariat**.

The HMPC Secretariat Team

Wieland Peschel
Scientific Administrator
Main responsibilities: Management of the HMPC Secretariat. Supervision of preparation of HMPC meetings, Quality DG and follow-up activities.

Tel: +44 (0)20 3660 7742
E-mail: Wieland.Peschel@ema.europa.eu

Orsolya Roza
Scientific Administrator
Main responsibilities: Management of the HMPC Secretariat. Supervision of preparation of MLWP and ORGAM DG meetings and follow-up activities.

Tel: +44 (0)20 3660 8110
E-mail: Orsolya.Roza@ema.europa.eu

Pia Chambers
Assistant
Main responsibilities: Organisational and secretarial support to the MLWP and Quality DG meetings.

Tel: +44 (0)20 3660 7106
E-mail: Pia.Chambers@ema.europa.eu

Monika Jaromi
Assistant
Main responsibilities: Organisational and secretarial support to the HMPC plenary and ORGAM DG meetings.

Tel: +44 (0)20 3660 8125
E-mail: Monika.Jaromi@ema.europa.eu

HMPC secretariat
(hmpc.secretariat@ema.europa.eu)

How are the Minutes prepared? *cont'd*

- The HMPC secretariat prepares the minutes **summarising the major discussion points** during the HMPC meeting for each topic.
- The **draft minutes** are also first circulated internally to relevant colleagues and to the HMPC Chair for review and afterwards to the HMPC members for comments.
- The **final minutes** are adopted at the following HMPC plenary meeting.
- After adoption, the minutes are published on the HMPC webpage.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Site-wide search GO

Advanced document search

Home | Find medicine | Human regulatory | Veterinary regulatory | Committees | News & events | Partners & networks | About us

- How the committees work
- CHMP
- CVMP
- PRAC
- COMP
- HMPC
  - Members
  - Meetings
  - Agendas and outcomes
- CAT
- PDCO
- Working parties and other groups

Home > Committees > HMPC

Committee on Herbal Medicinal Products (HMPC)

Email Print Help Share

The Committee on Herbal Medicinal Products (HMPC) is the European Medicines Agency's (EMA) committee responsible for compiling and assessing scientific data on herbal substances, preparations and combinations, to support the harmonisation of the European market.

The HMPC replaced the Committee for Proprietary Medicinal Products' Working Party on Herbal Medicinal Products in September 2004.

The Committee was established in accordance with Regulation (EC) No 726/2004 and the Herbal Directive, which introduced a **simplified registration procedure** for traditional herbal medicinal products in EU Member States.

The HMPC is composed of scientific experts in the field of herbal medicines.

Role of the HMPC

The HMPC prepares the Agency's opinions on herbal substances and preparations, along with information on recommended uses and safe conditions.

This work supports the **harmonisation** of the European market: national competent authorities are able to refer to one unique set of information on a herbal substance or

Related content

- Herbal medicinal products
- Find herbal medicines
- EU monographs and list entries
- About us
- European experts

Related documents

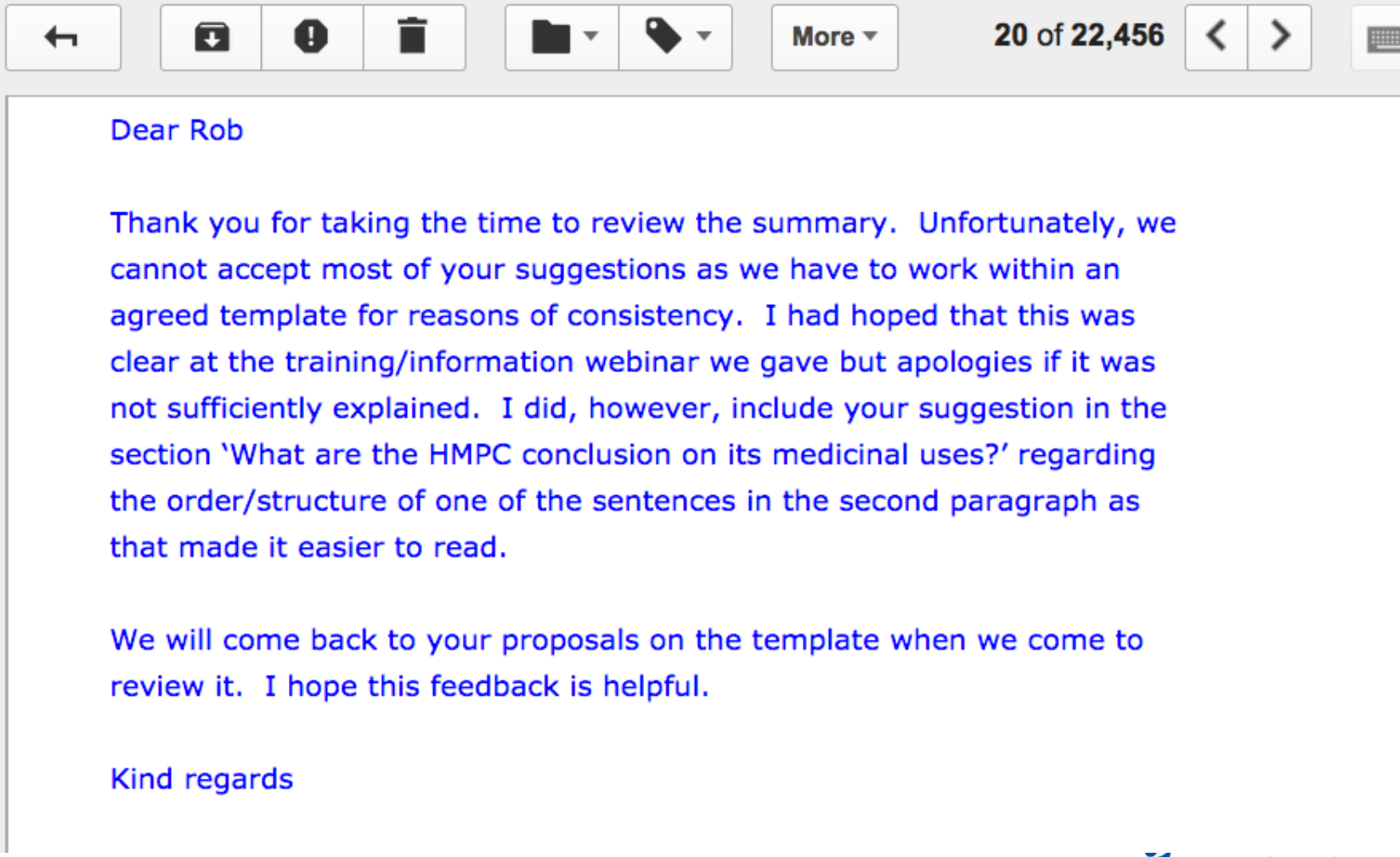
Policy on scientific publication and representation for European Medicines Agency scientific committees and their members (21/12/2010)

Contact point:

HMPC Secretariat
European Medicines Agency
30 Churchill Place
Canary Wharf

What is the HMPC public meeting report?

- **A public meeting report** is prepared by the HMPC secretariat to communicate to stakeholders and the public some of the decisions taken, in particular the documents which were adopted either for release for 3-month public consultation or as final.
- After review by the Chair, the draft public meeting report is sent to HMPC members for comments within 48 hours.
- The HMPC public meeting reports are published on the EMA website. They contain links to already newly published documents or links to the webpages where new documents are expected to be made accessible in the coming days/weeks.


More
20 of 22,456
Dear Rob
Thank you for taking the time to review the summary. Unfortunately, we cannot accept most of your suggestions as we have to work within an agreed template for reasons of consistency. I had hoped that this was clear at the training/information webinar we gave but apologies if it was not sufficiently explained. I did, however, include your suggestion in the section 'What are the HMPC conclusion on its medicinal uses?' regarding the order/structure of one of the sentences in the second paragraph as that made it easier to read.
We will come back to your proposals on the template when we come to review it. I hope this feedback is helpful.
Kind regards