25 January 2018
EMA/CHMP/672198/2017

Work plan for the CHMP Excipients Drafting Group (ExcpDG) for the revision of the EC guideline 'Excipients in the labelling and package leaflet of medicinal products for human use' for 2018

Chairperson: Dominique Masset

Status of the work plan: Adopted

The activities outlined in the work plan for 2018 have been agreed considering the respective business priorities, as well as the Agency's relocation as a result of the UK's exit from the EU and its impact on the Agency's business continuity, and may be subject to further review and reprioritisation in accordance with the business continuity plan of the Agency.

1. Meetings scheduled for 2018

Face-to-face meetings (F2F) and virtual meetings (VM) are planned for the following dates:

- 18 January 2018 (VM)
- 1 March 2018 (VM)
- 15-16 May 2018 (F2F)
- 5 July 2018 (VM)
- 13 September 2018 (VM)
- 8 November 2018 (VM)

The above mentioned dates may be modified as needed. Additional virtual meetings may be organised ad-hoc to respond to time-sensitive requests on products and to progress guidelines, as required.

2. Guidelines

Note: The ExcpDG reviews the safety information of individual excipients (update of an excipient of the list or addition of a new excipient) as appropriate and prepares in cooperation with QRD a revised version of the annex to the EC guideline including the new information for the package leaflet.

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2.1. New scientific reviews for excipients labelling updates

Action: Lead

Questions and answers (Q&A) on ethanol in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (EMA/CHMP/507988/2013)

Target date	Final Q&A to be adopted by CHMP in Q1 2018 Revised Annex to be published in Q2 2018
Comments	Cooperation with QRD and HMPC. Following the public consultation of 2014 many comments were received. Changes proposed in the final Q&A will be sent to SWP, QWP, BWP, VWP, BPWP, PCWP, HCPWP, PDCO, PRAC and CMDh for consultation prior to CHMP adoption. Background review document (EMA/CHMP/281628/2013) to be published.

Information for the package leaflet regarding lactose used as an excipient in medicinal products for human use (EMA/CHMP/ 186428/2016)

Target date	Draft to be released for 3-month public consultation in Q2 2018
Comments	Information for the package leaflet to be updated. Includes a background scientific review. Cooperation with QRD. Consultation of SWP, QWP, BWP, VWP, BPWP, PCWP, HCPWP, PDCO, PRAC and CMDh prior to CHMP adoption for public consultation.

Information for the package leaflet regarding polysorbate used as an excipient in medicinal products for human use (EMA/CHMP/ 190743/2016)

Target date	Draft to be released for 3-month public consultation in Q2 2018
Comments	Information for the package leaflet to be added to EC GL Annex. Includes a background scientific review. Cooperation with QRD. Consultation of SWP, QWP, BWP, VWP, BPWP, PCWP, HCPWP, PDCO, PRAC and CMDh prior to CHMP adoption for public consultation.

Information for the package leaflet regarding L-proline used as an excipient in medicinal products for human use (EMA/CHMP/ 332530/2015)

Target date	Draft to be released for 3-month public consultation in Q2 2018
Comments	Information for the package leaflet to be added to EC GL Annex. Includes a background scientific review. Cooperation with QRD. Consultation of SWP, QWP, BWP, VWP, BPWP, PCWP, HCPWP, PDCO, PRAC and CMDh prior to CHMP adoption.

Information for the package leaflet regarding dextrans used as an excipient in medicinal products for human use (EMA/CHMP/ 187129/2016)

Target date	Draft to be released for 3-month public consultation in Q2 2018
Comments	Information for the package leaflet to be added to EC GL Annex. Includes a background scientific review. Cooperation with QRD. Consultation of SWP, QWP, BWP, VWP, BPWP, PCWP, HCPWP, PDCO, PRAC and CMDh prior to CHMP adoption for public consultation.

Information for the package leaflet regarding azo-dyes (colouring agents)used as an excipient in medicinal products for human use

Target date Draft to be released for 3-month public consultation in Q2 2018

Comments Information for the package leaflet to be updated. Includes a background scientific review. Cooperation with QRD. Consultation of SWP, QWP, BWP, VWP, BPWP, PCWP, HCPWP, PDCO, PRAC and CMDh prior to CHMP adoption for public consultation.

Review of the information for the package leaflet for sucrose, polyethylene glycols (macrogols), maltose, maltodextrin, xylitol and maltitol as excipients in medicinal products for human use was included in previous WPs, and will be considered (with revised timelines) after the other excipients included in this work plan are finalised, in view of the priorities defined in the context of the UK's exit from EU.

2.2. Excipients labelling updates (language harmonisation)

Action: Lead

Annex to the EC Guideline on 'Excipients in the label and package leaflet of medicinal products for human use'

Target date Q4 2018 (English version). Delivery date conditional on resources available.

Comments The wording in English of the labelling of the excipients not reviewed by the ExcpDG (see 2.1) to be harmonised with the labelling of new/updated excipients and translated in all EEA languages. Multidisciplinary work to be done in collaboration with QRD.

3. Medicinal Products-specific activities

3.1. Pre-Authorisation activities

Response to ad-hoc requests about the safety and labelling of excipients

3.2. Evaluation and supervision activities

Requests from other Scientific committees (CHMP, PDCO, PRAC, CAT, HMPC) and working parties (e.g. SWP, QWP, BWP, etc.) on excipients in authorised products

4. Input in European activities

4.1. Training for the network and knowledge building

Assessor training on the Annex changes with examples on how to use the guideline (EU-NTC)

4.2. Other input in European activities

Close collaboration with EC (particularly NTA group).

Consultation of relevant groups such as EDQM, EFSA and ECHA where approriate.

5. Input in International activities (beyond ICH guidelines)

Interactions with international regulatory agencies as required.

6. Contribution to dialogue and engagement with stakeholders and external parties

Dialogue (ad-hoc) with academic organisations (EU or international) as relevant (e.g. IPEC, EuPFI, ESNEE), industry, patient organisations