15 December 2016
EMA/CHMP/750448/2016 Rev 0

Work plan for the CHMP Excipients Drafting Group (ExcpDG) for the revision of the guideline “Excipients in the label and package leaflet of medicinal products for human use” for 2017

Chairperson: Dominique Masset

Status of the work plan November 2016: Draft

1. Meetings scheduled for 2017

Face-to-face meetings are planned for the following dates:

- September 2017

The above mentioned dates may be modified as needed.

Additional virtual meetings may be organised monthly to progress guidelines, as required.

2. Guidelines

2.1. New EU Guidelines

Action: Lead

Questions and answers 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 Q2 2017
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 endorsed for information.

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Information in the package leaflet for L-proline 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/ 332530/2015)

Target date	Draft to be released for 3-month public consultation in Q2 2017
Comments	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 in the package leaflet for lactose 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/ 186428/2016)

Target date	Draft to be released for 3-month public consultation in Q2 2017
Comments	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 in the package leaflet for azo-dyes (colouring agents) in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use'

Target date	Draft to be released for 3-month public consultation in Q2 2017
Comments	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 in the package leaflet for dextrans in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use'

Target date	Draft to be released for 3-month public consultation in Q4 2017
Comments	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 in the package leaflet for polysorbate in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use'

Target date	Draft to be released for 3-month public consultation in Q4 2017
Comments	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 in the package leaflet for maltose in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use'

Target date	Draft to be released for 3-month public consultation in Q4 2017
Comments	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 in the package leaflet for maltodextrin (oral) in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use'

Target date	Draft to be released for 3-month public consultation in Q4 2017
Comments	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 in the package leaflet for polyethylene glycols, macrogols in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use'

Target date	Draft to be released for 3-month public consultation in Q4 2017
Comments	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 in the package leaflet for sucrose in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use'

Target date	Draft to be released for 3-month public consultation in Q4 2017
Comments	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 in the package leaflet for xylitol and maltitol in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use'

Target date	Draft to be released for 3-month public consultation in 2017
Comments	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.

2.2. EU Guidelines under revision

Action: Specialised input

Guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (CHMP/463/00)

Leading group	European Commission, Notice to Applicants group
Target date	Updated guideline in Q4 2017
Comments	The updated annexe will be published together with the final revised guideline

3. Medicinal Products-specific activities

None

4. Input in European activities

Collaboration with EC (particularly NTA group), the main guideline being an EC guideline. See 2.2.

Consultation of EDQM, EFSA and ECHA for relevant excipients.

5. Input in International activities (beyond ICH guidelines)

Collaboration with international regulatory agencies as required.

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

EU, international or academic organisations as relevant (e.g. IPEC, EuPFI, ESNEE)