25 January 2018
EMA/CHMP/519446/2017

Work plan for the Radiopharmaceutical Drafting Group for 2018

Chairperson: Anabel Cortés Blanco

Status of the work plan: January 2018 - 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 are planned for the following dates:

- 14 September 2018

Virtual meetings are planned for the following dates:

- 02 March 2018
- 13 April 2018
- 25 May 2018
- 20 July 2018
- 9 November 2018

Virtual meetings/web sharing will be planned to accommodate scientific input to products scientific advice and evaluation. Additional teleconferences will be organised ad-hoc to respond to time-sensitive input on products and to progress guidelines, as required.

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2. Guidelines

2.1. New EU Guidelines

Action: Lead

Reflection paper on generics for radiopharmaceutical medicinal products

Target date Draft reflection paper to be released for external consultation Q4 2018
Comments Quality working party to be consulted

Guideline on core SmPC and package leaflet for technetium (^{99m}Tc) macrosalb, EMA/CHMP/618238/2017

Target date Final guideline to be published Q2 2018
Comments External consultation until 31 March 2018.

Guideline on core SmPC and package leaflet for iopamidol 300 mg I/ml, EMA/CHMP/813269/2016

Target date Final guideline to be published Q2 2018
Comments External consultation ended 31 August 2017

Guideline on core SmPC and package leaflet for iopamidol 370 mg I/ml, EMA/CHMP/813144/2016

Target date Final guideline to be published Q2 2018
Comments External consultation ended 31 August 2017

Guideline on core SmPC and PIL of lutetium (^{177}Lu) chloride

Target date Draft guideline to be released for external consultation Q2 2018

Guideline on core SmPC and package leaflet for technetium (^{99m}Tc) exametazime

Target date Draft guideline for external consultation Q3 2018

Guideline on core SmPC and package leaflet for gadoteric acid, EMA/CHMP/337820/2016

Target date Final guideline to be published Q3 2018

Guideline on core SmPC and package leaflet for iobenguane (^{123}I)

Target date Draft guideline to be released for external consultation Q4 2018

Guideline on core SmPC and PL for technetium (^{99m}Tc) HDP and (^{99m}Tc) MDP (medronate)

Target date Draft guideline to be released for external consultation Q4 2018

Guideline on core SmPC and PIL of fluorocholine (^{18}F)

Target date Draft guideline to be released for external consultation Q4 2018

Action: Specialised input

Draft annex for harmonisation of wording on safety information in the core SmPC/PL of iodinated contrast agents.

Target date 2Q 2018

Comments In consultation with the SmPC advisory group, the RadDG will prepare an annex to harmonise class-related safety information aspects for core SmPCs of iodinated contrast agents. This annex will be released with the core SmPC and PL for iopamidol 300.

2.2. EU Guidelines under revision

None

2.3. ICH Guidelines

None

3. Medicinal Products-specific activities

None

4. Input in European activities

None

5. Input in International activities (beyond ICH guidelines)

None

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

None

In addition to the actions identified above, the working party can be involved in any other activities foreseen in its mandate:

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/08/WC500095453.pdf