14 December 2017
EMA/CHMP/BPWP/399637/2017

Work plan for the Blood Product Working Party (BPWP) for 2018

Chairperson: Jacqueline Kerr

Status of the work plan: December 2017 – 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) are planned for the following dates:

- 8-9 February 2018
- 2-3 October 2018

Virtual meeting dates:

- 10 April 2018
- 14 June 2018

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

2.1. New EU Guidelines

Action: Lead

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Reflection Paper on the Clinical Investigation of Activated Recombinant Human Coagulation Factor VII (rFVIIa) products (EMA/CHMP/BPWP/99228/2014)

Target date Finalisation of the reflection paper following public consultation expected by Q4 2018

Comments Other involved WP: SAWP, PDCO

2.2. EU Guidelines under revision

Action: Lead

Guideline on the Clinical investigation of Human normal immunoglobulin for intraveneous use (EMA/CHMP/BPWP/94033/2007 rev. 3)

Target date Finalisation following public consultation by Q1 2018

Core SmPC for Human normal immunoglobulin for intravenous use (EMA/CHMP/BPWP/94038/2007 Rev. 5)

Target date Finalisation following public consultation by Q1 2018

Guideline on the Clinical investigation of Human normal immunoglobulin for subcutaneous and intramuscular use (EMA/CHMP/BPWP/410415/2011 rev. 1)

Target date Finalisation following public consultation by Q2 2018

Comments In accordance with IVIG guideline

Core SmPC for Human normal immunoglobulin for subcutaneous and intramuscular use (EMA/CHMP/BPWP/1343744/2011 rev. 1)

Target date Finalisation following public consultation by Q2 2018

Comments In accordance with IVIG core SmPC

Clinical Investigation of Plasma derived fibrin sealant/haemostatic products (EMA/CHMP/BPWP/741603/2015, replacing CPMP/BPWP/1089/00)

Target date Revised draft guideline expected to be released for public consultation Q2 2018

Comments Other involved Committees/WP: PRAC

Core SmPC for plasma derived fibrin sealant/haemostatic products (EMA/CHMP/BPWP/598816/2010 rev. 1)

Target date Revised draft guideline expected to be released for public consultation Q2 2018

Comments Other involved Committees/WP: PRAC

Guideline on the clinical investigation of recombinant and human plasma-derived factor VIII products (EMA/CHMP/BPWP/144533/2009 rev. 2)

Target date Finalisation of the revised guideline following public consultation in Q2 2018.

Comments Other involved Committees/WPs: PRAC, PDCO. Update as a follow up from Haemophilia Registries workshop held in 2015

Core SmPC for human plasma derived and recombinant coagulation factor VIII products (EMA/CHMP/BPWP/1619/1999 rev. 2)

Target date Finalisation of the revised guideline following public consultation in Q1 2018.

Comments Other involved Committees/WPs: PRAC, PDCO. Update as a follow up from Haemophilia Registries workshop held in 2015

Guideline on clinical investigation of recombinant and human plasma derived factor IX products (EMA/CHMP/BPWP/144552/2009 Rev.1, Corr.1)

Target date Finalisation of the revised guideline following public consultation in Q1 2018

Comments Other involved Committees/WPs: PRAC, PDCO. Update as a follow up from Haemophilia Registries workshop held in 2015 and in accordance to revision of FVIII guidelines

Core SmPC for human plasma derived and recombinant coagulation factor IX products (EMA/CHMP/BPWP/1625/99 Rev. 2)

Target date Finalisation of the revised guideline following public consultation in Q1 2018

Comments Other involved Committees/WPs: PRAC, PDCO. Update as a follow up from Haemophilia Registries workshop held in 2015

Guideline on core SmPC for human albumin solution (EMA/CHMP/BPWP/494462/2011 rev.3)*

Target date Draft guideline expected to be released for public consultation in Q4 2018

Comments Other involved Committees/WPs: PRAC

2.3. ICH Guidelines

None

3. Medicinal Products-specific activities

3.1. Pre-Authorisation activities

- Contribution to the scientific advice and protocol assistance provided by the SAWP upon request of SAWP (including advice related to paediatric use): BPWP to provide a report to the SAWP on all the SA/PA requested for blood products
- Contribution to paediatric investigation plans (PIP) upon request of PDCO
- Respond to consultations arising from the CHMP/PDCO/PRAC/CAT

3.2. Evaluation and supervision activities

- Contribution to CHMP marketing authorisation or post-authorisation evaluation procedures upon request of CHMP
- Address issues related to the evaluation of the safety and benefit/risk of blood derivatives used as ancillary substances in medical devices
- Work with BWP and the EDQM on efficacy and safety issues linked to quality
- Support, as requested, to Inspections activities, quality defects, sampling and testing
- Recommendation to CHMP on applications for PMF certificates
- Contribution to referral discussions upon request from CHMP/PRAC
- Input into discussion of pharmacovigilance issues upon request from CHMP/PRAC
- Respond to consultations arising from the CHMP/PDCO/PRAC/CAT
- Contribute to risk management plans for blood products e.g. through development of post-marketing-investigation concepts

4. Input in European activities

4.1. Training for the network and knowledge building

None

4.2. Support to and cooperation with EU institutions and Network

None

4.3. Interactions with learned societies and specialised organisations

- Cooperation with WFH Treatment Product Safety, Supply and Access committee (TPSSAC)
- Cooperation with ISTH SSC FVIII/FIX working groups
- Cooperation with European Directorate for the Quality of Medicines and HealthCare (EDQM)
- Cooperation with relevant patients' organisations

5. Input in International activities (beyond ICH guidelines)

5.1. Activities with other regulators

Three virtual meetings on blood products with FDA and Health Canada (EMA/FDA/HC cluster)

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

6.1. Workshops

Organise a multi-stakeholders meeting in relation with the revision of the guideline on the clinical investigation of recombinant and human-plasma-derived factor VIII products (Q1 -2018) as appropriate

6.2. Joint activities with stakeholders and external parties

Participate in the joint EMA/Industry Task Force (JEIF) meeting (in conjunction with BWP if relevant) on pandemic preparedness

6.3. Other activities 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