14 December 2017
EMA/CHMP/365586/2017

Work plan for the Cardiovascular Working Party (CVSWP) for 2018

Chairperson: Kristina Dunder

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 are planned for the following dates:

- 3 May 2018
- 21 November 2018

Teleconferences are planned for the following dates:

- 7 February 2018
- 4 July 2018
- 26 September 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.

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2. Guidelines

2.1. New EU Guidelines

Action: Lead

Paediatric addendum to CHMP guidelines on the clinical investigations of medicinal products for the prevention and treatment of thromboembolic disease.

Target date Concept paper was released for public consultation in Q4 2017; first draft of the Addendum to be released in Q2 2018

Comments To be developed in collaboration with Paediatric Committee (PDCO).

2.2. EU Guidelines under revision

Action: Lead

Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus (CPMP/EWP/1080/00 Rev. 2)

Target date Draft guideline to be released for public consultation Q1 2018

Comments Public consultation of the concept paper ended in 31 Oct 2016. Guideline developed in collaboration with PDCO, Biostatistics Working Party (BSWP) and Scientific Advice Working Party (SAWP).

Paediatric addendum to CHMP Guidelines on the clinical investigations of medicinal products for the treatment of pulmonary arterial hypertension (CHMP/EWP/213972/10).

Target date Concept paper to be released for public consultation in Q2 2018

Comments To be developed in collaboration with PDCO.

Note on clinical investigation of medicinal products for the treatment of peripheral arterial occlusive disease (CPMP/EWP/714/98 rev.1).

Target date Concept paper to be released for public consultation in Q2 2018

Comments To be developed in collaboration with BSWP and SAWP.

Action: Specialised input

Reflection paper on the regulatory guidance for the use of health-related quality of life (HRQL) measures in the evaluation of medicinal products (EMEA/CHMP/EWP/139391/2004)

Leading Groups	Oncology Working Party (ONCWP)
Target date	Draft reflection paper to be released for public consultation by 3Q 2018
Comments	Concept Paper was written in Q1 2017, in close collaboration with the BSWP. Involvement of other WPs, including SAWP and PCWP.

Guideline on multiplicity issues in clinical trials EMA/CHMP/44762/2017

Leading Group	Biostatistics Working Party (BSWP)
Target date	Final guideline expected to be published in Q2 2018.
Comments	This is a revision of previous Points to Consider. The guideline was developed in collaboration with the SAWP and the Cardiovascular Working Party (CVSWP). A training of the assessors will be organised via webinar once the guideline has been finalised

Q&A on data monitoring committees CHMP/EWP/5872/03

Leading Group	Biostatistics Working Party (BSWP)
Target date	Draft Q&A document expected to be published in Q1 2018.
Comments	The guideline was adopted in 2003. Since then there have been questions on the role and necessity for a Data Monitoring Committee (DMC) in different phases of drug development as well as with regard to the responsibilities for implementing DMC decisions. The Q&A document would provide answers to such questions. The CVS WP and ONC WP were informed about this Q&A, and the Good Clinical Practice (GCP) Inspections Working Group (IWG) was consulted. Finalisation of the Q&A after the public consultation period is not expected in 2018.

2.3. ICH Guidelines

ICH E17 General Principles for planning and design of multi-regional clinical trials

Target date	Guideline in Step 5; Following the adoption in 2017 it will come into effect within 6 months in 2018.
Comments	This new Guideline is proposed to provide guidance on general principles on planning/designing Multi-Regional Clinical Trial (MRCT). It will complement the guidance on MRCTs provided in ICH E5(R1) Guideline, facilitate MRCT data acceptance by multiple regulatory agencies and promote conducting MRCT appropriately. Training activities to take place in 2018 where the involvement of

CVS WP is expected.

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
- Contribution to Innovation Task Force

3.2. Evaluation and supervision activities

- Contribution/recommendation to CHMP marketing authorisation or post-authorisation evaluation procedures upon request of CHMP
- Input on non-centralised products (NAPs) evaluation/referral procedures upon request of CMDh
- Contribution to referral discussions upon request from CXMP/PRAC
- Input into discussion of pharmacovigilance issues upon request from CHMP/PRAC

4. Input in European activities

4.1. Training for the network and knowledge building

Maintain awareness of issues arising in order to identify the need for review and update of Guidelines and development of additional guidance documents via analysis of the CHMP SAs in cardiovascular, diabetes and obesity fields.

4.2. Interaction with learned societies and specialised organisations

Contribution to IMI calls and projects.

4.3. Other input into European activities

Action: Specialised input

Trial integrity in the presence of interim results in on-going clinical trials

Target date Draft a regulatory position by Q3 2018.

Comments Discuss methodological issues of trial integrity when interim analysis results of an ongoing trial become available and are assessed for marketing authorisation assessments. This should consider sponsor involvement, acceptability of methods to maintain integrity such as 'firewalls', and publication of results, by sponsor or by regulator (in relation to EMA Policy 0070 on the publication of clinical data for medicinal products for human use). If additional guidance is proposed, BSWP will discuss whether existing guidance documents are most appropriate to include the different aspects, or if these aspects call for the development of new guidance

documents.
Collaboration with CVS WP. Other working parties of relevance for this subject, such as ONC WP, will be consulted.

5. Input in International activities (beyond ICH guidelines)

5.1. Activities with other regulators

- Increase interactions by organising 3 TC with FDA and HC to exchange experience cardiovascular, diabetes and obesity fields.
- Participation and contribution to upcoming FDA workshops in cardiovascular, diabetes and obesity fields.

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

6.1. Workshops

None

6.2. Other activities with stakeholders and external parties

Interaction with interested parties e.g., learned societies (European Society of Cardiology) under the supervision of the CHMP.

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