14 December 2017
EMA/CHMP/370931/2017

Work plan for the Pharmacogenomics Working Party (PGWP) for 2018

Chairperson: Krishna Prasad

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:

- 19-20 March 2018
- 8-9 October 2018

The above mentioned dates may be modified as needed. Additional virtual meetings will 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

Addendum to the guideline on the Use of pharmacogenetic methodologies in the pharmacokinetic evaluation of medicinal products on terminology in pharmacogenomics

Target date	Draft addendum to be released for 3 months public consultation Q2 2018
Comments	none

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Guideline on predictive biomarker-based assay development in the context of drug development and lifecycle

Target date	Draft guideline to be released for 6 month public consultation Q4 2018
Comments	The guideline will replace the reflection paper on co-development of pharmacogenomic biomarkers and assays in the context of drug development. An expert meeting with relevant stakeholders is envisaged (see section 6.1)

Guideline on good pharmacogenomic practice, (EMA/CHMP/268544/2016)

Target date	Final guideline to be released Q1 2018
Comments	One day drafting group meeting envisaged

2.2. EU Guidelines under revision

Action: Specialised input

Guideline on evaluation of anticancer medicinal products in man (CHMP/205/95 Rev. 6)

Leading group	Oncology Working Party (ONCWP)
Target date	Concept paper to be released for public consultation Q1 2018
Comments	Contribution to the development of the revised guideline with regards to Pharmacogenomics and Biomarker development

2.3. ICH Guidelines

Action: Lead

Consider the harmonisation to define quantitative concepts for different degree of genotype determined metabolism to be applied during development of medicinal products, i.e., poor, intermediate, extensive, ultra-rapid metabolisers.

Target date	DRAFT proposal for ICH Assembly consideration Q4 2018
Comments	Discuss suggestions once the addendum to the guideline on the Use of pharmacogenetic methodologies in the pharmacokinetic evaluation of medicinal products on terminology in pharmacogenomics is completed.

3. Medicinal Products-specific activities

3.1. Pre-Authorisation activities

- Contribution to the scientific advice and protocol assistance upon request of SAWP
- Input on genomic biomarker- and methodologies qualification upon request of SAWP
- Other requests received from EMA Committees and Working Parties (CHMP, CAT, PDCO)
- Contribution to Innovation Task Force

  Comment: Contribution to briefing meetings on pharmacogenomic and methodological topics with external parties, including pharmaceutical companies, academia, public/private partnership, patients' associations, through participation of experts in close collaboration

3.2. Evaluation and supervision activities

- Contribution/recommendations to CHMP marketing authorisation and PRAC post-authorisation evaluation procedures upon request
- Input on non-centralised products (NAPs) evaluation/referral procedures upon request of CMDh
- Contribution to referral discussions upon request from CHMP/PRAC
- Contribution to requests received from other EMA Committees and Working Parties

4. Input in European activities

4.1. Training for the network and knowledge building

- Contribute to PRAC training plan for pharmacogenomic assessors on key aspects for the use of pharmacogenomic methodologies in the pharmacovigilance evaluation of medicinal products to be broadcasted via EU-NTC
- Pharmacogenomics in pharmacovigilance guideline implementation: impact of Pharmacogenomic labelling on the use of medicines in clinical practice and the use and effectiveness of genomic biomarker testing.

4.2. Support to and cooperation with EU institutions and Network

- Input to relevant activities of the EU Institutions such as the European Commission DG SANTE, DG RESEARCH upon request
- Collaboration with other regulatory bodies such as Notified Bodies, National Competent Authorities, Competent Authorities for Medical Devices (CAMD), Heads of Medicines Agencies (HMA)

4.3. Interactions with learned societies and specialised organisations

- Input and proposals on selected EU research projects, e.g. IMI, Horizon 2020 upon request

5. Input in International activities (beyond ICH guidelines)

- Cluster teleconferences with FDA and PMDA pharmacogenomic experts at PGWP face-to-face meetings or via teleconference when appropriate
- Foster pharmacogenomic cluster activities in addition to TC's during F2F, e.g. related to guideline development, trainings and workshops

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

6.1. Workshops

- Expert meeting on predictive biomarker-based assay development in the context of drug development and lifecycle

6.2. Other activities with stakeholders and externals parties

- Following the CAT/PGWP expert meeting on gene editing technologies held on 18 October 2017, collaborate with CAT on the drafting of a meeting report including regulatory and scientific considerations related to the development of medicines based on, or produced by means of gene editing technologies.
- Reflect on the need to develop a dedicated guidance on medicinal product based on, or produced by means of gene editing technologies or the need to revise existing guidelines to include information on gene editing. Deadline: 3Q 2018

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