EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Stakeholders and Communication Division

PCWP/HCPWP joint meeting

3 March 2023

Chairs: Juan Garcia Burgos (EMA), Rosa Giuliani (HCPWP), Marko Korenjak (PCWP)

Welcome and introduction

Juan Garcia Burgos (EMA) opened the meeting, welcoming all participants in person and online as well as the Working Party co-chairs.

1. EMA Working parties

1.1 Reorganisation of EMA working parties

Alberto Ganan Jimenez (EMA) provided background information on the reorganisation of the EMA working parties under five domains - Quality, Non-Clinical, Methodology, Clinical and Veterinary – and elaborated on how European experts will be working together in this new model. The reorganisation was the result of internal EMA reflection as well as a recommendation from the EMA Management Board to allow for strategic oversight of the five domains.

The model of the working parties is based on three-year strategic plans, and aligns with the EMAN and RS strategies, and also include training to the wider network and structured and systematic stakeholder engagement.

The CHMP will establish four types of expert groups under the domains of quality, non-clinical, clinical and methodological expertise. These are i) Working Parties (WP), ii) temporary Drafting Groups (tDG), iii) Operational Expert Groups (OEG) and iv) European Specialised Expert Communities (ESEC).

The Scientific Coordination Board is responsible for the overarching coordination of the work across all domains.

The Working Parties will be responsible for preparing, reviewing and updating guidelines and for preparing specific scientific positions, while the temporary Drafting Groups may be set up to work on specific guidelines or other guidance documents. OEGs are temporary expert groups that will complement expertise for product-specific recommendations or other matters when additional expertise is needed. The OEGs will provide scientific advice on operational core business; Scientific Advisory Groups (SAGs) will be part of the OEGs.

ESECs are communities of experts with specific knowledge and interest in a given topic area who can contribute to the European Regulatory Network. ESECs should be the source of expertise when constituting tDGs, OEGs and WPs. The establishment of ESECs will facilitate dissemination of information/knowledge

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through the NCAs network and to ensure the development and training of assessors across the EU network

The five domains are connected to the CHMP or CVMP and both committees interact to ensure alignment of priorities with the Scientific Coordination Board and to deliver on the objectives of the RSS and EMAN strategies (see presentation).

1.2 Scientific Advice Working Party (SAWP) – interaction with other WPs

Iordanis Gravanis (EMA) presented an introduction to the Scientific Advice Working Party, its main tasks and interactions with other Working Parties and other committees of the Agency. It is a large group of 72 members nominated based on expertise needed and includes members of the COMP, CAT, PRAC and PDCO. The SAWP has three main tasks that include provision of scientific advice/protocol assistance, advice and opinions on qualification of novel methodologies and assessment of PRIME eligibility requests. More information on each of these activities was provided. Patient involvement in scientific advice is well established. Please see presentation for more information.

1.3 Methodology Working Party (MWP)

Andrew Thomson (EMA) explained the role of the Methodology Working Party in the context of the reorganisation of the WP and groups into the five domains described above. The MWP is the only working party in the methodology domain, while the other domains will have several working parties.

He described the different structures that will deliver the work plan, guidance documents and training. The working party structure allows for members of the MWP with specific expertise to contribute to topics by participating in different ESECs outside the MWP, contributing knowledge where needed. The intention is to break down silos.

The MWP will also contribute to guidance documents, with 15 guidance documents prioritised for this year. Knowledge and capacity building is available, even for non-methodologists such as members of PCWP and HCPWP. There will be a lot of collaboration across the regulatory network and internationally.

The MWP will contribute to EU projects such as ACT EU and BDSG. The role of the ESEC was emphasised as the crucial network for knowledge, engagement and agile delivery (see presentation).

1.4 3Rs Working Party

The 3Rs Working Party (3RsWP) was described by Stefano Ponzano (EMA), who provided context regarding the number of animals used annually in basic and applied research and in regulatory testing. An expert group on the 3Rs (JEG 3RsWG) was first created in 2010 following the adoption of Directive 2010/63/EU, which requires EU Member States to reduce or eliminate animal testing. A statement was released by EMA at that time to show its commitment to the 3Rs. Due to the increased importance of the topic and the strategic goals highlighted by EMA in its RSS, the working group, has been converted into the new joint 3RsWP of CHMP and CVMP.

Interactivity of the WP with the OEGs, drafting groups and ESECs was described along with the composition of the WP and it strategic goals (see presentation), which include discussing non-animal methods such as organs-on-chip that aim at increasing predictivity, efficacy and safety of new potential medicines. To achieve the goals of the Working Party, interactions with developers and international regulators, training, development of guidance and qualification advice will be needed. PCWP/HCPWP members invited to share any information on new methods related to work of the 3Rs working party with public-engagement@ema.europa.eu

During the **Q&A session**, Maja Sommerfelt Grønvold, co-chair of the Infectious Diseases Working Party (IDWP), addressed the PCWP and HCPWP and expressed the interest of the IDWP to work with patients and healthcare professionals and their organisations on developing guidelines and communicating on product information as well as on sharing information and keeping open channels of communication.

A lively discussion followed with many questions, and this topic will be brought to a future meeting to further discuss patient and healthcare professional input into these new structures.

2. Committee feedback

An update was provided from members of scientific committees on activities with a particular interest to patients and healthcare professionals.

2.1 CAT

Mencía de Lemus, CAT member representing patients, described the work of the committee and the main differences between advanced therapies and other medicines. She highlighted some elements of the CAT workplan for 2023 for the attention of the working parties (benefit-risk methodology, interactions with HTA bodies, post-authorisation safety and efficacy follow-up, and real-world data in regulatory decisions for ATMPs) as well as two recently approved ATMPs. An EMA funded pilot study investigating how real-world data could be used to follow up on a post-approval study using spinal muscular atrophy (SMA) as a model was presented. For more information see presentation.

2.2 CHMP

Fatima Ventura, CHMP alternate for Portugal, presented data following the pilot for CHMP early contact with patient and consumer organisations. She provided information on the rationale for reaching out at the start of the evaluation of the marketing authorisation application prior to the first CHMP assessment at day 80 and showed where patient engagement was included in the assessment reports (Day 120 or Day 180) that are sent to the applicants, which makes it more likely that the patient input will be included in the European Public Assessment Report. The results of the pilot resulted in continuation of this methodology in the monthly procedures and to its extension to non-orphan medicines and to healthcare professional organisations. Finally, she presented patient and HCP engagement with the CHMP in all activities including scientific advice/protocol assistance, Scientific Advisory/ ad hoc expert groups and participation in oral explanations. For more information see presentation

2.3 COMP

Tim Leest, COMP member for Belgium, presented the work done by the committee to determine a new ontology (a list of concepts and categories in a subject area that shows the relationships between them) for inherited retinal dystrophies (IRDs). An expert meeting with patients and healthcare professionals was held in 2022 and a proposal has been published for a new model for orphan designation. This template will be applied to other genetic spectrum diseases in the future.

Elisabeth Rook, COMP member for the Netherlands, presented the process for orphan designation at the initial stage and following a positive CHMP opinion and described the incentives for developing orphan medicines. Of the 30 orphan-designated medicines with a positive opinion for marketing authorisation from the CHMP in 2022, the COMP determined that 24 could maintain their orphan designation; the reasons were briefly presented. For more information see presentation.

2.4 HMPC

An Lê, HMCP member for France, presented a new communication initiative for HMPC stakeholders on herbal products, which was included in the 2023 committee workplan. The experience of one national competent authority with a patient network was described that led to a discussion at the level of the HMPC to improve sharing of scientific information, warnings and interactions, for better outreach to stakeholders in accessible language and for the creation of templates for reports.

The Herbal Committee would like to expand communication to patients and HCP to understand their needs and support them to contribute to safer use of herbal medicines. The planned activities for 2023 include a survey to capture national initiatives and that will form the basis for a proposal for improved presentation

of HMPC assessments to HCP and patients/consumers. For more information, see presentation.

2.5 PDCO

Jan Taminiau, PDCO member representing healthcare professionals, described two reports: the European Commission and EMA report on *Boosting the development of medicines for children* and the *Guidance for Stepwise PIP pilot*. He described the content of each report and the main implications to the PDCO and to developers of medicines for children. For more information, see presentation.

3. Medical Devices

3.1 Medical Device Regulation

In his presentation, Miguel Antunes covered the essence of the medical devices and *in vitro* diagnostic devices regulations, the activities of the expert panels and a pilot on advice from the expert panels to manufacturers as well as a discussion on patients and HCPs' potential involvement in expert panel activities. The different classes of medical devices and *in vitro* diagnostic medical devices were described along with the role of the Notified Bodies, the medical devices' conformity assessment entities.

He then explained the expert panels, their organisation and main activities along with the Clinical Evaluation Consultation Procedure (CECP) for medical devices and the Performance Evaluation Consultation Procedure (PECP) for in vitro diagnostic medical devices.

A pilot launched on 27 February will be used to build the final process for scientific advice to medical devices' manufacturers. The pilot consists of two phases, with a focus on devices for small populations (orphan or paediatric), unmet medical needs, or novel devices with major clinical or health impact.

The input of patients and healthcare professionals to expert panels' procedures is foreseen in the Medical Device Regulation. Existing vigilance systems at national level are used to collect safety issues regarding individual devices. As is the case for industry, patients and healthcare professionals can directly contribute to these national systems by reporting incidents. In addition, specific input is being considered into groups or categories of devices being discussed by the expert panels. For more information, see presentation.

4. Clinical Trials

4.1 ACT EU Multistakeholder platform: concept paper consultation and kick-off meeting

Maria Filancia presented an update of ACT EU with a focus on the Priority Action whose aim is to establish a multi-stakeholder platform (MSP). The proposal for the MSP was described, along with all of the key stakeholders that will take part, which include patients and healthcare professionals.

A concept paper that describes the scope and organisational aspects of the MSP was made publicly available for a four-week consultation, which was concluded in March 2023. Stakeholders were surveyed on the concept paper, interest in being part of the platform and priority topics for discussion. The PCWP and HCPWP will be regularly updated regarding the progress of the MSP. See presentation for more information.

5. Biosimilars and interchangeability

5.1 Update and report from shortage workshop breakout session

Steffen Thirstrup (EMA) provided feedback from the biosimilars breakout session that took place during the HMA/EMA multistakeholder workshop on Shortages. He described the objectives of the session and provided background to the topic of interchangeability of biosimilars. He also presented results the Statement on the scientific rationale supporting interchangeability of biosimilars in the EU.

He described the Q&A document that accompanies the statement and explained that this is a living document and the results of a survey conducted prior to the workshop. Please see presentation for more information. PCWP/HCPWP invited to review materials of biosimilars (patients and HCP) to identify any gaps in content or messages that need reinforcement and opportunities for further dissemination/promotion.

5.2 EMA's statement on interchangeability of biosimilars

Rosa Gonzalez-Quevedo (EMA) complemented the preceding presentation with context of how the interchangeability statement fits with the communication campaigns performed over the years concerning biosimilars in collaboration with European Commission and Member States. Both the PCWP and HCPWP had been involved in the campaign at the time, via focus groups to identify knowledge gaps and to outline and address specific concerns. These communication efforts aimed at reinforcing trust. The RSS and EMAN strategies list biosimilar uptake and communication in their priorities. The Q&A to complement the statement on interchangeability was described as an additional tool with important information for users, prescribers and dispensers of biosimilars. See presentation for more information.

5.3 Feedback on mini campaigns

Monika Benstetter (EMA) briefly described the specific biosimilar interchangeability information campaign that was run at the time of the release of the statement. This included web updates, news items and social media posts and was shared with national competent authorities. She emphasised the that it was important to understand each other's needs and limitations in joint campaigns.

The two main events listed that will provide an opportunity for further communication initiatives: European Immunisation Week taking place 23-29 April, and European Antibiotic Awareness Day on 18 November. The organisations were then invited to express their interest in joint campaigning with EMA on these two topics and others. See presentation for more information.

6. Multilingualism– a new EMA policy

6.1 Multilingualism on the EMA website and in external communications – a new policy

Monika Benstetter described the multilingualism policy that was recently published, which addresses the use of EU languages other than English. The policy also describes in which languages EMA publishes information on its website and defines criteria for translation. See presentation for more information.