11 April 2022
EMA/775191/2021
Stakeholders and Communication Division

PCWP/HCPWP joint meeting

2 - 3 March 2022

Co-Chairs: J. Garcia Burgos (EMA), K. Immonen (PCWP), U. Jäger (HCPWP) via WebEx

1. Welcome and introduction

1. Opening remarks

Juan Garcia-Burgos opened the meeting, welcomed all participants and highlighted the focus of the meeting. The co-chairs, Ulrich Jäger and Kaisa Immonen, also welcomed all participants and gave their introductory remarks.

2. Update on COVID-19

2.1 Update on vaccines and therapeutics

Marco Cavaleri (EMA), gave an update on EMA's activities related to COVID-19 vaccines and therapeutics since the last working party meeting (see presentation). He highlighted the latest information on vaccines and therapeutics development, assessment and authorisation, including vaccines effectiveness, impact of Omicron, booster doses, heterologous or mix-and-match vaccination, vaccine use in children and in pregnancy, overall status and safety of COVID-19 therapeutics and mis-information. (See presentation).

2.2 Safety surveillance on vaccines and therapeutics

Priya Bahri (EMA) provided an update on vaccines safety surveillance and strategy, cases of reported adverse reactions, information to healthcare professionals and the public, robust surveillance and engagement with the public, vaccine use in in pregnancy and breast-feeding and introduction of a new format for the monthly COVID-19 vaccines safety updates. (See presentation).

The Working parties will be kept up to date on COVID-19 developments.

For latest updates visit this link.

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3. Update on EMA projects and initiatives

3.1 Accelerating clinical trials in the EU (ACT-EU)

IJsbrand Den Rooijen (EMA) presented the new EU clinical trials regulation (CTR) and its three key pillars; transparency, harmonisation and safety. The Clinical Trials Information System (CTIS) is the business tool of the CTR and it harmonises the submission, assessment and supervision of clinical trials in the EU/EEA. Launched in January 2022, Accelerating Clinical Trials in the EU (ACT EU) is an initiative to transform the EU clinical research environment and its main objectives are to support conduct of large, multinational trials, heighten impact of EU CTs, engage all stakeholders and build capacity in drug development and regulatory science. The Clinical Trials Regulation, CTIS and ACT EU will support bigger and better CTs, drive innovation in CT methods, generate data about clinical trials to better understand and address health needs; and provide an opportunity to engage through the multi-stakeholder platform. (See presentation).

3.2 Big Data Steering Group (BDSG)

Jesper Kaejr (BDSG co-chair) gave a progress update on the HMA-EMA Joint Big Data Steering Group work plan since September 2021. Overall the workplan is on track and patients and healthcare representatives are contributing in all the key areas, e.g. as part of the DARWIN EU® advisory board, the raw data analysis advisory group and in the BDSG meetings, specific workshops and the annual multi stakeholder forum. The working parties will be kept up to date on activities and progress. Subscribe here for the BDSG Newsletter. (See presentation).

3.3 Data Analysis and Real World Interrogation Network (DARWIN-EU®)

Andrej Segec (EMA) gave an update on progress with the establishment of the Data Analysis and Real World Interrogation Network (DARWIN-EU®) which is a federated network of data, expertise and services to support better decision-making throughout the product lifecycle by generating reliable evidence from real world healthcare data. The Erasmus University Medical Center in Rotterdam has been appointed as DARWIN EU®'s coordination center which will be the entry point into the network on behalf of EMA and the EMRN. Once up and running, DARWIN EU® will increase the capacity of the medicines Regulatory Network to undertake high-quality observational studies in a reduced timeframe, based on RWD. During 2022 data partners will be onboarding and there will be the first pilot studies for a number of use cases along the medicines lifecycle. (See presentation).

3.4 Electronic product information (ePI)

Elizabeth Scanlan (EMA) gave an update on the ePI project. ePI is authorised, statutory product information for human medicines in a semi-structured format created using a common EU electronic standard. It is adapted for electronic handling and allows dissemination via the web, e-platforms and print. The three key achievements of 2021 have been to create an EU ePI Common Standard based on FHIR (Fast-Healthcare-Interoperability-Resources), to demonstrate a proof-of-concept prototype using the Common Standard and to develop a realistic medium-term vision and road map towards achieving the benefits for all stakeholders. Further in 2022, tooling and guidance material will be created for creation of ePI for new medicines and legacy data. (See presentation).

3.5 Nitrosamines impurities

Maria Filancia (EMA) provided an update on activities linked to presence of N-nitrosamines (Chemical compounds classified as probable human carcinogens on the basis of animal studies) in human medicines. Acceptable Intake (AI) limits are established by the Safety Working Party for each nitrosamine identified. Some medicines have been under investigation since 2018 (Sartans) and in July

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2020 the CHMP provided a scientific opinion with 2 main outcomes; general guidance on dealing with the presence of nitrosamines in human medicines and specific guidance for those called for a review (precautionary measure for medicines containing chemically and biologically synthesised active substances). For medicines where the content of a certain nitrosamine exceeded the established AI corrective actions were taken in order to ensure patient safety and availability of critical medicines. Significant progress has been made in understanding and controlling the risk of presence of nitrosamines in human medicines. (See presentation and dedicated site).

4. EMA Extended mandate

4.1 Engagement and Communication Plan

Inga Abed (EMA) provided an overview of how EMA will communicate and engage with all stakeholders and partners on its extended mandate. EMA's communication and engagement plan entails a mapping of key audiences, engagement needs and channels and includes three phases; preparatory phase of background work started prior to the new regulations being finalised, implementing phase in parallel to the development of the new processes and finally the delivery of procedures & activities with a dedicated crisis action plan for any future crisis. Existing tools and channels will be used to communicate key deliverables. In addition new tools will be used to engage with stakeholders. (See presentation).

4.2 Preparation for multi-stakeholder workshop

Ivana Silva (EMA) highlighted the upcoming multi-stakeholder workshop on the extended mandate taking place on 1 April 2022. See here for full details.

5. Advanced Therapies (ATMPs)

5.1 Awareness raising on the development and evaluation and access to patients issues of ATMPs

Ana Hidalgo-Simon (EMA) and Patrick Celis (EMA) presented an overview of ATMPs; what they are, how they are authorised and regulated, how they are different to other medicines, and how to support ATMP developers and improve patients' access via interaction with HTAs and payers. Real World Evidence, registries and international cooperation were also discussed. Following much interest from the audience it was agreed to hold a follow up session. (See presentation).

6. Members' voice

6.1 European Federation for Primary Care

"Convey Family Medicine principles in Health care and in Pharmaceutical care"

The EFPC gave an overview of their organisation's aims and objectives and specifically the EMA group. (See presentation).

6.2 European Hematology Association

"Recommendations for reducing bureaucracy in Clinical Trials"

'Reducing Bureaucracy in Clinical Trials' is cross-disciplinary coalition of medical societies and patient advocates. The overall goal is to have short/medium-term pragmatic solutions to reduce bureaucratic burden to improve the quality of studies and patient safety and achieve a simplified, more adaptable

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and less bureaucratic regulatory environment. (See presentation).

6.3 European Heart Network

"EU Medical Device Regulation implementation and availability of cardiac devices"

EHN highlighted issues related to the increased administrative burden in relation to the implementation of the new devices regulation. In Germany, more than 100 such products are at risk or have already vanished. Specifically devices for children and those with orphan/rare diseases will disappear from the market and lead to significant shortages. HCPs have to choose other techniques with more risks, worse outcome or have no treatment option. (See presentation).

6.4 European Federation of Allergy and Airways Diseases

"Improving lung health through the future European Health Data Space"

The European Lung Health Group (ELGH) connects European level lung disease patients and professionals to increase awareness and prevention for respiratory health by 2030, improving lung health care and research : BREATHE Vision for 2030: influencing European and EU policy priorities to maximise recognition and benefits for respiratory health. (See presentation). Breathe Vision for 2020: www.breathevision.eu

6.5 International Patient Organisation for Primary Immunodeficiencies

"Status of Primary Immunodeficiency Healthcare"

A global gold standard framework for primary immunodeficiency (PID) care, structured around six principles, was published in 2014. To measure the implementation status of these principles IPOPI developed the PID Life Index in 2020, an interactive tool aggregating national PID data: www.pidlifeindex.ipopi.org. The data demonstrates that, regardless of global scientific progress with a growing number of diagnostic tools and better treatment options, the accessibility and affordability of these remains uneven throughout the world. (See presentation).

7. Looking ahead into 2022

7.1 Call for new mandate 2022-2025

Ivana Silva (EMA) presented (see presentation) details on the upcoming call for the new PCWP/HCPWP mandates 2022-2025:

- March: call open to all eligible organisations –
- April: selection procedure & committees nomination of representatives –
- May: Executive Director decision and then organisations to nominate WP representatives –
- June: new mandate begins and call for co-chair candidates launched,
- September: election of co-chairs.

7.2 PCWP/HCPWP workplan and EMAN Strategy to 2025: topic prioritisation

Nathalie Bere (EMA) presented (see presentation) progress on the development and topic prioritisation for the PCWP/HCPWP workplan 2022-2025 (see presentation). A first draft has been put together based on the 2019-2022 work plan, the EMAN and RSS and the feedback received from WP members via the survey and slido (Nov 21). The format will be the same with a joint section as well as separate sections for each PCWP & HCPWP. The key areas for each were presented with the relevant sub-

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sections. The next steps will be:

- End March: WP members to comment on draft workplan
- April: share with CXMP for comments
- May: circulate final draft to working parties
- June: final presentation and adoption of workplan
- July: circulate to CXMP for adoption

7.3 Highlights of PCWP/HCPWP 2019-2022 mandate

Maria Mavris (EMA) presented a slide show with key highlights from the current mandate. (See presentation).

Wrap up / end of meeting