17 January 2024
EMA/510807/2023
Stakeholders and Communication Division

Meeting summary - PCWP/HCPWP and all eligible organisations meeting

14 and 15 November 2023, hybrid meeting - WebEx/Room 1D

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

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. Availability and accessibility of medicines

1.1. Strengthening the regulatory/HTA interface: Update on the support to the HTA Regulation implementation

Michael Berntgen (EMA) provided an update on EMA activities related to the implementation of the Health Technology Assessment (HTA) Regulation that will be applicable from January 2025.

He set the scene by describing the process (or ecosystem) fundamental for access for patients; from development to regulation, HTA assessment to pricing with its different players and remits with their roles in decision-making. With respect to different remits, the value of collaborations such as between regulators and HTA bodies is recognised within the new HTA Regulation.

Collaboration with EMA under the HTA Regulation covers three main areas i) joint scientific consultation (JSC), ii) join clinical assessment (JCA) and iii) identification of emerging health technologies and contribution to work plan. There will be six implementing acts that are currently in preparation and transversal elements that will facilitate the work between regulators and the HTA coordination group. He concluded by showing the implementation timeline and explained that once applicable, JCA will start for oncology and ATMP products in 2025, followed by all orphans from 2028 and all new active substances from 2030.

Francesca Cerreta (EMA) described the closing meeting of EUnetHTA consortium held on 14 September at the EMA building in Amsterdam. A report on the work plan 2021 -2023 has been published. She described the six implementing acts in more detail along with their prioritisation and timelines for preparation. She went on to explain some examples of thematic areas where work will be done such as i) real world evidence and DARWIN EU, ii) oncology specific interactions, and iii) challenges in evidence needs. She concluded by providing examples of opportunities to support and strengthen interactions and collaboration between regulators, HTAs and payers along the medicine lifecycle, which include scientific advice, evidence

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requirements, regulatory-HTA interactions, capacity building across regulators and across HTA bodies, and finally a collaborative approach amongst all stakeholders. Please see presentation for further details.

1.2. HTA Stakeholder network

Valentina Barbuto (EC) reiterated points regarding the implementation of the HTA regulation and the close collaboration between the European Commission and EMA to put the stakeholder network into context (see presentation).

She described the four main activities under the Regulation, their governance and the role of the Commission within them. The importance of engaging with stakeholders was recognised and included in the HTA regulation. The stakeholders include patient, consumer and healthcare professional organisations, clinical and learned societies, HTA developer associations, and other relevant non-governmental organisations. The role of the stakeholder network is to facilitate dialogue between the stakeholder organisations and the Member State Coordination Group on HTA.

Bela Dajka (EC) described article 29 of the Regulation in more detail. This article is about the establishment of a stakeholder network and the eligibility criteria for membership. A call for applications was made and in the three-month period 75 applications were received and 45 organisations were selected as members, which includes 15 patient organisations, 13 healthcare professional organisations, seven HTA developers, four learned societies and three payers and other NGOs.

The first meeting of the stakeholder network was held on 14 June. The meeting focused on the state of play in the implementation of the HTA regulation, the four areas of the joint work (methodology, joint clinical assessments, joint scientific consultations and the identification of emerging health technologies). The Terms of Reference of the stakeholder network was also presented and discussed. He concluded by sharing a list of upcoming meetings planned with stakeholders:

- Next Stakeholder Network meeting: 17 November 2023
- Third Stakeholder event focused on the implementation of the European Union's Health Technology Assessment (HTA) 22 November 2023, 10:30 – 14:00 CET in Seville.
- Fourth Stakeholder event focused on the implementation of the European Union's Health Technology Assessment (HTA) 30 January 2024, 09:00 - 12:30 (CET) in Utrecht.

1.3. Update on preparedness

Emilija Matelyte (EMA) provided a brief update on preparedness activities for antibiotics and paediatric analgesics, antipyretics and cough syrups for the 2023-24 autumn/winter season (see presentation).

At the beginning of the year, the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) and the Board of DG HERA agreed on the need to prepare for the upcoming autumn and winter season. Therefore, a joint EMA/HERA exercise was launched to identify any gaps between supply and demand of a subset of antibiotics to understand whether any shortfalls could be expected in the autumn and winter season of 2023-2024. In July, MSSG recommended extending the monitoring to paediatric formulations of over the counter (OTC) medicines commonly used in the autumn/winter season (analgesics, antipyretics, cough syrups). An overview of the exercise as well as the outcomes can be found in the update provided in September.

Discussions with industry to increase production capacity of the medicines concerned are ongoing and the supply situation in the EU/EEA is being monitored through the SPOC WP on a regular basis, in cooperation with the marketing authorisation holders, industry associations as well as community and hospital pharmacists' organisations, and follow-up actions will be undertaken when necessary. EMA reminded that healthcare

professionals and patients have a role to play in the prudent use of antibiotics and avoiding stockpiling.

During the discussion that followed, organisations were encouraged to report to EMA in case any early signals of supply disruptions of these medicines are identified. Clarifications were provided on the voluntary Solidarity mechanism announced in October. It was also suggested to liaise further with organisations representing patients covering respiratory diseases (e.g., EFA) and paediatricians (e.g., EAP) to help explain the current situation and avoid increased alarm and reduce anticipation from parents.

1.4. EU critical medicines list

Joao Ferreira (EMA) presented on the development status of the Union list of critical medicines (see presentation), building on from the discussions held at the HCPWP/PCWP September 2023 meeting. The initial version of the Union list will be published in December 2023. The list builds on the EC Structured Dialogue initiative and is based on a methodology agreed with multiple stakeholders back in 2021. The list is being progressively delivered in advance of the EU pharmaceutical legislation review. Medicines will continue being reviewed and classified throughout 2024 by Member States. The initial version leveraged the experience from 6 EU countries in national lists' development. Future versions will focus on medicines from therapeutic groups of major interest and will be drafted following consultation with key stakeholders.

As announced in the Communication dated 24 October 2023, the Commission will analyse the vulnerabilities in the supply chain of critical medicines in the list from 2024. This will provide the basis for future decisions on supply security measures, such as recommendations that companies diversify suppliers or increase production within the EU, investment incentives, additional regulatory obligations for companies, and procurement with strong contractual obligations for delivery.

Inga Abed (EMA) explained the planned communication activities and presented the proposed key messages. Volunteers were identified amongst all eligible organisations to review the communication materials.

Participants underlined the importance of clearly communicating in the EMA website about the different lists developed for preparedness purposes and crisis and health emergencies and to demystify that going live with such lists will avoid all shortages. This should not be seen as the sole measure to prevent shortages.

1.5. Restriction of the use of Per- and Polyfluorinated Alkyl Substances (PFAS)

Per- and polyfluoroalkyl substances (PFAS) are a large class of thousands of synthetic chemicals that are used throughout society (including in medicines for human and veterinary use). However, they are increasingly detected as environmental pollutants, and some are linked to negative effects on human health.

In the context of REACH, ECHA published earlier this year its PFAS restriction proposal which has undergone public consultation. Concerns on the impact of the proposed restrictions in medicines' availability have been raised by stakeholders and this presentation will provide an update on how EMA is monitoring the situation.

Maria Jesus Alcaraz Tomas (EMA) gave an overview of how EMA is monitoring developments related with this proposal (see presentation). It was noted that in some cases, alternatives may be possible but will imply variations in stability and packaging which will be difficult to implement within the timings currently proposed. Participants highlighted the importance of carefully assessing the implications of a ban in PFAs in many different therapeutic areas (e.g. respiratory, urology, cancer) as these substances are both used in drug development and drug delivery and the impact it will have for patients.

Participants were reassured that these are still early stages and further assessment will take place before final measures are agreed. Organisations are welcomed to share any further concerns in writing.

1.6. Update on repurposing activities

The topic of repurposing of medicines has been presented and discussed in different occasions at the level of PCWP and HCPWP (2019, 2021). Involvement of patient organisations and healthcare professionals has contributed to shaping the thinking around a pilot project launched in 2021 to support non-for-profit organisations and academic stakeholders.

Christelle Bouygues (EMA) provided an update on the EU repurposing pilot (presentation), which was initiated following a Commission initiative for a framework to support not-for-profit organisations and academia in drug repurposing. Not-for-profit organisations and academia would seek advice on their data generation with a purpose to gather a data package to support a new indication of a well-established substance. A few Member States volunteered for the pilot. The candidates ('champions') were free to submit to EMA or a NCA of their choice, then competent authorities selected the most relevant projects. Eligibility criteria considered for the selection of projects were presented; these include in particular the level of evidence and unmet medical need.

EMA has used a classification index for indications depending on the targeted condition vs the authorised indication and the mechanism of action. The profile of candidate projects was presented per indication index, therapeutic area, orphan designation and type of organisation.

A small number of projects were selected for the scientific advice phase, and benefit from a fee waiver. An informal meeting was introduced before the formal scientific advice procedure starts to help with the understanding of the process and the preparation of the briefing document. A debriefing meeting was also added to provide further explanations on the outcome of the scientific advice. Real-world evidence activities were also considered in collaboration with EMA colleagues.

Observations and opportunities based on the selected projects were then presented.

Next steps include completing scientific advice procedures for all selected projects, conducting a survey to collect feedback, and publishing a report once the pilot is completed.

2. COVID

2.1. Update on COVID – report on lessons learnt

As a follow up to the presentation to PCWP and HCPWP and all eligible organisations in November 2022 (COVID-19 Lessons Learned), Melanie Carr (EMA) presented some highlights from the draft report based on HMA-EMA analysis.

The finalisation of this report is targeted for the end of November. The European Medicines Regulatory Network's response to COVID-19 included the establishment of a dedicated emergency task force, the publication of guidance, transparency and outreach initiatives.

The analysis of lessons learned was conducted in collaboration with HMA, EMA's Management Board, MSSG, patients and healthcare professional organisations. Lessons learnt were identified in 10 areas, and briefly presented for the following areas, along with the learnings (all areas with details are in the presentation):

- Crisis preparedness
- Support to development and approval of medicines
- Regulatory framework and procedures
- Clinical trials and Real-World Evidence
- Safety monitoring
- Transparency, stakeholder engagement and communication.

Overall, the network successfully carried out the required regulatory work throughout the emergency period, with numerous products approved and procedures completed. The close and productive cooperation with MSs and partners was consolidated, and the work of the EMRN during the pandemic was recognised. Areas needing improvement were also presented. Finally, next steps were presented, highlighting the priority areas that the EMRN is currently working on.

During the discussion, it was noted that ongoing efforts to foster the conduct of large trials is part of the ACT EU work. Comments were made on the national lessons learnt which highlighted challenges in public health, mental health and GPs, with concrete actions yet to be identified. The involvement of vulnerable groups was also discussed, highlighting again the role of ACT EU in preparing guidance on clinical trials in public health emergencies.

The rise in vaccine hesitancy and vaccine fatigue was acknowledged. EMA set up a Vaccine Outreach Group before the pandemic; work is ongoing to tackle mis-/dis- information in collaboration with the ECDC and European Commission, including social media monitoring. Infodemic management was also re-discussed following a presentation at the last meeting, as well as the scope of the ETF workplan with an agreement to include/ clarify horizon-scanning activity for future threats.

Finally, it was commented that differences in vaccination campaigns at national level led to some confusion and there is a need to collaborate more closely with the respective public health authorities. It was confirmed that this is one of the topics addressed in the report.

2.2. EMA-Workshop on generating clinical evidence for treatment and prevention options for Long-COVID and Post-acute sequelae condition (PASC)

Stephanie Buchholz (EMA) presented the virtual EMA workshop on generating clinical evidence for treatment and prevention options for Long-COVID/PASC, which will take place on 17 November and will bring together academia, industry, healthcare professionals, regulators, and patient groups. There is currently no approved therapy for the treatment or prevention of long-COVID. The complexity of the pathophysiological mechanisms and clinical syndromes associated with long-COVID/post-acute sequelae condition (PASC) raises regulatory and methodological concerns related to the design of clinical trials to evaluate treatment and preventive approaches for these conditions. The objectives of this workshop are to address these complexities and to discuss clinical study designs including the appropriate patient population and efficacy endpoints in clinical trials.

Workshop on generating clinical evidence for treatment and prevention options for long-COVID / post-acute sequelae condition (PASC) | European Medicines Agency
The workshop goals, agenda and speakers were presented (presentation). An open discussion with all invited stakeholders will take place at the end of the workshop. Options for active involvement or passive listening were provided. There were no questions.

3. Members' Voice

3.1. Patient organisation:

2023 Skills Training for Young Patient Advocates (STYPA)

Claudia Louati (EPF) presented the 2023 skills training for young patient advocates (see presentation). This year's topic was shortages. The program includes a summary training as well as a welcome webinar and three follow-up webinars, with an aim to help young people to develop their advocacy skills.

Broader involvement of young patients in EPF activities, outside of STYPA, was also outlined.

3.2. **Healthcare professional organisation:**

Next generation health guidelines: how to integrate RWE & EBM

Ioana Agache (EAACI) presented on how to reach consensus for integration of randomised and non-randomised studies of interventions (RWE) into next-generation health guidelines (see presentation). EAACI guidelines for the use of biologicals in severe asthma were used as an example on the challenge to implement this approach. Next steps include the publication of a detailed methodological guidance incorporating feedback from all stakeholders followed by a pragmatic approach for all end-users and supported by a glossary of terms and the development of educational modules on how to use the new methodological approach.

Priya Bahri (EMA) commented that EMA has commissioned a study analysing the integration of risk minimisation advice in clinical guidelines which may be relevant to this topic.

Both presentations were then discussed by the group.

AOB

QRD working group

Kaisa Immonen (EMA) thanked the organisations who volunteered to take part in the working group and informed the attendees that an important survey would be sent out by email in the next few days, followed by a more in-depth consultation in December on information regarding benefits and the potential inclusion of a key information section. A virtual meeting in early 2024 will also likely be organised. Everyone who is interested in participating in these discussions will have an opportunity to be actively involved.

ACT EU PA #5 workshop (data analytics)

Kaisa Immonen (EMA) reminded the group about this workshop, which will address clinical trials and how the data generated by these trials can be better used in the future. A reminder email for registration was sent today, with a request for registration by 20 November; only in-person attendees will be able to participate in discussions in the breakout sessions.

4. Updates from EMA and Scientific Committees

4.1. 2023 Highlights

Ivana Silva (EMA) and Maria Mavris (EMA) presented the PCWP/HCPWP highlights and key topics covered in 2023 (see presentation).

4.2. Updates from Scientific Committees

- COMP

Tim Leest (COMP) gave an update on COMP activities (see presentation). A working group of COMP is currently working on defining requirements for "major contribution to patient care" as part of significant benefit assessment at the orphan designation and marketing authorisation stages. The next step in this process will be a concept paper. One of the important aspects is the qualitative data on patients' expectations and perspectives. At this point Maria Cavaller, Eurordis expert on COMP, took over to present a pilot collaborative project of COMP and Eurordis that aims to establish use of patient experience data (PED) for defining "major contribution to patient care" for orphan medicines using a patient-validated methodology. Rare diseases patient organisations, including the EMA eligible ones, will be involved in this project. Lack of harmonised standards for capturing and reporting patient experience data is a major challenge the project aims to address. Please see presentation for further details.

In the discussion it was clarified that significant benefit is assessed in about 60% of orphan applications.

There was agreement that the focus would need to be on what patients value most, whether it is a clinical or other type of outcome. It was clarified that outcomes lists could eventually be used to support clinical development plans in Scientific Advice and other regulatory procedures.

- CAT

Mencia de Lemus (CAT) gave an overview of CAT activities. Efforts are in progress to make the area of advanced therapy development easier and to link more with HTA. RWD/RWE is a challenge, but products often have long-term post-marketing authorisation obligations, so CAT needs to engage with registry holders and other stakeholders for evidence collection. A guideline on methodology is in progress. She explained the added value of CAT is in the cutting edge of science, balancing the urgency of unmet needs with studies that yield limited evidence. The deliberative approach of CAT can help make subsequent debates at national level easier. Please see presentation for further details.

In the discussion, long follow-up times were raised as a challenge also in terms of patient's access to the treatments. A question was asked on the price of gene therapy as not all patients are able to access curative treatments. Mencia said EMA acknowledges what is happening downstream and while CAT is not involved in pricing and reimbursement decisions, it can support these discussions by explaining why a decision for marketing authorisation has been made.

- CHMP

Concha Prieto (CHMP) gave a presentation of CHMP highlights, including the CHMP early contact which is now a standard methodology and was extended to healthcare professionals in May 2023. The assessment report now has a dedicated section to include feedback from patients and healthcare professionals and the aim is to have it systematically included. Scientific Advisory Groups, ad hoc expert groups and oral explanations maintain a consistent level of patient involvement. A drop was observed in Scientific Advice and this is being investigated internally to identify the reasons behind it. Looking at high-level data on CHMP opinions, around 1/3 were in oncology. Six conditional marketing authorisations were granted this year, all in cancer, and companies have post-marketing obligations to gather full data. One medicine was authorised under exceptional circumstance. Please see presentation for further details.

In the discussion, it was raised that in future there will be patient members of the CHMP and this will be complementary to, not a replacement of other interactions with patients. The important role of training patients on how best to contribute to committees was also raised, while it is important to get new representatives involved it is also crucial to ensure the representative are trained and supported in the best way.

- PDCO

Johannes Taminiau covered PDCO activities, focusing on the three topics, the first being the Accelerate Paediatric Strategy Forums, under which Paediatric Oncology Strategy Forums are organised together with FDA. These are biannual forums for pre-competitive information sharing. Patients/parents and industry are involved. The focus currently is on acute paediatric AML, also on Mature B cell malignancies. Next, a guidance for the Stepwise PIP pilot was published in February of this year and can be consulted online. This relates to a pilot phase for a stepwise PIP agreement where PIPs can be agreed for innovative medicines where crucial information is not yet available setting the steps for companies to return to PDCO and discuss once more data are available. Finally, there is strengthened focus on unmet medical needs and RWE in children, especially in children with cancer and inflammatory bowel disease. There is collaboration with the ERN on rare liver disease under DARWIN EU. Please see the presentation for further details.

A scientific paper on "Paediatric Inflammatory Bowel Disease: A Multi-Stakeholder Perspective to Improve Development of Drugs for Children and Adolescents" can be consulted here, and information about the Conect4Children initiative where the forthcoming multistakeholder meeting on paediatric irritability in March 2024 will be posted can be found here.

5. EMA data related initiatives and digitalisation

5.1. Update on patient experience data

Rosa Gonzalez-Quevedo (EMA) updated the group on progress of the work on patient experience data (PED) following the multi stakeholder workshop held in 2022 and the last update provided to the working parties in June. The key deliverable for 2023-24 is the reflection paper, together with an exploration on how to improve transparency regarding PED in the assessment reports. She presented the key elements being considered for the reflection paper and emphasised the importance of stakeholder input. The reflection paper will outline an EU approach that can guide developers and patient groups on the generation, collection and use of patient experience data; the reflection paper will not provide methodological guidance as such, these discussions on methodological guidance will be developed at ICH level to ensure international harmonisation and EMA is contributing to this ICH process. An EU network drafting group is being established for the reflection paper. During the drafting process it will be decided the best way to consult patient and healthcare professional organisations via the working groups, and in 2024 a wider public consultation will be opened. More will be communicated about this externally as the work develops. Please see the presentation for further details. EMA will follow up with more concrete timelines and steps for the involvement of the working groups and eligible organisations.

5.2. Big Data SG Work Plan

Denise Umuhire (EMA) presented an update of the activities of the Big Data Steering Group (BDSG). The new BDSG workplan has been published and mentions intensification of engagement with patient organisations as reflected in several items of the workplan. Denise explained the work follows a stepwise approach, with goals for the short, medium and long term, in close collaboration with patient organisations. Please see the presentation for further details. Denise also reminded the audience of the next Big Data Stakeholder Forum, taking place on 4 December and will be broadcasted here.

During the discussion, the new catalogue of data sources and non-interventional studies to be launched early 2024 was mentioned, and it was noted that potential differences in approaches, levels of quality and validity of data as well as ethical questions will be considered and appropriately managed.

5.3. DARWIN EU

Andrej Segec (EMA) presented an update of DARWIN EU, the EU regulators' network of real world data sources that delivers EMRN's vision to establish the value and enable the use of real-world data in medicines regulation. A report summarising experiences with RWD research requests to date was published recently and this report, together with an info sheet, can be accessed here. Most research requests originated in PRAC and focused mainly on safety, but requests from other committees and topics are increasing. RWE is useable across the entire medicinal products' lifecycle as well as in crisis planning and response. The first phase of DARWIN EU comprised of onboarding of 10 data partners and further 10 data partners are currently being onboarded in the second phase. Ongoing studies were presented in the slides and all studies in DARWIN EU are published in the EU PAS register, which can be accessed here (search for 'DARWIN EU' in the title of study field). Finally, a two-year pilot started in 2022 exploring use cases to inform the design, development, and deployment of secondary use of health data under the EHDS. Please see the presentation for further details.

In the discussion Andrej mentioned a workshop that took place with HTA bodies and payers last year to identify pilot use cases. Data sources selection is currently driven by availability and readiness in OMOP CDM, but recently there were new expressions of interest, and the goal is to have as broad representation of European countries as possible and that gaps may be filled through close collaboration with the heads of medicine authorities. As to the interrelationship of the DARWIN EU study and EHDS pilot, the pilot will inform the delivery of the EHDS as a way of ensuring all the steps including legal and governance aspects

have been tested. It was commented that it would be good to also include PED in DARWIN EU studies. This is foreseen but is currently limited by absence of such data in most sources, sometimes even in specialised disease registries. It was further discussed that RWE is seen as a complement to clinical trials and especially important in cases where RCTs may not be possible for ethical reasons or to inform on real world use of medicines, disease epidemiology or patient populations.

5.4. Delivering on stakeholders' requirements for AI

Luis Pinheiro (EMA) updated the group on the priorities and activities related to AI (see presentation). He highlighted training and upskilling, which is currently focusing on on-demand training delivered through the EU Network Training Centre resources, and building communities of practice which includes an internal technical group and a European specialised expert community (ESEC) with special interest in AI. Various collaborations include CIOMS, ICMRA and other regulatory agencies. He also presented the AI reflection paper that was published in July and covers the lifecycle of medicinal products. This paper reflects on the scientific principles relevant to regulatory assessment for both human and veterinary medicines, including risks and the responsibilities of the applicants or marketing authorisation holders.

The reflection paper is still under public consultation until 31 December 2023. The paper and the consultation survey can be accessed here. A multistakeholder workshop took place on 20-21 November; the meeting documents and recordings will be available here.

6. Regulatory science and innovation

6.1. Facilitating innovation in regulatory science: research needs and multistakeholder collaboration

Ralf Herold (EMA) presented on how EMA is advancing regulatory science and what are the opportunities for multistakeholder collaboration across European Union-funded projects on aspects related with research design and conduct which are conducive to results that can have regulatory use in medicines development and approval (see presentation).

In its Regulatory Science Research Needs, EMA has identified gaps in regulatory science and translated them into research needs aimed to support the development of research questions that could be addressed by research funding programmes. These include, for example, questions on how to conduct complex clinical trials that involve multiple companies and products and how to foster collaborative clinical trials and evidence generation to make clinical trials a platform for exploring novel treatments. Questions like these require interdisciplinary research and EMA is engaging with researchers and funders, both at EU and national levels to raise awareness and possible incorporation in funding programmes and calls. In addition, EMA is also collecting research results on these questions and assessing how to enable a regulatory translation and interpretation of their results.

Ralf gave some examples of how to engage stakeholders to get such research done highlighting the importance of generating results from such research that build knowledge for developing and regulating medicines. Patient, consumer, and healthcare professional organisations and learned societies can be both part of consortia under Horizon Europe-funded projects and act as amplifiers of research results. On its hand, EMA is involved with such consortia by providing guidance on regulatory considerations and overall advancing the projects' outcomes to become useful for regulatory purposes.

7. EMA communications

7.1. Biosimilar medicines

Bernard Duggan (Lead for biosimilar uptake programme at the Irish Health Service) provided the group

with information on biosimilars as a network priority, the HMA working group on biosimilars, experience communicating on biosimilars, the biosimilar toolkit for MSs which is currently being developed for patients and healthcare professionals, and the work conducted to date.

Rosa Gonzalez-Quevedo (EMA) then presented on the EU materials prepared on biosimilars so far and the upcoming Stakeholder gap analysis used to improve understanding of biosimilars. The presentation covered the EU strategy for improving understanding on biosimilars, the published EMA/HMA Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU and associated Q&A, the update of the HCP guides with links to the interchangeability statement as a disclaimer, the outcome of the March 2023 discussion with stakeholders which needs to feedback into the toolkits, and the external collaboration for the work to be conducted in 2023-2024. The deliverables planned in the frame of the external collaboration include the update of the EMA guide on biosimilars for HCPs and proposal for a potential update of other materials (patient Q&A, videos) as needed, including translations; the analysis of stakeholder's information needs on biosimilars; and input into national toolkit discussions. To sum up, a stakeholder survey to gather information needs on biosimilars will be carried out in Q1 2024 to inform ongoing work on the toolkit, and an additional consultation may be undertaken later that year. See presentation for further details.

7.2. Corporate website and accessibility

Christopher Gadd (EMA) began by asking participants to share their experiences dealing with web accessibility via a poll. He then provided an update on the relaunch of the EMA corporate website, which will be taking place in December 2023 and the background behind the rebuild. A snapshot of the new website was presented, pointing out key features that will be changing as well as those that will remain. Other new and improved features will be added progressively in 2024 and beyond.

The meeting participants then took part in a discussion on the challenges of accessibility, not only as users of websites but also as managers of them. The discussion touched upon the Web Content Accessibility Guidelines (WCAG) accessibility guidelines, the difficulties that users of websites with visual, cognitive and other disturbances can face, and examples of how the meeting participants and EMA have striven to make their websites as accessible as possible. The results of the poll guided the group discussion. The poll remained open for several days after the meeting to gather broader experiences from the organisations.

The working parties will be kept up to date on developments to the corporate website and any further outcomes of the accessibility discussion. See presentation for further details.

7.3. Collaboration with eligible organisations in the implementation of the social media strategy

Laure Herold and Giulia Gabrielli from EMA's social media team presented ideas for strengthening collaboration with the working parties and all eligible organisations in the implementation of EMA's social media strategy. Laure began by presenting the social media strategy whose aim is to position EMA as an authoritative source for social media users, to connect better with existing communities and to grow reach with new audiences. She detailed each channel currently used and the plans for future development of these platforms. Three topics (shortages, antibiotic resistance and biosimilars) were suggested as potential topics for a pilot campaign co-created with patients, consumers and healthcare professional organisations.

Giulia followed by presenting how EMA and the organisations could work together throughout this campaign in terms of support, communication resources and co-creation of content. Different levels of involvement for organisations based on resource capacity were proposed. She concluded with next steps and timing for the pilot and a successful example of co-created content from earlier in the year. For information For information, EMA shares an Instagram account with five other EU agencies that can be found at one_healthenv_eu. See presentation for more details.

8. Members' Voice

8.1. Patient organisation:

Francois Houyez (EURORDIS) presented on research conducted around Goal Attainment Scaling and its use as an outcome measure in clinical trials (see presentation).

8.2. Healthcare professional organisation:

Marcin Rodzinka-Verhelle (CPME) presented the results of a survey conducted amongst its members to map current activities related with antimicrobial resistance and including stewardship programmes, prescribing guidelines, medical education and public awareness campaigns (see presentation).