8 July 2026
EMA/150945/2026
Stakeholders and Communication Division

Meeting Summary - PCWP/HCPWP joint meeting

30 June 2026, hybrid meeting – MS Teams/Room 2A

Co-Chairs: Juan Garcia-Burgos (EMA), Marco Greco (PCWP), Piotr Szymański (HCPWP)

Welcome and introduction / Health and safety information

Juan Garcia Burgos (EMA) opened the meeting, welcoming the PCWP and HCPWP participants in person and online.

1. One Health approach

1.1. One Health Task Force in 2026

Ivo Claassen provided an update on the One Health Task Force, highlighting its cross-agency collaboration involving the ECDC, EFSA, ECHA, EEA and EMA, with the aim of fostering cross-disciplinary cooperation to strengthen the EU's ability to predict, detect, and respond to health threats. Operating under a framework for action, its focus areas include strategic coordination, research coordination, capacity building, communication and stakeholder engagement, as well as fostering partnerships and joint activities.

The presentation focused on One Health initiatives aimed at addressing a range of health challenges through integrated actions across human, animal, and plant health, food safety, climate change, and environmental sustainability. Particular attention was given to zoonotic diseases, antimicrobial resistance (AMR), and the importance of cross-sectoral data integration to show the added value of the One Health cooperation beyond 2026.

Regarding AMR, the findings of the JIACRA report were presented, showcasing links between antimicrobial consumption and resistance trends in humans and food-production animals. The report showed that countries that have reduced antimicrobial use in both humans and animals have experienced corresponding declines in AMR rates. Further information is available in the published JIACRA report and its analysis on the EMA website.

Another topic of discussion was the impact of azoles, which are widely used as fungicides in agriculture as well as in cosmetics and biocidal products. EMA, EFSA, ECDC, EEA, ECHA and JRC have been collaborating to assess their impact. The discussion emphasised that environmental exposure to azoles can promote the development of azole-resistant *Aspergillus fungi*, reducing the effectiveness of important antifungal treatments for humans and posing a growing public health concern.

Examples of zoonotic diseases, including COVID-19, Influenza, Chikungunya and Q fever were presented. The discussion highlighted the role of environmental pollution, climate change, biodiversity loss, and other issues in the emergence and spread of these diseases and reflected on their long-term impact. Early detection, preparedness, integrated surveillance, and vaccination were underscored as crucial measures to mitigate risk. Vaccination was also highlighted as a key strategy to reduce antimicrobial use and AMR.

The presentation concluded by acknowledging the importance of the One Health approach to respond to complex health challenges and stressed the importance of continued collaboration

between agencies to achieve integrated, evidence-based, and effective actions. For more detailed information, please refer to the presentation.

2. Antimicrobial resistance (AMR) and other health threats

2.1. Antimicrobial Resistance (AMR) activities

Radu Botgros (EMA) outlined the EMA's activities throughout the entire life cycle of antibiotics, with a particular focus on the fight against antimicrobial resistance (AMR) in humans.

He began by emphasising that AMR poses a significant and growing threat to public health, compromising patient outcomes and undermining the foundations of modern medicine.

Radu explained that EMA plays a key role across the antibiotic lifecycle by stimulating development through regulatory support and incentives, evaluating and authorising new antibiotics, promoting responsible use via harmonised product information and stewardship plans, as well as monitoring resistance through One Health surveillance in collaboration with other EU agencies.

He also highlighted that the revised pharmaceutical legislation (NPL) introduces robust measures to combat AMR by strengthening incentives for novel antimicrobials, including Transferable Exclusivity Vouchers (TEVs) to stimulate the research and development of novel antimicrobials. The legislation also includes stricter prescription requirements, mandatory stewardship measures, supply chain safeguards, stronger environmental regulations and risk assessments, and improved diagnostics to enable more targeted therapies.

Radu concluded by stressing the importance of partnership. Collaborative efforts with patients and healthcare professionals are essential to ensure an effective and credible response to the AMR challenge.

Marta Busana (EMA) presented the case of universal pneumococcal vaccination, demonstrating its effectiveness in reducing infection and resistance, especially in children, while noting the adaptive response of pathogens and the need for ongoing vaccine development and coverage improvements.

For more detailed information, please refer to the presentation and the presentation.

2.2. Update on vaccine confidence initiatives

Rosa Gonzalez (EMA) provided an overview on vaccine confidence initiatives. EMA continues to work to respond to public queries on vaccines and address existing concerns and the rapid spread of vaccine-related misinformation, particularly on social media platforms. To strengthen its response, the EMA is working through its internal Vaccine Outreach Group (VOG) to monitor emerging issues, address ongoing concerns, and recommend appropriate actions. The presentation focused on new elements, starting with the outcomes of the first meeting of a new Vaccine Confidence Advisory Group. EMA has also developed a new communication tool to facilitate conversations between HCPs and patients, called Vaccine Essentials. The first factsheet covers meningococcal B vaccines and was developed in collaboration with the European Academy of Paediatrics. Very good feedback was received to date from stakeholders. Members were asked to send proposals for topics of future Vaccine Essentials, and further feedback on these initiatives in general is welcomed.

For more details, please see the presentation.

3. European Health Data Space

3.1. Update on the European Health Data Space (EHDS) Regulation (EU) 2025/327 and preparations for implementation for information

Anne-Sophie Henry-Eude provided an update on the European Health Data Space (EHDS) including the timelines and EMA's preparations for its implementation. The EHDS was established under Regulation (EU) 2025/327 that aims to establish a secure single environment for the use and exchange of electronic health data across the EU for secondary analysis. The regulation entered into force in 2025 and become applicable in March 2027 for primary use and March 2029 for secondary use.

The EHDS would empower individuals to access and manage their own health information while supporting the secondary use of data for research, innovation, and regulatory activities. Under the EHDS framework, health data can be accessed and analysed within a secure technical environment, but the results of analyses can be shared externally. Key actors include data users, who request access to health data for approved permit, and data holders, who hold the original, often non-anonymised, health data that can be made available within this secure system according to the requirements stated in the approved permit. The request will be accessed by Health data access body (HDAB) who will issue a permit and liaise with the data holder. The data prepared according to the approved permit is then put into the secure environment where the data user can analyse the data. This approach strengthens data protection while facilitating broader use and re-use of health data for public health and scientific advancement.

The TEDHAS group creates guidance documents (procedural, administrative, technical, etc) that have been made available for consultation. EMA has contributed to the public consultation of more than 20 of these guidance documents over 3 rounds of consultations. In preparation for implementation of the EHDS, a working group has been created at EMA that engages with the European Commission and other stakeholders to contribute to the review of draft implementing acts, development of the EMA road map for implementation of EHDS and preparation of a metadata catalogue as well as looking for synergies with existing projects such as DARWIN EU. See presentation for more details.

4. Availability and supply

4.1. Update on Union list of critical medicines

Siofradh McMahon (EMA) provided an update on the Union List of Critical Medicines, outlining its purpose, methodology, and the ongoing process for annual review and stakeholder engagement to ensure the list remains relevant for supporting healthcare system resilience. The Union list of critical medicines identifies medicines that are critical for health care systems across the EU/EEA and for which continuity of supply should always be guaranteed for European patients.

During the meeting, the workflow for the second annual review of the Union List was described, including the criteria for triggering a review request (change in criticality of the therapeutic indication, change to the availability of appropriate alternatives, changes in the market dynamic, and historical critical shortages), as well as the associated timelines and next steps.

The consultation for the second annual update of the Union List of Critical Medicines was launched on 19 January 2026. The consultation focused specifically on requests for the inclusion or removal of medicines from the list, taking into account the guidance provided in the published methodology, and concluded on 27 March 2026. Member States' classification exercise is currently underway, with

a deadline of 31 July 2026. Stakeholders will be consulted on the proposed updated list in Q3 2026. The final review will be completed by the Member States, after which the list will be endorsed by the MSSG and submitted to the European Commission (EC) for adoption. For more detailed information, please refer to the presentation.

AOB

No AOB was presented

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1 July 2026, hybrid meeting – MS Teams/Room 2A/Auditorium

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5. Revised pharmaceutical legislation

5.1. Implementation of the revised pharmaceutical legislation

Melania Fanari (EMA) began the presentation outlining the programme governance structure for the implementation of the revised pharmaceutical legislation (NPL), including the NPL Oversight Group (which lies at the centre of this structure and brings together representatives from the EMA Management Board, the European Commission, national competent authorities and EMA's senior leadership), as well as the EMA programme management and the six delivery streams, each focusing on specific areas of the legislation and its operational impact. The governance of the NPL implementation is designed to ensure both strategic oversight and operational coordination.

One of the deliverables of each of the delivery streams is the development of concept papers. These will be internal working documents setting at a high-level, the scope, changes, impacts, deliverables and dependencies for the implementation of the legal provisions. This will require input from EC, the committees and specialised working groups, as well as experts from the national competent authorities. Once endorsed, they will become the reference document for the implementation of the legal provisions, including Delegated Acts and Implementing Acts.

A network collaboration model has been introduced to ensure the involvement of EU network experts in delivery teams from the outset, ensuring that concept papers and associated deliverables are developed jointly, aiming for operational feasibility and timely implementation by Q4 2028. The model, endorsed by the oversight group, emphasises simplicity and proportionality, and fit-for-purpose expert engagement, with expert proposals validated quarterly by the HMA management group. Experts are assigned to time-bound tasks, and prioritisation ensures timely input where most needed. Experts input will be required for the design/development of 40 Concept Papers.

The NPL governance structure builds on existing EU network and stakeholder platforms representing patients, healthcare professionals, and the pharmaceutical industry, enabling coordinated collaboration and engagement across the EU regulatory network.

Kristina Larsson (EMA) concluded the presentation by highlighting the key topics and projects within Delivery Stream 1 – Centralised Procedure and Committees, as well as Delivery Stream 2 – Development Support, while outlining the priorities for each of this delivery stream.

PCWP/HCPWP were encouraged to visit EMA's NPL webpage regularly to be kept updated and were invited to share suggestions for the regulatory sandbox. See presentation for more information.

6. Breakout session on leverage engagement with young patients, consumers and HCPs

6.1. Introduction to breakout sessions

Konstantina Boumaki (EPF) introduced the breakout sessions by sharing perspectives from her own experience as a young person living with a condition and as a young healthcare professional. She reflected on how patient and healthcare professional involvement has become an integral part of regulatory discussions, with both groups bringing complementary expertise that improves decision-making. While patients contribute lived experience and insights into the real-world impact of treatments, healthcare professionals provide practical clinical perspectives. Looking ahead, the

speaker argued that young patients, consumers and healthcare professionals have an important role to play in shaping the future of medicines regulation, bringing fresh perspectives on communication, treatment outcomes and the realities of living with or managing health conditions.

At the same time, young people remain underrepresented and often face practical barriers to participation. She called for a more inclusive and structured approach that provides opportunities, mentoring and meaningful roles for young patients and healthcare professionals alike, ensuring they are treated as equal partners rather than symbolic participants. Konstantina concluded that, just as patient engagement has successfully transformed regulatory culture over the past 20 years, the next challenge is to ensure that the next generation is actively involved in shaping the future of the regulatory system.

The working parties discussed the following topics in the breakout sessions:

- How can organisations better engage with young patients/HCP in order to inspire them and help them learn from one another?
- Explore how organisations can increase awareness of EMA, its activities, and the potential contribution of individuals as experts.

AOB

Two topics were presented:

- Update about therapeutic radiopharmaceuticals in oncology
- 2nd HMA/EMA Multi-Stakeholder Forum on EudraVigilance and Signal Detection