2 October 2025
EMA/342496/2025
Stakeholders and Communication Division

Highlights – European Medicines Agency (EMA) and European Association of Urology (EAU) bilateral meeting

2 October 2025, 16h30-17h30 CET

1. Introduction and tour de table

The Healthcare Professional Liaison welcomed the European Association of Urology (EAU) and UroEvidenceHub (UEH) delegates to this first formal bilateral meeting with the European Medicines Agency (EMA).

2. EAU updates

EAU focused their presentation on two key areas of work where they would welcome further engagement with EMA: 1) increase the representation of urological conditions in regulatory RWE and 2) joining efforts in addressing treatment of urologic tract infections and AMR.

UroEvidenceHub, is a data haven initiative of the EAU addressing the potential of real-world data to drive real-world evidence and advanced clinical decision support in urology. Urological conditions like prostate cancer, bladder cancer, kidney disease and rare urogenital disorders are underrepresented in regulatory RWE. By aligning UroEvidenceHub's disease-specific depth with EMA's regulatory expertise, EAU and UEH can support:

- expansion of the scope and quality of urology-focused RWE;
- coordination of regulatory, clinical and HTA evidence needs in a unified framework;
- acceleration of translation of real-world insights into regulatory decisions and clinical guidelines.

Urinary tract infections (UTIs) are now the fourth most common cause of deaths associated with antimicrobial resistance, and five out of the six top pathogens implicated in AMR-associated deaths are common UTI pathogens. UTIs high incidence and the rising antimicrobial resistance have gained increased interest in the past year at urology congresses. EAU, through its infections guideline panel, is

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closely collaborating with the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) on this front, to improve the diagnosis, treatment, and prevention of UTIs through collaborative research, teaching, and evidence-based guideline development.

EAU and EMA co-authored publication in the European Urology Journal to create awareness and promote prevention of inappropriate prescribing of fluoroquinolones is a concrete example of collaboration. EAU would like to propose complementing the collabration on specific medical information with an initiative to intensify the regulatory-clinical partnership, where the clinical knowledge of EAU members can be incorporated into the regulatory process at an earlier stage.

3. EMA updates on recent topics and opportunities for engagement

EMA provided a high-level update on:

- EMA's reflection paper on patient experience data and invited EAU to contribute to the ongoing public consultation:
    - Patient experience data (PED) reflection paper
- DARWIN EU® and other specific resources that could be of interest to EAU, for example to include the available data sources in the public RWD sources catalogue to increase their discoverability:
    - Catalogue of RWD sources | HMA-EMA Catalogues of real-world data sources and studies
    - DARWIN EU® DUS of Antibiotics in the 'Watch' category of the WHO AWaRe classification of antibiotic
    - EMA/HMA annual data forum
- Multistakeholder workshop to complement the recent public consultation on the concept paper on clinical evaluation of therapeutic radiopharmaceuticals in oncology (EMA/CHMP/451705/2024) for which a date will be communicated in the coming months.

4. Summary of discussion/next steps

There is a well stablished collaboration with EAU as a member of EMA's Healthcare professionals' working party (HCPWP) and as a source of expertise for EMA product-related activities in the field of urology. This is welcome and to be continued.

EAU will share more details on their data sources and request a technical meeting to follow up on aspects related with RWE/registries and DARWIN EU®.

A follow up discussion on further collaboration in the context of AMR-related activities will be organised.

It was agreed to **hold a regular bilateral** to continue the oversight of key strategic topics.

The meeting concluded with a shared sense of having had a constructive discussion, focusing on current and future opportunities for collaboration.