EU Policy and Regulatory updates by the RPP team

The Swedish Presidency of the Council of the EU publishes its priorities

The Swedish Presidency, which started its term in January 2023, has published the priorities for the ongoing semester, namely: **Security – unity, Resilience – competitiveness, Prosperity – green & energy transition, and Democratic values & the rule of law.** Although healthcare is not mentioned among the four top priorities set by the Swedish Presidency, it is important to note the great amount of legislative work envisaged in the healthcare field over the next six months, as discussions will start on some of the most relevant health-related files, including **medical devices, pharmaceuticals, and substances of human origins. Accordingly, the Swedish Presidency will inevitably be engaging on these topics and RPP will closely follow any relevant developments.**

Leaked: Draft Proposal for a revision of the general pharmaceutical legislation

An unofficial draft of the proposal for a revision of the EU pharma legislation has been leaked earlier last week. The draft greatly focuses on addressing drug shortages and antimicrobial resistance. It further covers changes in the provisions related to the market exclusivity period and the role of the European Medicines Agency, indicating substantial changes in how medicines are developed, tested, rolled out and regulated on the European market. Of relevance for Avicenna, is that the the proposal envisages the introduction of a regulatory sandbox that will allow regulators **to test alternative data collection practices to assess therapies in certain therapeutic areas.** Such practices will also include **monitoring real-world evidence of existing treatments.** Considering the legislative timeline and the extensive number of key files currently on the table in the European Parliament's ENVI committee, it is highly likely that the Pharmaceutical legislation will not be adopted on first reading during this legislative mandate. Instead, it could end up being pushed to the 2024 mandate, when advocacy activities will have to be re-established with new MEPs. Given the recent creation of a Health Subcommittee, it is also possible that the file will be given to its members, rather than the full ENVI committee.

The European Commission launches a database of cancer images to help train AI

On 23 January, the European Commission launched the European Cancer Imaging Initiative, a new database for cancer images to help train artificial intelligence to diagnose cancer. You can find a link to the publication here. After the recent **Council recommendation to expand cancer guidelines for lung, gastric and prostate cancer**, the **European Commission launched this project** aimed at **collecting and storing imaging cancer data**. Such a tool should help **tackle issues related to data access and fragmentation**. Alongside being a flagship action planned under Europe's Beating Cancer Plan, the European Cancer Imaging initiative is closely in line with the objectives of the European Data Strategy and the European Health Data Space, potentially **creating synergies for the establishment of a secure data framework for researchers, innovators and doctors**. Such initiative announced by the Commission at its Brussels-based launch event on 23 January, has already set ambitious targets, including the **development of tools for**

personalised medicine to advance cancer diagnostic and treatment.

RPP obtained the compromised proposal by the Swedish Presidency of the EU Council for a Regulation on the European Health Data Space (EHDS)

The changes proposed by the Presidency's document include several updates in the chapter on secondary use of health data, namely on the updated rules for requesters of such data. The compromise proposal provides that **Member States,** rather than health data access bodies, should be the ones to **decide** on **the possibility of adding another category of health data** which would then be made available for secondary use. The proposal also introduced some elements that will have to be provided in the usage plan when applying for a data permit for secondary use, such as the identity of the requester and their function and the identity of other persons who will have access to this data.

The European Parliament's ENVI and LIBE Committees' draft report on the EHDS

The report, co-drafted by the ENVI rapporteur, Tomislav Sokol (EPP – Croatia), and LIBE rapporteur Annalisa Tardino (ID – Italy), emphasises several key topics within the EHDS, such as **funding and the make-up of the EHDS board**. Compared to the Commission's proposal, **the draft puts more emphasis on the important role of real-world evidence for policy decision-making, research, clinical, and health technology assessment purposes.** In this sense, **the text introduces a recital highlighting the potential application of real-world evidence**, including the benefits for patients with certain diseases, including respiratory and rare diseases. The draft provides that health data access bodies shall only provide access to electronic health to a health data user where the processing of the data by the applicant is necessary for, inter alia, **scientific research ensuring high levels of quality and safety of health care.** Of particular relevance for Avicenna is that t**his shall extend to research on medicinal products or medical devices involving training, testing and evaluating of algorithms, including in medical devices, AI systems**. The draft ultimately envisages an opt-out option for patients of sharing their data for secondary use.

The EHDS proposed rules are now being examined and is set to be voted on by MEPs in July.

We hope you find these updates useful! Should you have any questions or thoughts, please don't hesitate to reach out to Mehi from the RPP team via m.holler@rpp-group.com