

EU Policy and Regulatory updates by the RPP team

[Commission's Proposal for a revision of the general pharmaceutical legislation gets further postponed](#)

According to a spokesperson for the European Commission, **the date of publication of the draft proposal has been once again postponed to April 26th**. Chances that the negotiations will be finalized by the end of the current mandate are increasingly slim. Policymakers have already expressed their dissent and urged the Commission to publish the document. During last week's [European Council meeting](#) EU leaders expressed the urgency of this new pharmaceutical legislation and called on the Commission to "step up efforts at national and EU level to reduce barriers to cross-border business and take work forward on access to medicines across Member States while also strengthening incentives for investments in innovation".



In the meantime, the NAT Commission of the European Committee of the Regions is discussing a proposal for renunciation. The NAT secretariat recommended not issuing an opinion on the Revision of the General Pharmaceutical Legislation, giving the explanation that the file is "very technical" and regions and local authorities have "limited competence" on the subject.

[Commission launches implementation of European Regional Innovation Valleys](#)

The Commission launched a [call for expression of interest for Regional Innovation Valleys \(RIVs\)](#) which will remain open until 18 September 2023 and aims at identifying local challenges and needs in various innovation domains. The main goal of RIVs, a flagship initiative of the [New European Innovation Agenda](#), is to **identify up to 100 regions committed to enhancing the coordination and direction of their research and innovation projects** through understanding the local challenges and needs. This call for expression of interest will **enable regions to express their interest to become regional innovation valleys and identify specific local challenges and needs**. Regions are also invited to **indicate in which innovation domain (including healthcare system, food security, renewable energy, circular economy, etc) they would like to strengthen their R&I investments**.



[Spain: New Minister of Health appointed](#)



José Manuel Miñones, has been appointed as new Minister of Health in Spain on 28 March. The new Minister is expected to hold the position during the Spanish Presidency of the Council of the EU. Most of the legislative and political priorities in the area of health had already been informally communicated by the previous Minister on different occasions. **More specifically, three legislative priorities were put forward, namely the EHDS, the modification of EMA fees and the SoHo regulation.** Three political priorities were furthermore announced: 1) combating childhood obesity, 2) fighting against HIV and its stigma and, finally, 3) mental health.

Despite this, some of the statements had been so far contradictory or not comprehensive. **Therefore, the new Minister could have a final say and influence on such priorities before the start of the Presidency.**

[New Subcommittee on Public Health elects its Chair and Vice-Chairs](#)

The Subcommittee on Public Health (SANT) held its constitutive meeting on 23 March and [appointed its Chair and Vice-Chairs](#). The chairs of the SANT subcommittee will play a leading role in shaping the future of European public health policy, among which is the EU's new pharmaceutical strategy.

Earlier in March, , the European People's Party (EPP) [announced](#) that MEP [Tomislav Sokol](#) (EPP, Croatia) will serve as EPP's Coordinator within SANT.

The newly created subcommittee is mandated to address issues in the field of **public health, pharmaceutical and cosmetic products, health aspects of bioterrorism, the European Medicines Agency (EMA), and the European Centre for Disease Prevention and Control (ECDC)**. However, the ENVI committee will remain responsible for examining and voting on legislative proposals.

The complete list of 30 SANT members can be found [here](#).

The first ordinary meeting of the subcommittee will take place on **20 April in Strasbourg**.

[European Commission adopts Digital Europe Work Programme for 2023/2024](#)

The European Commission has adopted its Digital Europe Work Programme for 2023/2024.

The areas covered under the 2023/2024 WP and its budget are:

- Health Data Space which is focusing on Federated European Infrastructure for Intensive Care Units (ICUs) and Genome of Europe.
- Under Artificial Intelligence, the focus is on testing and experimentation facilities for the use of AI and on the Virtual Human Twins Models.

It should be noted that the funding opportunities for the year 2024 do not include an indicative budget yet and that this will be specified with an amendment to the WP in the coming months.

[ENVI/LIBE Draft Report on EHDS under discussion](#)



Work is currently ongoing in EP Committees ENVI and LIBE on a joint report on the **European Health Data Space**. The complete list of negotiators can be found [here](#).

A [draft report](#) was published on 15 February. The deadline for amendments was 23 March. Consideration of amendments is set to start on 13 April.

Recent discussions on the EHDS file in the European Parliament has been mainly focused on allowing patients to decide whether to share their data or not for secondary use. This has caused a

heated debate among political groups, with EPP and Renew supporting an opt-out in opposition to an opt-in approach endorsed by the Greens and some representatives of the S&D.

Should more policymakers join the call for the inclusion of an opt-in option, the negotiations in the Parliament might risk coming to an impasse.

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