Council of the European Union

Brussels, 23 June 2025
(OR. en)

9865/25
CRS CRP 21

SUMMARY RECORD

PERMANENT REPRESENTATIVES COMMITTEE

4 June 2025

I. Adoption of the agenda

9485/1/25 REV 1 + ADD 1 OJ CRP1 22
9659/1/25 REV 1 OJ CRP2 21 COMIX 167

The Committee adopted the agenda.

II. Approval of the "I" items

The Committee approved the "I" items as set out in the Annex.

III. Discussion items II

COREPER (PART 1)

Transport, Telecommunications and Energy

2. Meeting of the Council (Transport, Telecommunications and Energy) on 5 and 6 June 2025: preparation

Regulation on air passenger rights
Political agreement

OC 8928/1/25 REV 1
+ ADD 1 REV 1
+ ADD 2 REV 1
+ ADD 3

The Committee finalised the preparation of this item for the Council meeting.

3. Regulation on the use of railway infrastructure capacity in the single European railway area, amending Directive 2012/34/EU and repealing Regulation (EU) No 913/2010 — 1 C — 9429/25 + COR 1
Preparation for the trilogue

The Committee agreed on a revised mandate for the trilogue on 10 June 2025.

Health

4. Pharmaceutical package — 1 C — 9270/25

a) Directive on the Union code relating to medicinal product for human use — 9285/25

b) Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency — 9286/25

Mandate for negotiations with the European Parliament

The Committee agreed on a mandate for negotiations with the European Parliament and agreed to make it public.
Statements by Belgium, Bulgaria, Malta and Sweden and a joint statement by Croatia and Czechia, a joint statement by France and Italy and a joint statement by Estonia, Cyprus, Czechia, Latvia, Luxembourg, Portugal, Slovenia are set out below.

Statement by Belgium

"Belgium has voted in favour of the compromise on the pharmaceutical package in a spirit of solidarity and constructive cooperation.

At the same time, we wish to underline that, in the current geopolitical context, promoting competitiveness — including a balanced framework for intellectual property — remains essential for Europe.

Equally, ensuring equal and timely access for patients across all Member States to innovative treatments must remain a central objective of our common pharmaceutical strategy."

Statement by Bulgaria

"Bulgaria supports the efforts for a balanced compromise on the Pharmaceutical package. An efficient EU regulatory framework should ultimately deliver for patients' access to safe, effective and affordable medicinal products.

Access to medicines is a complex matter, where Union and Member States' efforts complement each other in a mutually respective manner with regard to competencies. Cooperation with manufacturers at national level is essential if agreements are to correspond to national specifics, needs of the population and differences in the GDP. It is worth bearing in mind that Member States remain responsible for the organisation and delivery of healthcare, as enshrined in EU primary law.

Against this backdrop Bulgaria supports the compromise as a good balance. Still, several issues could benefit from improvement, also in view of the upcoming trilogues.

The current modulation of the incentives (Art. 81 ff. of the Directive) is an obvious improvement as compared to the initial proposal. We note though that the status quo remains the most predictable and stable framework for industry and authorities.

Art. 56a of the Directive contains specific requirements that could enhance access whenever a Member State lacks a product and requests it from a MAH (Marketing Authorization Holder). Contrary to this provision, Art. 5a of the Regulation raises questions of legal and practical nature and appears redundant. A predictable and clear legal framework would rather benefit from a streamlined approach, with one clear provision (Art. 56a) that could potentially trigger consequences at Union level if many Member States face similar difficulties.

Bulgaria supports as wide Bolar exemption as legally feasible (Art. 85 of the Directive). The inclusion of public procurement in this provision however is misleading and raises concerns when it comes to legality and implementation - our preference is for a deletion.

We fully support the changes on the transferable exclusivity voucher – TEV (Art. 40 ff. of the Regulation). The Council has found the right balance between ambition and prudence. This generous incentive for antibiotics development should be the outcome of the trilogies, with no additional incentives.

When it comes to antibiotics, we note that the priority goal is to keep new and old products on the market. ERA requirements should not jeopardise availability and affordability.

We are grateful for the support at Union level for transparency obligations such as in Art. 120a of the Regulation that will enhance Member States informed, justified and proportionate decisions for access to needed medicines.

We note that the new Art. 207a of the Regulation on redispersing can result in a serious loophole in the regulatory framework. While we understand the rationale, we are truly worried that it may negatively impact medicines safety and patients' trust.

We remain committed to constructively contribute to the upcoming trilogues, with the aim to achieve a reasonable, clear and legally robust regulatory framework."

Statement by Malta

"Malta welcomes the long due revision of the pharmaceutical framework.

Malta acknowledges that the proposed texts (ST9285/25 and ST9286/25) to be adopted as the Council's negotiating mandate represents a step forward in improving access to innovative and off-patent medicines also to Maltese patients, however Malta calls for a more patient oriented framework. Malta regrets that the ambition set by the Council throughout several Council Conclusions adopted in the past years is not reflected in this legal framework and that commercial interests are still being prioritized over the health of EU citizens residing in Member States that face challenges with access to medicines. Whilst Malta fully supports innovation in the health sector in the EU, this should be to the benefit of all EU citizens, irrespective of where they reside within the Union. The numerous financial and non-financial incentives provided to the pharmaceutical industry should be linked to obligations, such as a public service obligation.

Malta is also concerned that compromise offers no remedy to bridge the gap that will be created between the end of the Brexit derogation in December 2026, and the date of implementation of this new framework. It is not clear therefore, how Malta should ensure a security of supply for its medicines throughout this period of several years. The Brexit derogation was intended to transit Malta to this new revised framework, yet this will not materialise due to the delays in the legislative process and in extended transposition periods. These delays and extensions should not come at the expense of access to medicines and patient safety in Malta.

Malta also has concerns about the legal soundness of certain provisions, such as on the new Article 120(1a) introduced by the Council within the Regulation. This Article introduces a wide derogation based on Article 36 of the Treaty of the Functioning of the European Union, without a proper impact assessment and without any data to substantiate it. These legal concerns we laid out in the WK 14978/2024 ADD 2, dated 29 November 2024. Malta considers that this derogation does not fulfil the required criteria set by the Court of Justice of the European Union (CJEU).

Malta hopes that these shortcomings are appropriately addressed throughout the forthcoming inter-institutional negotiations."

Statement by Sweden

"Sweden believes that the compromise text in most parts achieves a good balance between the need for creating incentives for the pharmaceutical industry and the need to ensure access to medicinal products for the union's patients.

In the current uncertain geopolitical situation, it is important to have a viable and growing life sciences sector, strengthening Europe's competitiveness and making our societies healthier and more resilient. It is important that EU remains attractive for investments in research, innovation and manufacturing. The path Europe chooses will affect how we manage to tackle health challenges for years to come.

Expansion of the Bolar exemption and the introduction of conditions to the final year of market protection are concerning and risk weakening the European life science industry and, in the long run, has the potential to result in fewer medicines for our patients.

In order not to hinder the innovation-promoting parts of the directive from coming into force Sweden has nevertheless chosen to accept the proposal, and we remain committed in the continued negotiations with the European Parliament for the best possible outcome."

Joint statement by the Republic of Croatia and the Czech Republic

"Croatia and Czechia welcome and recognize the intensive efforts by the Presidency and Member States over the course of almost two years in trying to reach an agreement on the Pharmaceutical package and can express their support for the compromise texts proposed by the Polish Presidency in view of approving the mandate of the Council for negotiations with the European Parliament.

However, Croatia and Czechia remain concerned about the provisions related to the transferable data exclusivity vouchers (Articles 40-43 of the proposed Regulation) and would like to state the following:

Within the original proposal for the Pharmaceutical package, the European Commission proposed that the revised pharmaceutical legislation would add, as an additional regulatory incentive, transferable data exclusivity vouchers that would be given to encourage the development of new antimicrobial medicinal products (priority antimicrobials). Such vouchers would provide an additional year of regulatory data protection to the holder of the voucher, who can use that voucher for any medicinal product from their portfolio, thus extending the entering of competitive, generic medicinal products on the market by one year. The initial analysis of the Commission confirms that this will indeed require significant costs, but it has been repeated on numerous occasions that this newly proposed systems seems as the only tangible incentive for the industry to intensify research with the aim of developing a new generation of antimicrobials.

Croatia and Czechia express serious concerns with the effect of the aforementioned vouchers in relation to the availability of medicines, the increased prices of medicinal products, financial obligations of Member States as well as the financial sustainability of national health systems.

Without bringing in the question the need for the development of new antimicrobials, we express doubts about the effectiveness of vouchers in relation to their cost (cost-benefit analysis) and in relation to the transferable nature of the vouchers.

More specifically in relation to the financial burden, there is a number of uncertainties about the actual benefit of such a financial incentive, since it represents significant financial implications for healthcare systems, without any financial participation coming from the EU level. All voucher costs will be financed exclusively by national healthcare systems and taxpayers, without any EU participation.

An additional issue is that the vouchers will represent additional income for large pharmaceutical companies that would be able to buy them in order to obtain an additional year of regulatory data protection for other medicines within their portfolio and by doing so cause delays for the launch of generic medicines on the market. This also brings to question the overall benefits for the developers of much-needed new generations of antimicrobials who will invest significant resources into the research and development of new antimicrobials.

Croatia and Czechia therefore advocate considering other proposed models aimed at incentivising the development of new generations of antimicrobials, which will be focused entirely on the benefit of the developers of new antimicrobials.

This comment is intended as a constructive contribution for further discussions and negotiations on the Pharmaceutical package, without in any way questioning the undeniable value of the revised pharmaceutical legislation for patients, which is clearly recognized overall. Therefore, and this must be emphasized in conclusion, Croatia and Czechia support the proposed mandate of the Council for negotiations with the European Parliament."

Joint statement by France and Italy

"In an evolving geopolitical context that affects access, availability and affordability of medicines, the EU must ensure access to the best possible healthcare for patients. The pharmaceutical package will determine the EU's ability to ensure European patients' access to novel treatments and innovative medicines, as well as the generics and biosimilars that follow.

To this end, the EU must send a strong political message in order to strengthen its competitiveness and remain a hub for investments in innovation, manufacturing, and research in the pharmaceutical sector. Predictability for our industries is key.

During the trilogue phase, France and Italy will continue to maintain a high level of commitment and ambition to ensure the predictability and attractiveness of the European regulatory frameworks and the objective of simplification, including with regards to the issue of market exclusivity modulation as well as the balance between access to generics and protection of intellectual property rights.

Moreover, France and Italy will continue to promote the objective of securing fair and faster access to medicines for all patients across the Union, including by reducing regulatory uncertainty for all market players, while not undermining affordability. In parallel of the trilogues, the negotiations of the Critical Medicines Act will also be instrumental to reach this common goal."

Joint statement by Estonia, Cyprus, Czech Republic, Latvia, Luxembourg, Portugal and Slovenia

"In a spirit of compromise, Estonia, Cyprus, Czech Republic, Latvia, Luxembourg, Portugal, Slovenia support the mandate to start negotiations with the European Parliament with a view to reaching an agreement on the EU pharmaceutical package. We reiterate the importance of this legislative package in ensuring more equitable access to innovative medicines in the EU as one of the core objectives of the reform. We regret that the Commission proposal, which was well-balanced in terms of stimulating pharmaceutical innovation and improving patient access, has been considerably weakened in this regard.

It is worrying that pharmaceutical companies launching their products in the EU have been overlooking some Member States, in particular those with smaller market size, leading to significant delays for our patients in accessing essential treatments. This situation creates a troubling disparity within the Union, where access to medicines depends on market attractiveness rather than patient needs. The revision of the EU pharmaceuticals' legislation offers a unique opportunity to steer the market to better target the public health needs in a more equitable manner. Reducing the geographic disparities in access to medicines requires decisive action at the EU level underpinned by a strengthened regulatory framework, including proportionate and enforceable market launch and supply obligations, serving general public health interests.

There is a clear public health and internal market imperative that medicinal products with EU central marketing authorization should be made available throughout the EU. We call for a strengthened role of the European Commission in overseeing the market launch and supply of medicinal products, especially for centrally authorized medicinal products that are in a dominant market position due to regulatory protection and market exclusivity. Measures at EU level should be effective, proportionate and evidence-based, addressing the consistent and unjustified failure to supply in several Member States.

We underline that the internal market for pharmaceuticals should deliver for patients in all Member States, so that all EU citizens could benefit from innovation, regardless of their residence. We urge the Presidency to tightly keep to this mandate in the negotiations and not to make further concessions that would weaken the provisions aiming to support improved patient access in all Member States."

Environment

5. Meeting of the Council (Environment) on 17 June 2025: preparation

The Committee took note of the AOB requests by France on "Launch of a preparatory study of a delegated act on switchgears", by Czechia together with Lithuania on "Proposed ban on lead in ammunition and fishing tackle under REACH regulation" and by the Commission on "Water Resilience Strategy", and decided to hold them in public session.

Regulation on circularity requirements for vehicle design and on management of end-of-life vehicles — 1 C — 9440/1/25 REV 1
General approach

The Committee prepared this item for the Council meeting.

Transport

6. Regulation on the European Maritime Safety Agency and repealing Regulation (EC) No 1406/2002 — 1 C — 9436/25
Analysis of the final compromise text with a view to agreement

The Committee analysed and confirmed agreement on the final compromise text.

Internal Market and Industry

7. Regulation on detergents and surfactants, amending Regulation (EU) 2019/1020 and repealing Regulation (EC) No 648/2004 — 1 C — 9019/25 + ADD 1
Preparation for the trilogue

The Committee agreed on a revised mandate for the trilogue on 10 June 2025.

Agriculture and Fisheries

8. Meeting of the Council (Agriculture and Fisheries) on 23 and 24 June 2025: agenda
(For the items in the remit of the Permanent Representatives Committee)

The Committee took note of the main items to be included in the provisional agenda of the Council meeting, as presented by the Presidency. It also took note of the AOBs by the Commission on "Mandatory use of 'IT catch' to fight illegal, unreported and unregulated fishing" and on "Implementation of the fisheries control regulation", and by the Presidency on the "Conference on current challenges in forestry (Warsaw, 29-30 May 2025)", and decided to take them in public session.

Environment

9. One Substance One Assessment Package — 1 C — 9439/25

a) Regulation amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals — 9221/1/25 REV 1

b) Directive amending Directive 2011/65/EU as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency — 9230/1/25 REV 1

c) Regulation establishing a common data platform on chemicals — 9331/25

Preparation for the trilogue

The Committee agreed on a revised mandate for the trilogue on 12 June 2025

Employment and Social Policy

45. Revision of Regulations on coordination of social security systems (883/04 and 987/09) — 1 C
Presidency debriefing on the outcome of the trilogue

The Committee took note of the debriefing by the Presidency on the outcome of the trilogue on 3 June 2025.

COREPER (PART 2)

General Affairs

15. Meeting of the Council (General Affairs) on 24 June 2025:
Agenda

The Committee took note of the main items to be included in the provisional agenda of the Council as presented by the Presidency.

Foreign Affairs

16. Meeting of the Council (Foreign Affairs) on 23 June 2025:
Agenda

The Committee took note of the main items to be included in the provisional agenda of the Council as presented by the Presidency. The Committee also agreed to invite the Ukrainian foreign affairs minister.

17. 30th EU-Japan summit (Tokyo, July 2025) 9173/25 **R-UE**
Orientation debate

The Committee held an orientation debate on the upcoming summit.

Economic and Financial Affairs

18. Meeting of the Council (Economic and Financial Affairs) on
20 June 2025: Agenda

The Committee took note of the main items to be included in the provisional agenda of the Council as presented by the Presidency. The Committee also agreed to invite the EIB President to the dinner, breakfast and ECOFIN sessions, the ESM Managing Director to the dinner and breakfast sessions, and the IMF managing director and the Ukrainian finance minister to the dinner session.

Justice and Home Affairs

19. Meeting of the Council (Justice and Home Affairs) on
12 - 13 June 2025: Preparation

Justice

a) Accession of the European Union to the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR) 8994/25
State of play

The Committee prepared this item for the Council meeting.

Home affairs

b) Overall state of the Schengen area

i) Commission State of Schengen Report 2025 — 8235/25 + ADD 1-2

ii) Priorities for the Schengen Council Cycle 2025-2026 — 9380/25

Exchange of views

The Committee prepared this item for the Council meeting.

c) Implementation of interoperability — 9314/25
State of play

The Committee prepared this item for the Council meeting.

d) Regulation to prevent and combat child sexual abuse — 1 C — 9277/25
Progress report

The Committee agreed to withdraw this item from the agenda and instead add it to the list of "A" items.

e) European Internal Security Strategy — 9267/25
Exchange of views

The Committee prepared this item for the Council meeting.

f) The impact of the current geopolitical environment on the EU's internal security

i) Ukraine — 9396/25

ii) Moldova — 9396/25

iii) Syria — 9268/25

State of play

The Committee prepared this item for the Council meeting.

g) Other items in connection with the Council meeting

The Committee took note of the requests Lithuania, for any other business items:

- by the Presidency on progress report and intended next steps on the fight against drug trafficking and organised crime, and
- by the Presidency on the outcome of the high-level meeting of the EU-CELAC coordination and cooperation mechanism on drugs;
- by Lithuania on the need to promote shared European remembrance narratives across the Union (Justice), and
- by Slovenia on the Brdo process (Home affairs).

Furthermore, Coreper took note of the request by Italy for a new discussion item on the situation in Libya and impact on the migratory flows towards the EU.

IV. Any other business

COREPER (PART 1)

None.

COREPER (PART 2)

Preview of the G7 Summit (Kananaskis, 15-17 June 2025).

The Committee took note of the information provided by the cabinet of the President of the European Council and the Commission.

Ad hoc meeting for members of the Special Committee on Agriculture (SCA) and of the Antici subgroup on simplification (AGS).

The Committee took note of the information provided by the Presidency.

State of play of EU-US relations

The Committee took note of the information provided by the Commission.

ANNEX

Non-discussion items "I"

COREPER (PART 1)

Non-discussion items (I)

Institutional Affairs

Other

10.	Attendance of third parties at the Working Party on Animals and Veterinary Questions (Chief Veterinary Officers) on 9-12 June 2025 (Gdansk, Poland) *Approval*	9401/25 VETER

Environment

11.	The Nice wake up call for an ambitious plastics treaty *Authorisation to sign a non-binding instrument*	9456/25 + COR 1-2 ENV

Agriculture

12.	Decision on the equivalence of seed produced in the Republic of Moldova and in Ukraine *Adoption of the legislative act*	9324/1/25 REV 1 PE-CONS 9/25 AGRILEG

EU positions for international negotiations

13.	ICAO - EU coordination for the 235th session of the ICAO Council (Montreal, 9 to 13 June and 23 June to 4 July 2025) – items falling under Decision (EU) 2023/746 *Approval*	9241/25 + COR 1-2 + ADD 1 + ADD 1 COR 1 AVIATION

A statement by the Commission is set out in document 9241/25 ADD 1 + COR 1.

14.	ICAO - EU coordination for the 235th session of the ICAO Council (Montreal, 9 to 13 June and 23 June to 4 July 2025) – Policy items *Approval*	9242/1/25 REV 1 + REV 1 COR 1 + REV 1 ADD 1 + REV 1 ADD 1 COR 1 + REV 1 ADD 2 AVIATION

A statement by the Commission is set out in document 9242/1/25 REV 1 ADD 1 + COR 1.
A statement by Hungary is set out in document 9242/1/25 REV 1 ADD 2.

COREPER (PART 2)

Judicial Affairs

20.	Case C-240/25 P, plea of illegality, Directive 2014/59/EU and Regulation (EU) n°806/2014 (ex-ante contributions 2022) *Information note*	8921/25 JUR
21.	Cases T-295/25 and T-295/25 R, action for annulment and request for stay of execution, restrictive measures (Ukraine) *Information note*	9480/25 JUR
45.	Affaire T-597/24, recours en annulation, mesures restrictives (Ukraine) *Authorisation to produce a copy of or an extract from a Council document for use in legal proceedings*	9716/25

Institutional Affairs

Minutes of Council meetings 🕮
Approval

22.	a) FAC on 14.04.2025	8010/25 + ADD 1

Letters

23.	Partial renewal of the European Court of Auditors 🕮 *Approval of a letter*	8953/25 CMPT

Other

24.	Attendance of third parties at the Horizontal Working Party on Enhancing Resilience and Countering Hybrid Threats (HWP ERCHT) meeting on 10 June 2025 *Approval*	9284/25 HYBRID DISINFO
25.	Attendance of third parties at the Security Committee (CSC) meeting on 11 June 2025 *Approval*	9381/25 CSC
26.	Attendance of a third party at the Working Party on the Western Balkans region (COWEB) on 30 June 2025 *Approval*	9484/25 COWEB

Transparency

27.	Public access to documents Confirmatory Application No 08/c/01/25 *Approval*		7962/25 API
28.	Public access to documents Confirmatory Application No 11/c/01/25 *Approval*		8154/25 + ADD 1 INF

Economic and Financial Affairs

29.	Regulation amending Regulation (EU) No 575/2013 on prudential requirements for credit institutions as regards requirements for securities financing transactions under the net stable funding ratio *Adoption of the legislative act*	1 C	9322/25 PE-CONS 14/25 EF
30.	Council conclusions on European Court of Auditors' Special Report No 07/2025 - EFSI *Approval*		9518/25 9496/25 ECOFIN
31.	Council conclusions on the European Court of Auditors' Special Reports Nos. 09/2025, 10/2025 and 13/2025 – RRF *Approval*		9520/25 ECOFIN

General Affairs

32.	Declaration launching a High-Ambition Coalition for a Quiet Ocean *Authorisation to sign a non-binding instrument*		8693/25 POLMAR
33.	Third UN Ocean Conference (Nice, France, 9-13 June 2025): political declaration *Authorisation to sign a non-binding instrument*		9089/25 POLMAR

Justice and Home Affairs

35.	Council conclusions on the Pact addressing new synthetic drug threats in the European Union *Approval*		8892/25 CORDROGUE
36.	40 years and beyond – Schengen Declaration, a joint commitment for Freedom, Security and Justice *Approval*		9329/25 SCHENGEN

Foreign Affairs

37.	Council Decision and Implementing Regulation concerning restrictive measures in view of the situation in Guatemala *Adoption*		8341/25 8338/25 8340/25 CORLX
38.	Regulation on the modification of customs duties of certain agriculture goods and fertilisers from Russia and Belarus *Adoption of the legislative act*	1 C	9323/1/25 REV 1 PE-CONS 5/25 POLCOM
39.	Regulation on suspending certain parts of Regulation 2015/478 as regards Ukraine *Adoption of the legislative act*	1 C	8889/25 + COR 1 PE-CONS 7/25 POLCOM
40.	Tenth EU-NATO progress report *Information note*		8981/25 COPS
41.	Commission's intention to negotiate a Joint Statement with the OACPS in view of the 4th UN Conference on Financing for Development *Authorisation to negotiate a non-binding instrument*		9633/25 ACP
42.	High-level political declaration on an ambitious implementation of the agreement on biodiversity beyond national jurisdiction (BBNJ) for the BBNJ High Ambition Coalition *Approval of a non-binding instrument*		9029/25 COMAR

EU positions for international negotiations

43.	Council Decision on the EU position in the Council of Members of the International Olive Council (IOC) as regards the trade standard for olive oils and olive pomace oils *Adoption*	C	9194/25 9197/25 + ADD 1 PROBA

A joint statement by Portugal and Spain is set out in document 9194/25 ADD 1.
A statement by Germany is set out in document 9194/25 ADD 2.

Other items

44.	Cryptographic product for the protection of EUCI *Approval*		8592/1/25 REV 1 CSCI