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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
Subject:	Pharmaceutical package a) Directive on the Union code relating to medicinal product for human use 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 *- Mandate for negotiations with the European Parliament* *- Statements*

Delegations will find in Annex statements related to the above-mentioned subject.

ANNEX

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.

STATEMENT of the REPUBLIC OF 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.

Belgian statement on the pharmaceutical package

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 OF ESTONIA, CYPRUS, CZECH REPUBLIC, LATVIA, LUXEMBOURG, PORTUGAL, 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.

Statement on behalf of France and Italy on the pharmaceutical package

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.

STATEMENT OF 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.

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.