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NOTE

From:	Presidency
To:	Permanent Representatives Committee/Council
Subject:	Pharmaceutical package *- Policy debate*

Delegations will find in Annex a background note from the Presidency to steer the policy debate on the incentives system within the proposed pharma package at the EPSCO Council (Health) on 21 June 2024.

ANNEX

Incentives system within the proposed pharma package: ways forward to achieve an agreement in the Council

On 26 April 2023, the Commission submitted proposals for a revision of the EU pharmaceutical legislation: a proposal for a Directive establishing an EU code relating to medicinal products[1] and a proposal for a Regulation laying down EU procedures for the authorisation and supervision of medicinal products and the rules governing the European Medicines Agency (EMA)[2] (hereafter 'the package'). These will constitute the EU regulatory framework for all medicines for human use, simplifying or repealing the current pharmaceutical legislation and are based on Article 114(1) and Article 168(4)(c) of the Treaty on the Functioning of the European Union (TFEU).

One of the key objectives of the proposals is to ensure access to innovative and affordable medicines in all Member States whilst protecting the EU's competitiveness and attractiveness for innovation in the pharmaceutical sector. The 'incentives-cluster' within the package (Commission proposal), includes, amongst other things, a modulated system of regulatory data and market protection in which protection periods are granted based on the fulfilment of certain conditions (this is mirrored in the orphan framework with market exclusivity):

- The basic regulatory data protection or 'RDP' period (prohibition of reference to dossier data by another applicant) is reduced to six years, but may be extended by:
  - two years - when the product is continuously supplied in sufficient quantity and the presentations necessary to cover the needs of patients in all Member States, unless a waiver has been issued ('market access incentive');

[1] 8759/23
[2] 8758/23

- six months – when at the time of the initial marketing authorisation application, the applicant demonstrates that the medicine addresses an unmet medical need or 'UMN' ('UMN incentive');
- six months – for medicines containing a new active substance, where the clinical trials supporting the initial marketing authorisation application use a relevant and evidence-based comparator in accordance with scientific advice provided by the EMA ('comparative clinical trials incentive'). This incentive is not mentioned further in this note as there seems to be strong agreement on both its merit and its design;
- one year – for medicines still protected by RDP and for which an additional therapeutic indication with a significant clinical benefit is obtained (only granted once).

- The RDP period of a product is followed by a two year market protection period (prohibition of the product being placed on the market by another applicant).
- For orphan medicinal products, a standard market exclusivity period of nine years is granted (protection from similar medicinal products for the same therapeutic indication being placed on the market), with an extension of one year for high unmet medical need orphan medicines.

In particular the modulation of the total length of the RDP period, the accompanying reduction of the basic RDP period to six years, the introduction of the market access incentive, and the provisions on (high) unmet medical needs represent a significant departure from the current system which requires an in-depth political discussion at ministerial level. The specific aim of this paper is to propose a 'way forward', based on feedback by Member States, with regard to these key discussion points. On the market access-incentive, which is central to the redesign of the system, we present four different options from which to choose.

We invite ministers to express their views on this way forward, and to indicate which policy option on the 'market access incentive' they prefer. We want to focus on the principles of the redesign of the system, not on the details. We aim to define the contours within which a compromise on new rules for regulatory data and market protection is possible, and give direction to the Council working party.

Issues to be addressed

Based on discussions at technical level, the Presidency considers that the *modulation* of data and market protection periods, as well as the *types* of incentives proposed by the Commission, could be acceptable for the Council provided that a number of issues are addressed:

- Predictability: the total data and market protection periods for a product should be known within an appropriate timeframe.
- Transparency: data and market protection periods that apply to a certain product should be publicly consultable.
- Legal certainty: the criteria for granting an extended protection period should be 'measurable' and clear, to avoid legal uncertainty and misuse.
- Affordability: the length of and criteria for the extension of the protection period should ensure value for money.
- Impact: the incentives should be fit for purpose and achieve tangible results for patients.
- Competitiveness: the length of and criteria for the extension of the protection period should make the EU sufficiently attractive for innovation and investment, whilst ensuring sufficient competition in the market.
- Burden for authorities and companies: the redesign of the incentives system should be tailored and proportionate in terms of burden.

Modulation of regulatory data protection periods: proposed way forward (Question A)

Modulating data and market protection is considered an important tool to incentivise companies to fulfil key public health objectives. Based on discussions in the working party, the Presidency proposes keeping this modulation as a guiding 'principle' for the negotiations, but it considers it too early to decide on the length of the reduction in basic RDP (from 8 to 6 years in the Commission proposal and from 8 to 7.5 years in the European Parliament's position). The specific **duration** of the protection periods coupled to the incentives (and consequently the length of the reduction in basic protection) should be **proportionate** to the eventual **design** of the respective incentives. The Presidency therefore proposes focussing first on the design and purpose of the incentives and is not yet proposing changes to the duration of the protection periods or to the reduction of basic RDP.

In order to avoid the modulated system has a disproportionate impact on health budgets (affordability), several Member States called for a capping of total data and market protection. The Presidency therefore proposes introducing a cap of 11 years of data and market protection, which should still be considered 'competitive' in comparison with other systems. Whether or not the 'AMR voucher' and the one year of data protection linked to it should be included in this capping should be covered in the discussion on the voucher itself.

The Presidency considers that part of the solution to achieve greater **predictability** is to allocate one year of market protection instead of one year of regulatory data protection for an additional therapeutic indication. For these products, generics companies will be able to start their preparations for generic entry one year earlier.

In order to achieve **transparency** and facilitate generic entry, a public register should be developed in which the data and market protection periods that apply to a product can be consulted.

With regard to **orphan medicinal products** the Presidency considers that the proposal, to have a basic market exclusivity period of nine years, with a further one year for 'high unmet needs' strikes the right balance.

Market access incentive: four options for a way forward (Question B)

Ensuring access to (innovative) medicines in all Member States is a key objective of the package. The main question is whether this should be achieved through a 'market access incentive' or, alternatively, through an obligation on companies (decoupled from the modulated/incentives system) to make certain efforts to(wards) supply. Any incentive or obligation, however, should be effective, implementable, proportionate and predictable.

The four options presented below aim to fulfil these requirements. The first three options imply a gradually weaker 'definition' of the 'effort' the company should engage in to receive the incentive within the modulated system. The fourth proposal 'decouples' the access-issue from the incentives structure and formulates a proposed solution in terms of an obligation.

The first three options have **two 'basic requirements' in common**. Firstly, the system should work via an 'opt-in': the Member State should make a request to a company within a certain timeframe, indicating it wishes to have the product on its market and it wishes to receive a pricing and reimbursement (P&R) application (see below). The step forward compared to the current situation is that this gives Member States leverage in contacting companies from which they wish a product to be marketed. Moreover, an 'opt-in' ensures that the burden for both companies and authorities is kept to a minimum. Secondly, if a Member State makes a request, the company is required to submit an application for P&R. The submission (and subsequent negotiations) should be done 'on reasonable terms'; this should ensure the submission is not a 'tick-the-box-exercise' or non-committal, but is adequate and serious. The step forward here is that the company is incentivised to engage into a serious dialogue with the Member State, and commits itself in good faith to find a workable outcome to P&R negotiations.

To avoid that the condition to apply for or to have a positive decision on P&R (as mentioned in the first three options) unintentionally would limit the scope of the incentive (not covering all products), it could be considered to broaden the condition and include all products that are financed through the public system ('coverage'). This would ensure that, next to products for which there is a P&R application or decision, also products attained through public procurement (e.g. by hospitals) or through a market entry agreement could be included.

The first option then adds to these two basic requirements the following cumulative conditions:

a. The outcome of the P&R negotiation is positive. Only when there is an agreement can the company receive the associated protection. This would give strong leverage to the Member State. It also has the advantage of objectivity.
b. The company submits a detailed access plan for the medicinal product in the market of the Member State. This plan requires effort as it would need to contain plans on production, supply chains, distribution, etc. Specific criteria which this plan should meet could be developed. Optionally, the plan could be made subject to approval by the Member State (the Member State knows which quantities are needed for which population, and the need for approval would also give the Member State additional leverage).
c. The product is released and supplied in the Member State in accordance with to the access plan. Granting the associated protection only when there is actual supply is close to the logic of the Commission proposal.

The second option does not include a requirement to actually release and supply the product in the market. The associated protection is granted when the basic requirements and conditions (a) and (b) mentioned in the first option are fulfilled. The underlying philosophy of this option is that the company is required to make significant efforts/engagements towards supply. Although supply in itself is not required for the company to receive the associated protection, there will be a situation in which there is a positive P&R decision, and in which an access and plan has been developed. This could sufficiently set the scene for actual supply (but without guaranteeing eventual supply).

The third option only requires the company to fulfil the two basic requirements mentioned above. In addition, the company should share information on the steps it has taken to make the product available in the respective Member State.

All conditions should be fulfilled within two or, for some entities, three years after the granting of the marketing authorisation. This should ensure predictability.

(The same conditions should apply to the market access incentive of one year of market exclusivity for orphan medicinal products).

The fourth option, or 'delinked option' would pursue the aim of achieving EU wide access, not through an RDP-incentive, but through an obligation-structure. Several modalities of this obligation could be envisaged, including - but not limited to - an obligation to file for P&R and to negotiate on reasonable grounds within a Member State that would make a request (along the lines of the European Parliament's position). This fourth option would also need to be considered in parallel with the evaluation of the length of the basis RDP protection.

Unmet medical need incentive and high unmet needs for Orphan Medicinal Products: proposed modifications (Question C)

A UMN-incentive could have its place in a modulated system provided that more legal certainty can be achieved in the application of the criteria for receiving the incentive. To avoid litigation, these criteria for the identification of products addressing a UMN should be objective and measurable. In addition, the incentive should be fit-for-purpose and provide value for money.

As a first step in addressing these issues, the comparison-criterion can be stretched beyond medicinal products only (treatments, diagnosis). The fulfilment of the effect criterion should, in addition, be supported by evidence from comparative clinical trials, where possible. Lastly, the EMA should be obliged to prepare guidelines, in the development of which it should involve a number of actors, on applying the article. Further specifications of indicators in these guidelines should address measurability and objectivity.

Whether orphan medicinal products should be automatically considered as addressing a UMN, as proposed by the Commission, has been subject to discussion. This would mean that all orphan products are automatically granted the UMN-incentive of an additional six months of RDP protection (on top of the market exclusivity regime for orphans), even when these products do not fulfil the UMN-criteria.

With regard to orphan medicinal products and the incentive for products addressing a high UMN, the issues and potential solutions are similar to the above.

Questions for discussion:

A. Can you agree to a modulated incentives system? Do you agree with the conditions (register, capping, modulate one year with market protection, reduction of basic RDP) mentioned in this paper?

B. Do you agree that incentives should be used as the way forward to improve access? Which option (set of conditions) described in this paper could you support? If none, under what conditions could you agree to a possible solution for the access-issue?

C. Can you agree to a UMN incentive (for normal and orphan medicines) under certain conditions? Do you agree with the conditions set out in this paper for such a system and what possible additional conditions would you like to see?