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NOTE

From:	General Secretariat of the Council
To:	Council
Subject:	Applying a needs-driven approach to pharmaceutical innovation *- Information from the Austrian, Belgian, Irish, Luxembourg and the Netherlands delegations*

Delegations will find in Annex an information note from the Austrian, Belgian, Irish, Luxembourg and the Netherlands delegations on the above mentioned subject to be raised under "Any other business" at the meeting of the EPSCO Council (Health) on 13 June 2023 .

ANNEX

Applying a needs-driven approach to pharmaceutical innovation

In a patient-centred healthcare system, research and development should be driven by needs of patients and of the society as a whole. However, as things stand today, private investments in R&D tend be aimed towards the highest expected return on investment. This not only drives which therapeutic interventions are developed, but also for which indications. These are not necessarily areas with the highest unmet health needs. Regulatory incentives and financial support for R&D are still mainly supply driven; i.e. granted following a request of a developer of a product or therapeutic intervention, rather than based on previously defined unmet patient and societal needs. Decisions are often made on an ad hoc basis and there is little discussion on priorities.

The time has come to think of new systems, allowing for a change in business models. Models that focus more on societal and patient needs rather than on supply. It requires a clear, joint message as to which therapeutic interventions have the greatest health benefits for society as a whole. It will allow us to:

- Use public research funding more strategically;
- Direct our market incentives for most needed products;
- Cleary signal on what we are willing to pay for specific types of medicines.

The EU has a crucial role in these mechanisms through its important research funding programs, as well as through regulatory incentives. We believe that these leviers should be used in a more targeted way to better address the public health needs in the EU.

Therefore, we propose to work with a life-cycle approach to create a needs-driven system, involving (1) the identification of the highest unmet needs, both on the individual and on the societal level, (2) the creation of smart and predictable incentives towards health technology developers to steer R&D activities towards the highest needs and (3) approval and reimbursement processes that take predefined performance of new health interventions on these unmet needs into account, as well as provide for a predictable financial compensation for innovation in selected indication areas.

All throughout this life-cycle approach, coordinated EU-action will have strong added value.

(1) Identification of unmet needs

At the heart should be a common system to identify, assess and appraise unmet patient and societal needs and to set a graded classification of the unmet needs Member States intend to address at EU or at national level. In this new approach the definition of unmet needs should be based on transparent criteria and standardised ways to assess the criteria and determine the levels of need. The collection of evidence on health issues to be included in a needs database should be based on a scientific methodology. As needs may change over time, this database is to be kept up-to-date. The appraisal and ranking of the unmet needs should be based on predetermined transparent criteria and using the scientific data and evidence included in the evidence database.

⇨ **We therefore call for a common approach to identifying unmet needs at EU level**

(2) Creation of smart and predictable incentives

Unmet needs should be identified independently of health interventions in the pipeline. To ensure that developers invest by priority in health interventions for which there is a real patient or societal need, regulatory incentives and financial support for R&D should focus on these identified unmet health needs. The revised EU legal framework on pharmaceuticals should allow for this needs-driven approach.

⇨ **We therefore call for a dialogue on an evidence-based operationalisation of the definition of unmet needs in the EU pharmaceutical legislation**

(3) Approval and reimbursement processes

If incentives have been awarded for the development of a health intervention aimed at addressing a high unmet need, due attention should be paid to the follow-up of the development of the health intervention.

The development of a graded classification of unmet patient and societal needs can finally be used to provide predictability to developers of health technologies as to the medical interventions that are eligible for inclusion in the national healthcare benefit packages, after due assessment of their performance. While fully respecting national competencies on pricing and reimbursement, Member States can truly impact the current supply driven system by jointly exploring changes and best-practices in pricing and reimbursement systems. This can help shifting the business model of developers of products or therapeutic interventions toward a sustainable, needs driven model.

We invite Member States to provide predictability to healthcare developers as to health interventions addressing high unmet needs they intend to include in their benefit package

- ⇨ **We welcome Member States in a discussion on a voluntary coordinated approach to needs driven reimbursement systems**

(4) A joint systematic approach to change

The pharmaceutical system is complex, yet change is essential in order to warrant our European health systems based on solidarity. Sustainable change that benefits patients, payers and industry requires a broad support for new policies.

- ⇨ **We invite Member States to engage in a dialogue on shifting toward a needs driven pharmaceutical model**