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Subject:	**Employment, Social Policy, Health and Consumer Affairs Council** meeting on 8 December 2017 Pharmaceutical policy in the EU – current state and future perspectives – *Exchange of views*

1. On 24 November 2017, the Permanent Representatives Committee was informed by the Presidency about the preparations for the exchange of views on Pharmaceutical policy in the EU scheduled to take place at the Council (EPSCO) session on 8 December 2017[1].

2. The Permanent Representatives Committee agreed that the exchange of views in the Council should be public.

3. The Council is therefore invited to hold a public exchange of views on the basis of the Presidency note set out in the Annex to this document.

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[1] See document 14357/17.

ANNEX

Presidency note

I. General Background

Member States have the overall responsibility for their health policy and the organization of health systems to ensure that the health systems are accessible, effective and sustainable. Pharmaceutical policy is an indispensable component of health systems in ensuring continuous access to effective, safe and high quality medicinal products and should contribute to creating a basis for supply of medicinal products, including innovative medicinal products, with clear added value at reasonable prices.

The European Union (EU) regulatory framework for pharmaceuticals has the internal market as one of its legal bases (Article 114 of the Treaty on the Functioning of the European Union). At the same time, when it comes to access and availability of medicines, Member States, in accordance with Article 168(7) of the Treaty, have the responsibility for the definition of the pharmaceutical policy as an indispensable part of their health systems.

While the internal market creates opportunities, it also poses challenges, as not all national markets in the EU are economically attractive for the pharmaceutical industry. Several health ministers have recently raised concerns in relation to equal access and availability of medicines across Europe, emphasising the need for a comprehensive approach and a common vision for sustainable solutions within the pharmaceutical systems to the benefit of patients.

Currently, medicines are not equally affordable and available to all EU Member States and to all persons living in the EU. Frequently, a medicinal product that has obtained an EU marketing authorization only reaches some of the national markets with a substantial delay, or not at all, especially in the case of small markets. It is up to industry to decide where and when to market their products. The situation is the same in the case of launching generic medicines after the period of market exclusivity has elapsed. As a result, in some Member States even essential medicinal product are not available on the market. Shortages of medicines, a growing problem in Europe, is another aspect of availability of medicinal products that needs appropriate policy responses to address the challenges across the supply chain.

Furthermore, the price formation of medicinal products is not always transparent and the added-value of new innovative medicines is not clear in terms of meeting medical needs. In view of the sustainability challenges faced by the health systems, high prices of medicines create tensions between the need to ensure equal access and effective treatment on the one hand and the limited resources and sustainability of funding on the other hand.

Availability and affordability of medicinal products is a complex matter with many facets, which need balancing between creating a supportive environment for innovation and ensuring that medicines remain safe and affordable. For example, the objective of accelerating access to innovative products, by shortening the time from development to market, should not compromise patient safety.

Many of the pharmaceutical policy challenges persist despite continuous efforts and ongoing discussions at the EU level, among Member States and with stakeholders. Therefore, it is necessary to take stock of recent developments and reflect on ways for intensifying actions intended to overcome these challenges.

II. State of play

In June 2016, the Council adopted conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States. Discussions have been taken forward by all subsequent Presidencies. During the Slovak Presidency, the health ministers' discussions focused on the shortages of human medicines in Europe and during the Maltese Presidency discussions were held on the structured cooperation to improve access to innovative technologies for rare diseases.

As a follow up to the 2016 Council conclusions, subsequent Presidencies have organized informal High Level Pharmaceutical Policy meetings (*hereinafter HLPPM*), where high-level representatives from the Member States responsible for their pharmaceutical policy have discussed current and future developments in the pharmaceutical systems in the EU and its Member States.

In addition, a number of voluntary cooperation initiatives have been launched, bringing together groups of Member States to identify common issues and to investigate how to deal with some of these issues in a collaborative way. Under the BeNeLuxA initiative the Belgian, Dutch, Luxembourg and Austrian governments have started to collaborate on sharing of information, horizon scanning, health technology assessment and joint negotiations. In May 2017, eight countries (Ireland, Greece, Spain, Italy, Cyprus, Malta, Portugal and Romania) subscribed to the Valletta Declaration, committing to set up a technical committee to explore possible ways of voluntary cooperation including, but not limited to, sharing information, identifying best practices, horizon scanning of innovative medicines and therapies, exploring possible mechanisms for price negotiations and joint procurements. Other regional collaboration initiatives are ongoing, for example among the Baltic states and the Visegrad Group countries.

Building on the Council conclusions of 17 June 2016, three Round Table meetings have been held to bring together EU health ministers, leaders of the pharmaceutical industry, innovative and generic industry associations, as well as patients' organizations, to promote a broader dialogue on the main challenges in the pharmaceutical realm. A High Level Group (HLG) was set up to prepare and inform the Round Table meetings and oversee the implementation of the actions. The HLG will jointly identify and characterize the challenges in the pharmaceutical system and suggest ways for possible action, including sustainable prices of new medicines, promoting competition including generic and biosimilars policies, increasing transparency and the search for alternative business models.

III. Long term agenda 2017-2020 for EU and Member States-driven voluntary cooperation on pharmaceutical policy

Based on the Council conclusions adopted in 2016, the previous Presidency trio (The Netherlands, Slovakia and Malta) elaborated a draft document setting out a Long-Term Agenda for EU and Member States driven voluntary cooperation on pharmaceutical policy 2017-2020 *(hereinafter Long-Term Agenda)***,** which has been discussed at the HLPPMs in Malta (13 March 2017) and in Estonia (4-5 September 2017).

The overall aim of this Long-Term Agenda is to ensure that by 2020, significant progress should have been made in re-balancing the pharmaceutical systems in the EU and its Member States so that they will be sustainable and future-proof. The Long-Term Agenda has the objective of promoting voluntary cooperation between Member States bilaterally, regionally and at EU level and invites them and the European Commission, within the remit of its mandate, to contribute to the implementation of the identified actions within existing working bodies and structures operating within the EU pharmaceutical system. Member States are invited to support implementation of this Long-Term Agenda, including by engaging in debates at informal meetings, but also by actively contributing to the various actions bilaterally or multilaterally and/or at the EU level.

The Long-Term Agenda 2017-2020 is Member States-driven and the coordination and monitoring of implementation of this document is carried out through regular HLPPMs. By 2020, the HLPPM will conduct an evaluation of the implementation of the Long-Term Agenda and consider the formulation of a new agenda for the period thereafter.

In order to achieve the objectives of the Long-Term Agenda, the following priorities have been identified during the discussions held at the HLPPMs:

- **Improving coordination of and cooperation on pharmaceutical policy at EU level**
  Coordination and cooperation on pharmaceutical policy can be strengthened at national, bilateral and European level so that greater coherence and efficiency is obtained; relevant information is shared on a structural basis, whilst respecting existing competences in this field.
- **Promoting voluntary cooperation between EU Member States**
  Member States are invited to engage in voluntary bilateral and multilateral cooperation, in particular in the field of health technology assessment, pricing and reimbursement of pharmaceutical products, by joining forces in sharing relevant information and expertise, the exchange of best-practices and – where appropriate – joint negotiations.
- **Strengthening the EU regulatory framework in the field of pharmaceuticals**
  Through an exhaustive assessment of the current EU regulatory framework in the field of pharmaceuticals, insight can be obtained on the functioning and effectiveness of the existing regulatory instruments, including the effects of special incentives to promote innovation on accessibility, availability and affordability of medicinal products, as well as on the functioning of the pharmaceutical markets within the EU.
- **Ensuring accessibility, availability and affordability of medicinal products for human use**
  Rapid developments in medical technology results in new and promising innovations in the treatment of serious diseases. These new developments challenge existing practices and procedures for the assessment of new products, business models and reimbursement strategies of EU Member States. Through an exhaustive reflection on these new developments, appropriate policy responses can be identified.

- **Improving research, monitoring, information exchange and evaluation**
  Through better coordination of research and research funding, the defining of research needs, improved and more structural data collection, public resources can be used more effectively in research and development whilst better insight can be obtained in the quality, safety and efficacy of medicinal products.
- **Improving international cooperation in the field of pharmaceutical affairs**
  The challenges and concerns as highlighted in the Council Conclusions of 17 June 2016 are also relevant in other parts of the world. As the pharmaceutical market is global, it is important to improve cooperation and coordination between EU Member States in international fora and structures to ensure greater coherence.

IV. Questions for the exchange of views

The Presidency invites the Council to hold an exchange of views based on the following questions:

1) What kind of actions, in addition to those that are already ongoing, which include voluntary cooperation between Member States, are needed in order to achieve a comprehensive approach towards balanced pharmaceutical systems?
2) Do you see a need for changes to the current EU legislative framework in order to improve continuous access, availability and affordability of medicines in all Member States, including on economically less attractive markets?
3) In which areas do you see a need for reinforced cooperation? In what form should such cooperation be taken forward?