



Council of the
European Union

Brussels, 22 November 2019
(OR. en)

14307/19

SAN 474
PHARM 48

NOTE

From: General Secretariat of the Council
To: Permanent Representatives Committee/Council

Subject: Preparation of the **Employment, Social Policy, Health and Consumer Affairs Council session** on 9 December 2019
European pharmaceutical policy - strengthened cooperation and coordination with the aim to improve access to medicines
- Policy debate

Delegations will find a note from the Presidency in Annex. This note is intended as a basis for the policy debate on 'European pharmaceutical policy - strengthened cooperation and coordination with the aim to improve access to medicines' taking place at the Council (EPSCO) session scheduled for 9 December 2019.

European pharmaceutical policy – strengthened cooperation and coordination with the aim to improve access to medicines

Introduction

The European Union's policies are determined by its values, objectives and principles. The European pharmaceutical policy has gradually been established in this context through a combination of measures at the EU and national levels. Medicinal products are regulated at EU level and are part of the EU's research, innovation, economic and trade policies. On the one hand, the 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 Union¹) and has a direct impact when it comes to access and availability of medicines in the EU. On the other hand, the overall responsibility for defining national health policy and the organisation of national health systems lies with the Member States. Member States, in accordance with Article 168(7) of the Treaty, having the responsibility for the definition of pharmaceutical policy as an indispensable part of their health systems, play an essential role in ensuring access to and availability of medicines.

Medicinal products are a special type of consumer goods and the most common treatment in healthcare. They are governed by a unique combination of the EU's horizontal objectives and the objectives and policies of national healthcare systems. Notwithstanding this, the pharmaceutical sector constitutes no exception to the application of EU competition rules as regards anticompetitive conduct by companies or the control of mergers and acquisitions.

¹ Following the Lisbon Treaty, a complementary legal basis under Article 168(4)(c) lays down the procedure for adopting EU law that aims to ensure high standards of quality and safety for medicinal products.

Need for cooperation to improve access to medicines

Today, shortages and withdrawals of old medicines pose a risk to patient safety and increase the workload of healthcare staff. Furthermore, patients in the EU still have different levels of access to new medicines due to market failures, high prices and companies' marketing strategies.

Safeguarding access to medicinal products is an example of a challenge requiring measures both at EU level and in the Member States. The Council, the European Parliament and the European Commission, as well as different Presidencies and Member States, have all addressed this challenge via various measures and initiatives.

The Council and the Presidency

During recent years, access to medicines has been on the agenda in a number of formal and informal fora, including different working groups and conferences organised by some of the rotating presidencies of the Council of the European Union. During the Dutch Presidency in 2016, the Council adopted conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States (17 June 2016)². As a follow-up to the 2016 Council conclusions, subsequent presidencies have organised informal meetings of directors of pharmaceutical policy. The latest informal meeting was organised by Finland's Presidency and the Netherlands delegation in Brussels on 10 September 2019 under the title 'Addressing the challenges of the EU pharmaceutical system: what changes are necessary from the perspective of Member States'. The Council Working Party on Pharmaceuticals and Medical Devices deals with the Commission's proposals for legislation in the field. However, it does not have any tasks regarding monitoring or coordination of the implementation of measures identified as necessary to improve access to medicines.

² Council conclusions on strengthening the balance in the pharmaceutical system in the EU and its Member States.

Other EU institutions or bodies

On 2 March 2017, the European Parliament adopted a resolution on options for improving access to medicines³. The Commission and the European Medicines Agency (EMA) have also sought to promote access to medicines with various initiatives, studies and evaluations. Policy discussions to address the challenges of the pharmaceutical system related to the European Union's policies and legislation take place with the Member States in several fora, notably the Pharmaceutical Committee. The European Medicines Agency (EMA)-Heads of Medicines Agencies (HMA) Task Force on Availability has launched a number of soft measures to mitigate the problem of availability and shortages of medicines. The Commission has also published an interpretative paper agreed with Member States on the obligation to supply laid down in the pharmaceutical legislation.

Member States' initiatives

New forms of voluntary cooperation between Member States have emerged during recent years. The Network of Competent Authorities on Pricing and Reimbursement (CAPR) has been meeting for more than ten years. Moreover, recently, various Member States have increased their bilateral and multilateral cooperation, including – inter alia – the Valletta, Beneluxa, FINOSE and Nordic Pharmaceuticals Forum (NLF) initiatives.

Despite the measures described above, a balanced overall outcome leading to improved access to medicines has so far not been achieved. In the view of the Presidency, there is an urgent need to focus on incorporating health objectives into all policies that have relevance for access to medicines, including research, innovation, trade and competition policies, and on efforts to find new ways to strengthen the strategic cooperation between Member States. It is equally important to monitor whether EU measures have the intended impact and to evaluate pharmaceutical policy at EU level and its objectives.

³ European Parliament resolution of 2 March 2017 on EU options for improving access to medicines.

Case study: Access to medicines from the perspective of the four phases of a medicine's lifecycle

The lifecycle of a medicinal product can be divided into four phases (see figure in Appendix):

- 1) Research and development ('R&D'): during this phase incentives often play an important role;
- 2) New medicines: during this phase post-authorisation incentives (such as market protection, data protection and market exclusivity), controlled introduction and achieving equal access are important elements;
- 3) Price competition: during this phase a well-functioning market is crucial; and
- 4) Old medicines: during this phase maintaining medicines on the market and controlling shortages are important objectives.

Phase 1: R&D

In the first phase, ***R&D, incentives play an important role***. Pharmaceutical development is boosted through both national and EU financial instruments and through research-supporting infrastructures. Significant incentives affecting pharmaceutical development and the operating conditions of pharmaceutical companies include intellectual property rights, and tax and trade policy. The European Medicines Agency (EMA) has reformed its practices to respond to objectives set by the Commission by increasing scientific advice and parallel consultations and by introducing accelerated assessment procedures. In particular, the development of medicines for rare diseases is supported by means of scientific advice, through EU-funded research programmes, by market exclusivity, and by waiving marketing authorisation fees. The Commission is in the process of reviewing the incentives for developing orphan and paediatric medicinal products.

Phase 2: New medicines

It is widely recognised that ***controlled introduction*** of medicines is of vital importance to healthcare systems in order to reduce risks associated with new medicinal products. Some new medicines are granted marketing authorisation under accelerated assessment on the basis of early and limited research evidence. In such cases, the efficacy, safety and financial risks of the uptake of new medicines are to a great extent shifted to national healthcare systems. This trend is bound to continue with the evolution of personalised medicine. Therefore, new procedures on managed entry require further development. Real-world evidence (RWE) can be used to support the re-evaluation of the safety and efficacy of medicines, especially in cases of conditional marketing authorisation or managed-entry agreements. Cooperation at EU level is necessary for creating the structures, practices and definitions on scope, quality, validity and consistency of data required for the efficient use of RWE.

However, ***equal access to medicines*** is not always achieved. Pharmaceutical companies place their new products on the market at different times in different Member States, despite having been granted marketing authorisation through the centralised procedure and despite having benefited from European incentives for the development of medicines. Therefore, Member States are in very different positions in terms of entry into market and uptake.

Phase 3: Price competition

Effective ***price competition*** in the pharmaceutical sector reduces medicine prices and facilitates people's access to affordable medicines. Price competition can start if there is a well-functioning market for medicines and a sufficient level of competitive pressure that maintain the conditions for healthy competition. Competition dynamics are affected by certain special characteristics of the pharmaceutical sector, including the structure of supply and demand, national legislative and regulatory frameworks and national healthcare systems.

Phase 4: Old medicines

Maintaining medicines on the market and controlling shortages seems to be one of the most challenging phases in the lifecycle of a medicinal product. While the greatest effects of medicine shortages and uncontrolled market withdrawals are the workload increase for healthcare staff and the rise in costs for the treatment of a disease, shortages can also endanger patient safety.

The increasing concentration outside Europe of the manufacturing and logistics chains and the fragmentation caused by subcontracting chains has been identified as one of the reasons for medicine shortages. The vulnerability of production and logistics chains, in particular of old medicines, puts the availability of these medicines at risk. Moreover, supply-chain-associated risk management measures vary greatly between products at different stages of their lifecycle.

Medicine shortages and uncontrolled market withdrawals have placed different market areas in a differing position with regard to prices. If availability of a specific product cannot be guaranteed, healthcare systems may need to introduce more expensive medicines or less effective alternatives.

In order to manage unexpected and critical shortages of medicines, Member States use different kinds of practices and approaches relating to the introduction of restrictions on parallel export, increased stockpiling and building national plants for manufacturing of medicines. These measures indicate that Member States see insufficient supply of medicines as a threat.

Conclusion and Presidency recommendations

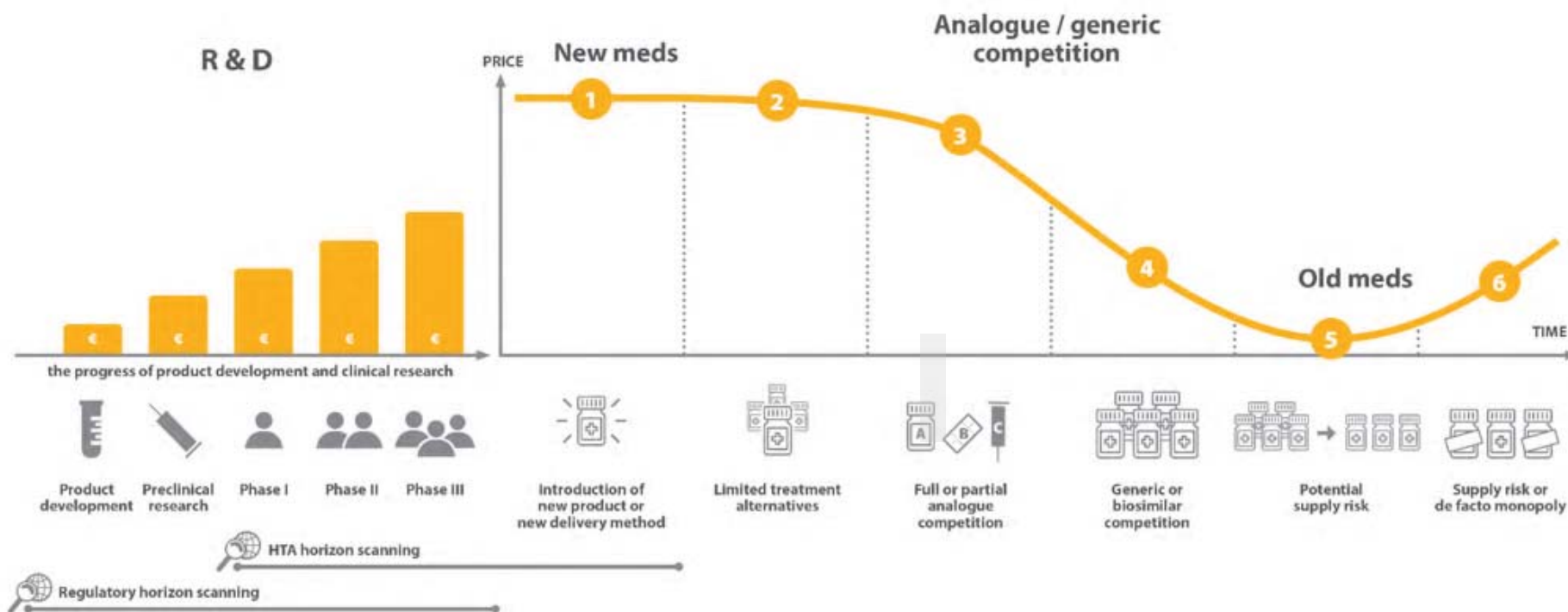
The lifecycle approach allows an analysis of existing measures that contribute to access to medicines as well as the targeting of new measures to those phases where measures already taken seem to be insufficient. Ensuring access requires efficient measures at all phases of the lifecycle of a medicinal product. Mechanisms supporting research and development, controlled introduction, achieving equal access to new medicines, price competition, continuous supply and maintaining old medicines on the market should be sustainable, while taking into account the needs of the national healthcare systems. In this context, it is noted that the management and prevention of shortages and uncontrolled withdrawals of medicines is crucial for the continuity of care.

The Presidency holds the view that implementation of measures identified in the 2016 Council conclusions should continue systematically. In the view of the Presidency, there is a need to further strengthen strategic cooperation among Member States as well as to monitor the impacts of the EU measures and to evaluate pharmaceutical policy at EU level and its objectives.

Against this background, the Council is invited to hold a policy debate on access to medicines based on the following questions:

- 1) What concrete measures could Member States and the Commission take to ensure access to both old and new medicines for national healthcare systems and patients, and to avoid problems caused by shortages?
 - 2) One of the reasons for shortages and supply disruptions is that the medicines' supply chain has become longer, more complex and fragmented as companies have located a large part of production of medicines outside the EU. In order to ensure a reliable supply, is there a need to call for EU legislative measures to require back-up manufacturing capacity, earlier notification of interruptions and stronger measures to ensure continuity of supply? In your view, would this help reduce the risk of supply disruptions and shortages?
 - 3) Strengthened cooperation between Member States and related coordination of activities, such as monitoring, could contribute to mitigating the problems related to shortages of medicines and the sustainability of budgets. How could such cooperation be further strengthened?
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LIFECYCLE OF A MEDICINAL PRODUCT



Picture modified from WHO Access to medicines, vaccines and pharmaceuticals

Figure. Lifecycle of a medicinal product (from WHO 2017).