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NOTE

From: General Secretariat of the Council
To: Council

Subject: The EU pharmaceutical legislation from an industrial and competitiveness perspective
- Information from the Austrian and German delegations

Delegations will find attached an information note from the Austrian and German delegations on “The EU pharmaceutical legislation from an industrial and competitiveness perspective” with a view to the meeting of the Competitiveness Council on 25 September 2023.

The EU pharmaceutical legislation from an industrial and competitiveness perspective
Information from the Austrian and German delegations

Based on the initiative of the Austrian Federal Ministry of Labour and Economic Affairs and the German Ministry for Economic Affairs and Climate Action, a position paper for COMPET Ministers on the necessity of discussing the draft EU pharmaceutical package from the perspective of industrial policy and competitiveness was prepared. The paper will again be circulated ahead of the upcoming Council meeting on the 25th of September 2023, with the aim of support by further Member States.

The initiative calls for a balanced approach of health/social policy and economic/industrial policy in the interest of fostering the competitiveness of related industrial sectors in the EU and strengthening the EU as a reliable location for business, investment and innovation. In order to maintain a globally competitive pharmaceutical industry in Europe, it is even more important to ensure a legal environment, which is attractive for investment and innovation by offering stable and secure legal framework conditions. This will only succeed if all pillars of the EU pharmaceutical package are taken into account.

Therefore, the aims for the Competitiveness Council should be:

1. to discuss the EU pharmaceutical package from the perspective of industrial and competitiveness policy in future Competitiveness Council meetings,
2. ensuring a balanced "health policy - economic policy" approach to negotiations,
3. ensuring a clear, predictable and competitive pharmaceutical regulatory framework.

Position paper by the Competitiveness Ministers from Austria and Germany
about the need to discuss and reflect the EU pharmaceutical package from an
industrial and competitiveness perspective

On 26 April 2023, the European Commission proposed a reform of the **European pharmaceutical legislation** with the aim of meeting the needs of patients across Europe while promoting innovation in the EU. Delivering faster, more equitable access to medicines, avoiding and mitigating shortages as well as ensuring that Europe can be a world leader in medical innovation are goals we share.

At the same time, we are convinced that innovation and pioneering spirit are being pushed-forward by a trustful and globally competitive investment climate. To achieve this, the right framework conditions for an excellent research landscape, securing access to innovative medicines and strengthening the innovative potential of the pharmaceutical industry in Europe are fundamental.

Some of the measures contained in the European Commission's proposal have the potential to create negative effects on the European economic performance, the labour market and, consequently, the financing of our social and healthcare systems. The 'net' impact of policies set out across the proposal, in its current form, puts European competitiveness at risk: Overall, it may weaken the attractiveness for investment in innovation and hampers European science, research and development. In order to truly realise a patient-focused EU life science ambition, it is vital to conduct a comprehensive analysis on the impact of the revised pharmaceutical legislation from a competitiveness and industrial policy perspective.

- 1. Safeguard a clear and predictable pharmaceutical regulatory framework including an adequate and global competitive protection of business secrets (in the form of regulatory data protection/RDP)**

By promoting further innovation, Europe will be better able to cope with future pandemics and provide state-of-the-art medicines. This is at the core benefit of patients across Europe. Framework conditions can foster or hinder the development and introduction of innovative new products. To keep Europe at the forefront of global innovation, the regulatory framework must create globally competitive and predictable conditions that support development and approval of new drugs. The pharmaceutical sector is also an important source of highly skilled jobs and growth in Europe. Protecting and strengthening the European economy - of which the pharmaceutical sector is a significant part - is an important objective. To maintain the strong culture of innovation in Europe, it is essential to ensure adequate legal protection periods, as they are at the heart of the pharmaceutical research and innovation cycle. Tying protection periods to certain conditions that are not globally competitive and not at the discretion of pharmaceutical companies can lead to great uncertainty for long-term and risky investments - this is especially true for SMEs.

What we see is considerable uncertainty with businesses and industry. Therefore, it must be avoided, that the proposal has the potential to jeopardise upcoming investments in Europe as a business location and as an innovation-hub.

Therefore, we call to **inclusively discuss and critically reflect the current regulation regarding RDP (Regulatory Data Protection) including market exclusivity** and, if necessary, elaborating on additional measures to promote innovation.

2. Finding balance of the industrial and health policy perspective

The European Commission's proposal should be equally discussed from a health and industrial policy perspective and should take into account the goals, targets and measures from other relevant EU initiatives. As examples, reference is made to the European Commission's document "Long-term competitiveness of the EU: Looking beyond 2030", the conclusions of the European Council of 23 March 2023 as well as the speech of President of the European Commission Ursula von der Leyen of 30 March 2023 on the future of an "economic de-risking" strategy. In these documents, the health industry is defined as a key industry sector and great importance is attached to the ability to remain a leader in this sector.

In any case, some of the proposed measures of the current draft of the pharmaceutical package do not send a trustworthy signal for future investment decisions to the industry in the EU. It is to be

feared that future investments will be made in other regions. Consequently, in order to ensure that Europe remains a driving force in the global pharmaceutical innovation system, it is essential to conduct the discussion also from a geopolitical economical perspective focussing on competitiveness aspects.

The reform of the pharma legislation is also about strengthening or at least maintaining the long-term competitiveness of the EU. Therefore, we ask the current Spanish Presidency and the following Belgium Presidency to put the EU pharma package on the agenda of upcoming meetings of the COMPET to discuss the proposal's effects on competitiveness and economic growth in the EU. Additionally, a detailed, scientifically-based examination of the EC's proposal with regard to its impact on competitiveness should be carried out.