# Press information

Informal meeting of health ministers on 10 and 11 September 2018

The informal meeting of health ministers on 10 and 11 September 2018 will place a particular emphasis on two priorities defined by the Austrian EU Council Presidency. Based on the priority “A Europe that protects”, regulatory and health policy challenges in connection with the European marketing authorisation will be discussed in the context of safeguarding social systems. At the same time, participants will – on the basis of the Austrian Presidency’s “digitalisation” priority – also examine how EU financing instruments can be used for investments in new digital structures in the healthcare sector.

## Regulatory and policy-related challenges in securing supply of centrally authorised medicines

On the first conference day, participants’ discussions will focus on regulatory and health policy **challenges in connection with the European marketing authorisation**, with contributions from **Beate Hartinger-Klein** (Federal Minister of Labour, Social Affairs, Health and Consumer Protection), **Vytenis Andriukaitis** (Commissioner for Health and Food Safety, European Commission), **Hans Kluge** (WHO) and **Guido Rasi** (Executive Director of the European Medicines Agency).

Other key issues to be addressed in the discussions relate to challenges and possible solutions with respect to access to and availability of innovative medicines. One of the reasons for growing awareness of this problem is the significant increase in expenditure on high-priced medicines in Europe, especially in the hospital sector. The exchange on regulatory challenges in the pharmaceutical sector will build on earlier discussions held under previous presidencies and focuses on regulatory measures within the direct scope of European health policy. In this context, the health ministers will examine current challenges. A particular focus will be placed on examining four fields of action from different perspectives: optimisation of the exchange of information, strengthening of patient benefit, European-wide availability of newly approved drugs and theapproval of drugs with orphan labelling. The exchange of view will especially centre on potential measures aimed at ensuring the long-term and sustainable supply of European patients with such medicines.

Other challenges to be addressed include the exchange of information between regulatory authorities and all affected stakeholders in the health system. A structured exchange of information between regulatory authorities and with the involvement of all stakeholders could make a significant contribution to improving the predictability of public health systems and enable these systems to prepare in good time for innovative and high-priced medical technology. The goal is to both strengthen national systems set up by individual countries and promote the exchange with European activities in this field. Another topic to be dealt with is patient benefit of newly approved medicinal products. Patients’ safety must always be key and thus efficacy is to be evaluated in an ongoing manner, even after approval has been granted. In this respect, the aim of the discussion is to jointly consider what type of proof in the form of studies and data is to be provided during

authorisation. In a number of European Union member states, newly approved drugs are only marketed with a delay, and in others they are not marketed at all. In principle, a central marketing authorisation remains valid if at least one market within the European Economic Area (EEA) is actually supplied. The deliberations in Vienna will focus on proposals for solutions and incentives to ensure that the whole of Europe is provided and supplied with innovative products.

## Orphan drugs for rare diseases

With a view to promoting the development of drugs for the treatment of rare (orphan) diseases, it is possible in Europe to authorise active substances with orphan designation. This possibility was introduced based on the assumption that there is a general lack of research into diseases with small patient populations. Thus the fees for marketing authorisations with orphan designation are lower and the European Medicines Agency provides technical support during the approval process. In addition, orphan drugs enjoy longer market exclusivity through protection against early competition within their respective field of application. This incentive is to be welcomed in principle. The European Union has arranged for a comprehensive evaluation of the respective regulations on orphan designation, also with a view to evaluating the existing criteria. Suggestions for improvements should focus on patient benefit. It is necessary that findings are discussed, implemented and communicated without delay. The criteria for granting orphan designation therefore need to be scrutinised and examined on a regular basis. This, in turn, requires clear regulations on the planned reviews of the eligibility for funding as orphan in order to ensure the pursuit of the social goals addressed by the regulation.

The objective is to jointly formulate concrete approaches to solutions and to sketch out ways in which these can also be implemented quickly. A patient-centred European medicines policy must seek to strike a balance between promotion of innovation and ensuring the financial sustainability of health systems, while providing the best-possible and safest care for patients.

## Investment in digital health

On the second day of the conference, European health ministers will discuss how EU funding instruments can be used for **investments in new digital health structures**. Contributions will be made by **Beate Hartinger-Klein** (Federal Minister of Labour, Social Affairs, Health and Consumer Protection), **Vytenis Andriukaitis** (Commissioner for Health and Food Safety, European Commission), **Roberto Viola** (Director-General for Communication Networks, Content and Technology, European Commission), representatives from the European Parliament, **Hans Kluge** (WHO) and **Volker Amelung** (Hannover Medical School – Institute for Epidemiology, Social Medicine and Health Systems Research).

In their discussions, participants will focus on concrete steps to overcome the undoubtedly still existing barriers to making full use of digital data in the health sector. Even if there are already ways and means of exchanging personal diagnostic data to ensure treatment continuity, or even if health data is made available in medical research registers, Europe is still far away from actually exchanging data across all areas of the health systems. Insufficient use of the potential benefits of digital data exchange is being made in the health sector.

Although public health systems are indeed clearly committed to the goal of exchanging data with a view to optimising quality of care, large parts of the existing digital infrastructure in the health sector – especially the software used by private practice physicians, but also many hospital information systems – are not, or only to a very limited extent, suitable for data exchange outside their respective organisations. As long as such barriers to a truly interoperable infrastructure – regarding, for instance, standards, formats, comparability, reliability or accessibility – have not been overcome, many of the already highlighted objectives for optimising the quality of care or research will ultimately remain unattainable.

This is, however, precisely the key issue: health data is primarily generated at outpatient and hospital healthcare facilities. In line with the overarching goals of the health system, it is ultimately necessary to focus on the many individual "data producers", ensuring they are equipped with a new generation of infrastructure and fit for the age of digital health.

As there is a strong public interest in the exchange of health data, public funding of the digital infrastructure of private and public healthcare facilities must also focus on the conditional promotion of such an infrastructure’s interoperability. The fact of the matter is that this interoperable eco system in the health sector will not be developed without the incentive of public funding.

Therefore, the member states’ health ministers and the Commission are invited to deliver on their repeated political declarations of intent and commitments by agreeing on more concrete measures that will guarantee and implement better use of EU funding to promote the interoperability of digital health infrastructures.

Financial instruments recently proposed by the European Commission, such as the Digital Europe programme, indeed contain a more detailed description of this issue than has been the case in previous documents, but still no proposals for concrete measures to address it. Therefore, it is still necessary to work out the details of a transparent health policy strategy that is well adapted to the specific needs of health service providers and which can then also be jointly defended against other policy areas.

As a working presidency, Austria is committed to contributing to developing concrete proposals for solutions. In this spirit and on the basis of the Council conclusions of December 2017, the health ministers will agree at this informal meeting on taking the next concrete steps:

1. For the development of a digital infrastructure that is interoperable at both European and national level and covers if not all, then the largest possible number of different forms of outpatient and inpatient healthcare service providers, a European-wide politically coordinated and agreed catalogue of requirements, standards and formats is needed. Such a catalogue is not yet available.
2. Based on this catalogue and in collaboration with the relevant Directorates-General of the Commission, the eHealth network that brings together the member states' authorities responsible for eHealth are then to draw up a concrete guideline for European-wide promotion and investment programmes by mid-2019. The aim is to develop a clear focus of the various financing instruments in order to achieve the greatest possible effect in healthcare facilities.
3. In the context of such a framework definition, the priorities are defined by the member states.