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NOTE

From: General Secretariat of the Council

To: Delegations

Subject: Furthering a member state driven voluntary cooperation to support access to medicines

- *Update on follow-up to Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its member states*
- *Information by the Presidency and Exchange of views*

In view of the meeting of the Working Party on Public Health at Senior Level on 3 February 2017, delegations will find attached a note from the Presidency on the above-mentioned subject.

Furthering a Member State driven voluntary cooperation to support access to medicines

Introduction

In June 2016, the Council of the European Union adopted the *Council Conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States*¹.

The need for a bottom-up approach characterised by the adoption of voluntary measures was also highlighted in the aforementioned Council Conclusions². To that end, the Council invited Member States to further develop voluntary cooperation while keeping in mind and respecting Member States' competences and exploring possible areas in which such voluntary cooperation can contribute to increased affordability and thus better access to medicinal products.³

Member States were invited to identify a set of mutually experienced concerns and challenges that could be considered and/or modified by the future Presidencies in the period 2017–2020, with full respect for Member States' and EU level competences⁴.

Member States and the Commission have been invited to foster enhanced cooperation with respect to HTA beyond 2020⁵ and to review current fora and technical bodies in order to assess their relevance, roles and mandates, thereby avoiding duplication and fragmentation of work, and to provide better insight into ongoing discussions within those fora⁶.

¹ Council of the EU. *Council Conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States*, June 2016.
<http://www.consilium.europa.eu/en/press/press-releases/2016/06/17-epsco-conclusions-balance-pharmaceutical-system/>

² Ibid

³ Paragraph 33

⁴ Paragraph 37

⁵ Paragraph 40

⁶ Paragraph 42

Several cooperation activities in various areas have been organised and supported through the EU Public Health Programme.

In the meantime, the European Commission launched a public consultation in October 2016 on strengthening EU cooperation on Health Technology Assessment⁷. This consultation exercise ended on 20 January 2017. In addition, an impact analysis of policy options for strengthened EU cooperation on HTA is also being conducted^{8,9}.

The Commission has also initiated an analysis of the impact of supplementary protection certificates and pharmaceutical incentives and rewards on innovation, availability and accessibility of medicinal products in the EU¹⁰. Details of the methodology of this analysis will be presented to the Member States during the meeting of the Working Party on Pharmaceuticals and Medical Devices to be held on 16 February 2017.

Potential areas for voluntary Structured Cooperation

Below are some potential areas where voluntary structured cooperation between Member States could be deepened:

Joint horizon scanning

There are currently a number of horizon scanning initiatives, such as EuroScan and UKMi Horizon Scanning. This is a technical area where there appears to be scope for joint efforts to produce a single 'joint horizon scanning' effort in order to optimise the exercise and reduce duplication of resources.

Information-sharing

There appears to be scope for Member States to encourage the proactive exchange of information. While technical information seems to be more available and better communicated, greater transparency and trust are required with regard to pricing aspects.

⁷ https://ec.europa.eu/health/technology_assessment/consultations/cooperation_hta_en

⁸ https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/ev_20161107_sr_en.pdf

⁹ http://ec.europa.eu/health/sites/health/files/technology_assessment/docs/ev_20160922_mi_en.pdf

¹⁰ <http://data.consilium.europa.eu/doc/document/ST-14568-2016-INIT/en/pdf>

Voluntary price negotiations

In its Conclusions, the Council encourages the exploration of possible strategies on voluntary joint price negotiations in coalitions of Member States that have expressed an interest in this approach. However, in practice there is still a lack of information on how successful current initiatives for collaboration have been in this area. Implementing this recommendation may be quite challenging, particularly as it also requires direct involvement of other stakeholders.

Collaborative approaches addressing unavailability of medicinal products and situations of market failure

Parallel exports were extensively covered during the Slovak Presidency. Other reasons for unavailability of medicines and market failure need to be tackled. At this point the possible implications need to be considered of implementing the legislation on Falsified Medicines and using the information emanating from it.

Tangible initiatives need to be consolidated and implemented to address all the issues raised by unavailability of medicinal products and situations of market failure.

HTA cooperation

HTA was set as a political priority in 2004 and this led to the introduction of the European Network for Health Technology Assessment (EUnetHTA) in 2007. The Commission is supporting this initiative through Public Health Programme funding from 2009 up until 2020. In 2016, the Council expressed a wish to find a more permanent way of continuing this work beyond 2020 when the current funding runs out.

Member States are a major stakeholder in the HTA process and may come together and agree on a model for collaboration on HTA which takes into account the maximisation of benefits amongst participating Member States. Unless the current issues which dissuade Member States from deepening collaboration are openly addressed, the future framework for HTA could be irreversibly affected so that Member States risk ending up with a model that does not meet their needs. Given the diversity of health systems, the future model needs to incorporate some elements of flexibility for the participating Member States to find a consensus on the way forward.

Disinvestment as a means of tackling healthcare waste

Disinvestment is currently a difficult decision to implement at Member State level. Collaboration between Member States in monitoring treatment outcomes for new medicines and jointly communicated decisions on disinvestment may strengthen the position for such decisions to actually be implemented.

Examples of European experiences of cross-border collaboration

Over the past months several initiatives have been pursued by groups of Member States, signalling a commonly felt need to address the situation jointly.

- **BENELUXA** – collaboration on procurement of pharmaceuticals for rare diseases.

This initiative to jointly negotiate prices for medicines for rare diseases was initiated by Belgium and the Netherlands (April 2015), later joined by Luxembourg (September 2015) and Austria (June 2016). This group of countries, known as 'BeNeLuxA', intends to collaborate more closely across a range of areas: health technology assessment; horizon scanning; exchange of information on pharmaceutical markets; prices and disease-specific cross-border registries; and pricing and reimbursement, including joint negotiation.

- **Nordic Pharmaceuticals Forum**

This was started in June 2015, and involves Denmark, Iceland, Norway and Sweden. Areas covered by this collaboration include: horizon scanning and information-sharing on prices and markets.

- **Romanian and Bulgarian Initiative**

This collaboration between Romania and Bulgaria was initiated in June 2015. Areas covered include: joint negotiation in purchasing and cross-border exchange of medicines in short supply.

- **Baltic Partnership Agreement**

Collaboration under the Baltic Partnership Agreement, involving Latvia, Lithuania and Estonia, started at the end of 2014. The first joint procurement effort focused on vaccines. An important component of the Partnership Agreement is the lending of centrally procured medicines, which enables countries to prevent and alleviate shortages of medicines.

What needs to be considered and followed in terms of the Council Conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States?

it is deemed opportune for the Working Party on Public Health at Senior Level to maintain oversight on the issues described in the Council Conclusions and to provide direction on pursuing voluntary cooperation in a sustainable and practical manner. A better understanding of the pharmaceutical framework model could lead to better prioritisation of processes affecting access to medicines. The supportive factors and barriers impacting on cooperation initiatives should thus be explored in order to propose tools, models and methodologies which can potentially be used for structured voluntary cooperation. There must therefore be follow-up to the analysis being carried out by the Commission on the impact of EU legislative instruments and related incentives. Options for voluntary collaboration should ideally prioritise small populations – which may be geographically defined or characterised on the basis of Rare Diseases.

In the light of the aforementioned considerations, delegations are invited to consider the following questions:

1. What are the important contextual factors at European and global level that are driving Member States to explore models of voluntary cooperation for access to affordable medicines?
2. What are the factors that dissuade voluntary cooperation between Member States?
3. Do you see any other potential areas for Voluntary Structured Cooperation other than those listed above?
4. What are the next steps that need to be taken to support sustainable voluntary cooperation initiatives in order to better enable access to medicines?