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WORKING PAPER

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WORKING DOCUMENT

From: General Secretariat of the Council
To: Working Party on Pharmaceuticals and Medical Devices (HTA)
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ADD 2 + ADD3 + COR 1

Subject: Working Party on Pharmaceuticals and Medical devices on 28 January 2019
- Flash from the Presidency

Delegations will find enclosed the Presidency Flash for the meeting of the Working Party on Pharmaceuticals and Medical devices that will take place on 28 January 2019 (CM 1283/19).

FLASH

Working party on Pharmaceuticals and Medical devices

28 January 2019, LEX 2, 10.00
(CM 1283/19)

Dear Colleagues,

First, we would like to thank you for your input during the first Working Party under the Romanian Presidency, as well as for all your written contributions.

For the second Working Party on HTA we intend to cover Article 18 on Emerging Health Technologies as well as Chapter IV (Support Framework) in the form of Articles 24 to 28.

We will start at 10:00 and hope to finish at approximately 17:30.

For **Article 18, the identification of emerging health technologies**, we will first have a presentation concerning the current horizon scanning activities in BeNeLuxA, as one of the examples of how such a task could be fulfilled. The Presidency sees the main purpose of this identification in helping to plan for the next Annual Work Programme(s), but is interested in hearing other views you might have.

On **Article 24, Union funding** we looked carefully at comments you have made so far and noted that some delegations have proposed fees to allow for better financing the system, while others feel that fees would jeopardise independence. We would like to hear the views of everyone.

The Presidency sees **Article 25** as specifying tasks of the Commission in its role as the secretariat of the Coordination Group. We would like to discuss what changes are necessary in this sense.

On **Article 26, the Stakeholder Network**, we would like to clarify what kind of stakeholders should be involved and how, and what is the contribution of such a network to the work of the Coordination Group. The Presidency is currently exploring the possibility of a presentation by EUnetHTA. Once these two aspects elucidated, we can discuss the selection procedure and possible criteria, while balancing the need for transparency and stakeholder engagement with the need to assure efficiency and timely delivery for the Coordination Group work.

For **Article 27, the IT Platform**, we intend to discuss the different components needed for supporting the work of the Coordination group and the level of access. It will be important to clarify the level of detail needed in the Regulation.

For **Article 28**, the Presidency intends, before our discussion, to invite the Commission to explain the differences between this report and the report in Article 29 and their aims.

In case there are any points that you would like to raise under AOB, we kindly invite you to inform the Presidency (presedintie.sanatate@ms.ro) and the Council Secretariat in advance (secretariat.pharmaceuticals@consilium.europa.eu).

The Romanian Presidency health team,

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