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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)
N° Cion doc.: 5844/18 PHARM 6 SAN 49 MI 61 COMPET 53 IA 43 CODEC 133 + ADD 1 +
ADD 2 + ADD3 + COR 1

Subject: Working Party on Pharmaceuticals and Medical devices on 15 February 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 15 February 2019 (CM 1541/19).

FLASH

Working party on Pharmaceuticals and Medical devices

15 February 2019, LEX 1, 10.00
(CM 1541/19)

Dear Colleagues,

We are rapidly approaching our third meeting on HTA, so we wish to give you further information on the plans we announced in the last meeting.

We will start at 10:00¹ and hope to finish at approximately 17:30.

First, we intend to tackle the topics that we identified in the previous Flash and which we had no time to discuss at the last Working Party meeting. So, we will continue the discussion on Article 24 (Union funding) and talk about Article 25 (Commission role) as well as Article 28 (report). For those articles we intend to proceed as set out in our previous Flash (WK 888/2019).

Then, we intend to turn to a Presidency paper that you will receive shortly and in which we set out the thoughts we have on the redraft of Articles 12 to 17. The Presidency has thoroughly considered the written comments received as well as those made during the first Working Party - and would like to thank you very much for those. We believe we can propose a way forward for most parts of those Articles. However, for some other parts, we feel that a discussion is still needed.

Based on the outcome of the discussion on the above mentioned Presidency paper, we intend to come up with a revised text for Articles 12 and 17 that we will examine on 25 February. On that day we also propose to tackle conflict of interests and transparency issues.

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 (life.pharmaceuticals@consilium.europa.eu).

The Romanian Presidency health team,

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¹ Some delegations have approached the Presidency about a seminar on Medical Devices and Brexit starting 11:30. The Presidency is checking the possibility to start 9:30 and break for lunch in time for this seminar.