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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° prev. 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 8 April 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 8 April 2019 (CM 2424/19)

FLASH

Working Party on Pharmaceuticals and Medical devices

8 April 2019, LEX 1, 10.00
(CM XXX/19)

Dear Colleagues,

For this meeting of our Working Party on Pharmaceuticals and Medical Devices we intend to start 10:00 and to finish at 18:00. Besides HTA, at the request of some of you, you will receive information from the Commission (DG GROW) on the implementation of the medical devices and *in-vitro* medical devices regulations.

First, we will discuss the Presidency proposals for Articles 24 to 28 in Chapter IV (Support Framework), which you can find in WK 3755/2019.

A second point of discussion is the topic of conflict of interest and transparency. You can find a Presidency text focusing on general principles on WK 3993/2019 and a text of the Netherlands delegation on safeguards for quality, transparency and impartiality in WK 4090/2019. The Presidency intends to discuss on general principles first and will then focus on other points that may need to be included in the Regulation. The Presidency sees two dedicated articles: one on transparency and impartiality and one on quality assurance. For the conflict of interest article, we see two major points for our first discussion:

- what needs to be included in the regulation, what in implementing acts and what in guidance;
- who should be responsible for checking conflicts of interest.

Last, if time allows, we propose to start discussing on the tasks of the Coordination Group and sub-groups, as they should be laid down in the text.

As already mentioned, we will receive some brief information from DG GROW on the implementation of the medical devices and in-vitro medical devices regulations, probably right after lunch.

At our Working Party on 13 May we expect to discuss the opinion of the Legal Service on Article 7. In addition, we intend to continue the discussion on the items mentioned above.

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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