



Council of the European Union  
General Secretariat

Brussels, 03 May 2019

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**WORKING PAPER**

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**WORKING DOCUMENT**

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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 13 May 2019 - Flash from the Presidency

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Delegations will find enclosed the Presidency Flash for the meeting of the Working Party on Pharmaceuticals and Medical devices that will take place on 13 May 2019 (CM 2710/19).

## FLASH

# Working Party on Pharmaceuticals and Medical devices

13 May 2019, JL 20.1, 10.00  
(CM 2710/19)

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.

First, we will invite the Council Legal Service to present its opinion (doc. 8637/19) in response to questions raised by the Working Party in relation to Article 7, that will be followed by an opportunity for delegations to ask relevant questions.

Based on our discussion on Chapter IV, the Presidency incorporated comments from the last meeting in a revised version which you will soon receive. When discussing the revised text we will focus on the changes proposed by the Presidency.

Thirdly, the Presidency has further developed the text on Articles 12 to 18. We intend to release this document during the next days and would like to have a general feed-back on the changes.

The Presidency has thoroughly revised the text of the first draft of an Article on conflicts of interest, based on our discussion at the last meeting and has also looked into the Netherlands' paper to extract main points for a quality assurance article. These two new articles will be released soon.

At our next and last Working Party on 4 June we propose to discuss the structure and tasks of the Coordination Group and sub-groups, based on a revised paper for which the Presidency intends to involve the incoming Finnish Presidency.

In preparation of the 14 June Health EPSCO Council, we wish to inform you already now that, as regards HTA, we intend to present a Progress report under AOB, which will only cover the part of the proposal discussed during our Presidency.

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](mailto:presedintie.sanatate@ms.ro)) and the Council Secretariat in advance ([life.pharmaceuticals@consilium.europa.eu](mailto:life.pharmaceuticals@consilium.europa.eu)).

*The Romanian Presidency health team,*

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