



Council of the European Union
General Secretariat

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WK 11334/2019 REV 1

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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)

Subject: Working Party on Pharmaceuticals and Medical devices on 13 and
14 November 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 13-14 November 2019 (CM 4656/19).

In this revised Flash the subject line correctly refers to the dates for the meeting, 13 and 14 November 2019. There are no other changes to the original Flash.

6.11.2019

FI Presidency Flash: WORKING PARTY ON PHARMACEUTICALS & MEDICAL DEVICES

Wednesday, 13 November 2019, 15.00-18.30, JL 35.6

Thursday, 14 November 2019, 10.00-18.00, JL 35.6

Dear Colleagues,

The next meeting of the Working Party on Pharmaceuticals and Medical Devices will be a one and a half-day meeting on 13 and 14 November (CM 4656/19).

On Wednesday, 13 November, we shall start at 15.00 and continue until 18.30. Immediately afterwards we warmly welcome you to join us for drinks at Wine bar Tiago's (Rue Archimède 7).

We shall continue on Thursday, 14 November from 10.00 until 18.00. Please note that a family photo will be taken at 13.15 in JL floor 50.

Our intention is to continue discussions on Articles 5-8 and also to have a discussion on JCA of medical devices. Two separate Presidency papers, WK 12510/2019 for medical devices and WK 11333/2019 for the Presidency text for Articles 5-8, are being prepared for these discussions, and we hope to be able to distribute them to you at the latest on 8 November.

Before the meeting, you will also receive a document with all corrections to Regulation (EU) 745/2017 on medical devices and to Regulation (EU) 746/2017 on *in vitro* diagnostic medical devices that will be included in the forthcoming corrigenda. During the meeting, it will be verified that all delegations can agree that those corrections should be included in the corrigenda.

In case there are any other points that you would like to raise under AOB, we kindly invite you to inform the Presidency [REDACTED] and the Council Secretariat in advance [REDACTED].

The Finnish Presidency Health Team

[REDACTED]



Steps to HTA

Photo: [REDACTED]

CONTACTS:

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