



Council of the European Union  
General Secretariat

Brussels, 12 May 2021

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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 (General)  
Working Party on Pharmaceuticals and Medical Devices (HTA)

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**Subject:** Informal videoconference of the members of the Working Party on Pharmaceuticals and Medical Devices on 18 May 2021  
- Flash from the Presidency

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Delegations will find enclosed the Presidency Flash for the informal videoconference of the members of the Working Party on Pharmaceuticals and Medical Devices scheduled for 18 May 2021. The draft agenda is set out in CM 3156/21.



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## Presidency Flash

### Virtual Meeting of the Working Party on Pharmaceuticals and Medical Devices

Tuesday, 18 May 2021

10:00 am - 1:00 pm / 2:30 pm - 6:00 pm

Brussels, 12 May 2021

Dear Colleagues,

We are delighted to invite you to the twenty-fifth meeting of the members of the Working Party on Pharmaceuticals and Medical Devices under the Portuguese Presidency. This meeting will be dedicated to the draft Council Conclusions on Access to Medicines and Medical Devices and to the proposal on the European Medicines Agency (EMA). It will be held in a virtual format from 10:00 am to 6:00 pm. The agenda has been circulated and is available in the Delegates Portal as document CM 3156/21.

Following the discussions at last meetings, the Presidency has prepared a revised compromise text on the EMA Proposal (8643/21), taking also in consideration the written comments received from delegations. We will start this meeting by highlighting the changes made to the text and then invite the delegations to present their comments on the text, focusing on the main concerns of Member States.

Afterwards, we will invite the delegations to discuss the draft Council Conclusions on Access to medicines and medical devices for a Stronger and Resilient EU (8644/21), after a short presentation from the Presidency.

Lastly, we will also have a short update by the Presidency on the ongoing interinstitutional negotiations on the Health Technology Assessment file.

We would welcome very much any **written comments** you may have on both the EMA revised Presidency compromise text and the draft Council Conclusions by **21 May COB**, focusing on the main concerns of Member States.

In case you have any point that you wish to raise under AOB, please do not hesitate to contact the Presidency and the Council Secretariat.



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**Regulation on serious cross-border threats to health and repealing Decision No 1082/2013/EU**

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**Regulation amending Regulation (EC) nº 851/2004 establishing a European Centre for Disease Prevention and Control**

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**Regulation on Health Technology Assessment and regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices**

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- ✧ With the Portuguese Presidency bringing forward the motto "Time to Deliver", alongside the stress and workload caused by the COVID-19 pandemic, the Portuguese Health Team decided to present you with some sights of our country during each Working Party. Hopefully it can contribute to cheer you up and, who knows, maybe even provide you with some inspiration for the next and well deserved vacation period.

### Serra da Estrela



**Historical Facts:** In summer or winter, mainland Portugal's highest mountain is the perfect scenery for a few relaxing days in contact with nature. At 1,993 metres at its highest point, Serra da Estrela is an area of rare landscape beauty, with striking mountain drops, where you can have a deep experience of the silence of the heights. This natural park is excellent for trekking, horse-riding or mountain biking, boasting some 375km of marked trails. Serra da Estrela also earmarks the mountain stage of the 'Tour de Portugal', luring thousands of cycling enthusiasts.



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