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WORKING DOCUMENT

From: General Secretariat of the Council
To: Working Party on Pharmaceuticals and Medical Devices (HTA)

Subject: Informal videoconference of the members of the Working Party on Pharmaceuticals and Medical Devices on 11 June 2021
- Flash from the Presidency

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 11 June 2021. The draft agenda is set out in CM 3456/21.



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Presidency Flash

Virtual Meeting of the Working Party on Pharmaceuticals and Medical Devices

Friday, 11 June 2021

10:00 am to 1:00 pm

Brussels, 10 June 2021

Dear Colleagues,

We are delighted to invite you to the thirtieth meeting of the members of the Working Party on Pharmaceuticals and Medical Devices under the Portuguese Presidency. This meeting will be dedicated to the Health Technology Assessment (HTA) Regulation. It will be held in a virtual format from 10:00 am to 1:00 pm. The agenda has been circulated and is available in the Delegates Portal as document CM 3456/21.

The 4 Column Table, where you can see, in the 4th column, the text tentatively agreed with the European Parliament on several items. As Presidency, we believe that this text is in line with the Council's mandate, even though on some items we had to adapt the Council's text slightly to address some concerns from the EP, namely on transparency, on stakeholders' involvement and on preservation of the added value of HTA cooperation at Union level.

During the last political trilogue, we could also agree on a possible way forward on two political issues:

On Article 6d, the EP agreed with the Council's approach to endorse the JCA reports but raised concerns on the risk of having a JCA report with too many diverging opinions and asked for safeguards on this issue. A possible compromise that could be acceptable to the EP would be to explicitly state in the text that the scientific grounds of the diverging opinions would have to be provided. We deem that this adaptation is acceptable and within the boundaries of the agreed mandate.

On article 9, the Parliament raised concerns on the risk of duplication of assessments at MS level. In order to address this concern, as a possible compromise, it was agreed to introduce



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a requirement for Member States that intend to carry out national updates on a health technology subject to a JCA to notify the Coordination Group of their intention. Here again we believe that this adaptation would be acceptable and ultimately of benefit to all Member States.

On two other political issues, no agreement could be reached.

On article 5, the EP agreed with the Council's approach on a stepwise approach, and showed readiness to drop the transitional period (which they kept in their mandate), but raised two concerns related to the assessment of medicines: the excessive length to reach full scope and the date to initiate JCA on orphan medicines. After being informed about the reasons for this 8 years' period to reach full scope, in particular the need to guarantee manageable workload, the EP proposed to merge the first two steps of the stepwise approach in order to anticipate the JCA on orphan medicines. We could not agree to this proposal. However, it remains clear to us that something will need to be given on Article 5 to the EP.

On article 8, the main concern of EP is to guarantee that the regulation is meaningful and that joint work is not simply ignored. EP asked for safeguards in this regard, including a justification from the MS which would choose to completely disregard the JCA reports. This is also an issue that will need further consideration at political level. Here again, we believe that we will need to consider a possible move.

Finally, there is another political issue that we didn't discuss so far in the absence of Council's position, i.e. the voting mechanism in the Coordination Group. We will need to be ready to engage a discussion on this point at the next political trilogue too.

We trust you will share our understanding of the state of play on the tentatively agreed text in the 4 column document and we will also invite Member States to share their views on the above political issues, in order to facilitate discussion at Coreper and hopefully reach a common understanding with a view to the final negotiation with the EP on this regulation.

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





☀ **Contacts of the Portuguese Health Team at the Permanent Representation:**

██████████ - e-mail: ██████@reper-portugal.be ; Tel: ██████████ ; Mob: ██████████

██████████ - e-mail: ██████@reper-portugal.be ; ██████████ ; Mob: ██████████

██████████ - e-mail: ██████@reper-portugal.be ; Tel: ██████████ Mob: ██████████

☀ **Contacts of the Portuguese Health Team in Lisbon:**

General Coordination

██████████ - Director of Coordination of International Relations/Directorate-General of Health - e-mail: ██████@dgs.min-saude.pt ; Tel: ██████████ ; Mob ██████████

██████████ – Coordinator of European Affairs at the Directorate of Coordination of International Relations/Directorate-General of Health – e-mail: ██████@dgs.min-saude.pt; Tel: ██████████ ; Mob: ██████████

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

██████████ – Deputy Director-General of Health/Directorate-General of Health - e-mail: ██████@dgs.min-saude.pt ; Tel: ██████████ ; Mob: ██████████

██████████ - Public Health Emergencies Operations Centre, Directorate-General of Health - e-mail: ██████@dgs.min-saude.pt, Tel: ██████████ Mob: ██████████

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

██████████ - Member of the Executive Board at National Institute of Health Doutor Ricardo Jorge - e-mail: ██████@insa.min-saude.pt; Tel: ██████████ ; Mob: ██████████

██████████ - Coordinator of the Department of Epidemiology at National Institute of Health Doutor Ricardo Jorge - e-mail: ██████@insa.min-saude.pt; Tel: ██████████ ; Mob: ██████████

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

██████████ - President of the National Authority for Medicines and Health Products - e-mail: ██████@infarmed.pt ; Tel: ██████████ ; Mob: ██████████

██████████ - Head of Office for International Affairs and Development at National Authority for Medicines and Health Products - e-mail: ██████@infarmed.pt; Tel: ██████████ ; Mob: ██████████





- ✦ 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.

Azenhas do Mar



Historical Facts: Azenhas do Mar is one of the most beautiful pearls of the Portuguese coast, and an indispensable stop on any tour of Portugal. Literally embedded in the coastal cliffs, this small coastal town, looks like a village out of a fairy tale. Besides the beautiful scenery, the visitor can also walk along the cliffs and wander through the narrow streets of the village and appreciate the passionate little houses, adorned with tiles, enclosed in the coastal cliffs. The first water mills that gave this town its name ('Azenhas' which can be translated to 'mills') date back to the Arab occupation period.

