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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés) Pharmaceutical package
Subject:	Pharma package - Maltese reply to the Presidency questionnaire on incentives

Delegations will find in annex a reply from the Maltese delegation to the Presidency questionnaire on incentives.

MALTA

	Questions	MS Response
	Section 1: Nature of the incentives	
1	Do you agree with the proposed maximum duration of the protection period?	Yes.
	Section 2: Different proposed regulatory incentives	
	Market launch" incentive (Art. 81 (2), 1st subparagraph, point (a) and 82 Dir.)	
2.a	Do you agree with the conditions for this incentive (predictability for different actors involved)?	The conditions would need to be clarified, but in principle we can agree. The current system is unpredictable for the Member States and this issue must be addressed. The Commission proposal is an effective way to address.
2.b	Is the proposed reward (24 additional months of RDP) proportionate? If not, should it be longer or shorter?	Considering the reaction of industry, the 24-month period seems to be an effective incentive.
	"Unmet Medical Need" incentive (Art. 81 (2), 1st subparagraph, point (b) and 83 Dir.)	
3.a	Do you agree with the conditions for this incentive?	These would need to be clarified further. Consultation process involving HTA and P&R stakeholders is highly supported.
3.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	Yes
	"Comparative clinical trials" incentive (Art. 81 (2), 1st subparagraph, point (c) Dir.)	
4.a.	Do you agree with the conditions for this incentive?	Yes. In general, ideally this is mandatory especially if suitable alternatives are available (randomized RCTs are gold standard). It is acknowledged that there are some exceptions such in the case of rare diseases. Otherwise, it needs to be ensured that HTA evidence needs are addressed to support the EU HTA regulation. Again, any consultation with HTA and P&R stakeholders is supported.
4.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	Yes
	"Additional therapeutic indication" incentive (Art. 81 (2), 1st subparagraph, point (d) Dir.	
5.a	Do you agree with the conditions for this incentive?	Yes
5.b	Is the proposed reward (12 additional months of RDP) proportionate? If not, should it be longer or shorter?	Yes.
	Incentive for repurposed medicinal products (Art. 84 Dir.)	
6.a	Do you agree with the conditions for this incentive?	Yes

6.b	Is the proposed reward (4 years of RDP) proportionate? Are the efforts adequately compensated?	Yes