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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)
N° Cion doc.:	5844/18+ADD1+ADD2+ADD3
Subject:	Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU

The next meeting to discuss the Commission proposal for a Regulation on Health Technology Assessment is scheduled for 17 April 2018. At that meeting, the Presidency plans to hold an in-depth discussion on the Impact Assessment carried out by the Commission. In order to better prepare the discussion, the Presidency kindly invites delegations to provide written comments by 26 March 2018 to the Presidency (██████████@bg-permrep.eu) and the Council Secretariat (secretariat.pharmaceuticals@consilium.europa.eu). Delegations that have a national impact assessment relevant to this proposal are invited to inform the Presidency and the Secretariat and are welcome to present it at the meeting.

In order to help delegations prepare their comments and structure the discussion, an indicative checklist is enclosed. It is taken from the current Indicative guidance on Impact Assessment for Working Party chairs (doc. 9790/16).

**Examination of Commission IAs in the Council
in the context of the consideration of Commission proposals**

Title of proposal	
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on health technology assessment and amending Directive 2011/24/EU	
Lead DG	DGB
1. <u>Context of the IA</u>	
<p>a) Is the IA carried out at the initiative of the Commission, the Council, or the European Parliament? <input type="checkbox"/> Commission <input type="checkbox"/> Council <input type="checkbox"/> Parliament</p> <p>b) Is the policy context explained clearly? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Partly Comments:</p> <p>c) Is the legal basis of the initiative clear and appropriate? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Partly Comments:</p>	

2. Problem definition

a) **Are the existence, scale and consequences of the problem clearly demonstrated?**

Yes No Partly

Comments:

b) **Is the analysis of the problem supported by evidence, including comments and studies submitted by Member States or stakeholders during consultations?**

Yes No Partly

Comments:

c) **Is any gap in evidence acknowledged?**

Yes No Partly

Comments:

3. Methodology

Is an appropriate methodology applied? Are the methodological choices, limitations and uncertainties clearly set out?

Yes No Partly

Comments:

4. Policy objectives

a) **Does the IA set out clear policy objectives, including general aims and more specific/operational objectives?**

Yes No Partly

Comments:

b) **Do the policy objectives correspond to the identified problems?**

Yes No Partly

Comments:

c) **Are the policy objectives consistent with the broad EU policy strategies and the Strategic Agenda?**

Yes No Partly

Comments:

d) **Are the objectives linked to measurable monitoring indicators?**

Yes No Partly

Comments:

5. Subsidiarity & Proportionality

a) **Is the Union's competence clearly established?**

Yes No Partly

Comments:

b) **Does the IA analyse whether the proposed action is consistent with the principle of subsidiarity, and are necessity and added value of EU action clearly demonstrated?**

Yes No Partly

Comments:

c) **Does the IA analyse whether the proposed action is consistent with the principle of proportionality?**

Yes No Partly

Comments:

d) **Does the IA take into account action already taken or planned at EU or MS level?**

Yes No Partly

Comments:

6. Policy Options

**a) Which of the following options does the IA identify to meet the objectives?
(more than one answer is possible)**

- No EU action Policy alternatives
 Alternatives to regulation Further harmonisation

Comments:

b) Are the most affected public/stakeholders identified?

- Yes No Partly

Comments:

c) Does the IA contain elements on how public and stakeholders consultations informed the policy options ?

- Yes No Partly

Comments:

d) Where relevant, are there reasons given for discarding options that were favoured during public and stakeholders consultations?

- Yes No Partly

Comments:

7. Analysis of impacts

a) Are the criteria used to determine the impact of the different policy options transparent?

Yes No Partly

Comments:

b) Are the impacts of the different policy options set out in a comparable format?

Yes No Partly

Comments:

c) Where appropriate, are both the short and long-term costs and benefits of the different policy options taken into consideration?

Yes No Partly

Comments:

d) Are impacts on affected public and stakeholders clearly analysed, for each policy option, in particular for the selected option?

Yes No Partly

Comments:

8. <u>Specific aspects included in the IA</u>	
Where applicable, indicate whether the impact has been sufficiently assessed, both in qualitative and quantified terms, and whether the data and evidence used were appropriate.	
a) Economic impacts	
Impacts on competition	
Sufficiently assessed	<input type="checkbox"/> Yes <input type="checkbox"/> No
Based on appropriate data/evidence	<input type="checkbox"/> Yes <input type="checkbox"/> No
If not, please elaborate:	
Impacts on consumers	
Sufficiently assessed	<input type="checkbox"/> Yes <input type="checkbox"/> No
Based on appropriate data/evidence	<input type="checkbox"/> Yes <input type="checkbox"/> No
If not, please elaborate:	
Impacts on competitiveness	
Sufficiently assessed	<input type="checkbox"/> Yes <input type="checkbox"/> No
Based on appropriate data/evidence	<input type="checkbox"/> Yes <input type="checkbox"/> No
If not, please elaborate:	
Impacts on Small and Medium Enterprises, including micro-enterprises¹	
Sufficiently assessed	<input type="checkbox"/> Yes <input type="checkbox"/> No
Based on appropriate data/evidence	<input type="checkbox"/> Yes <input type="checkbox"/> No
If not, please elaborate:	

¹ Impact assessments should assess SME impacts, and should also analyse the case for allowing (a) exemptions for micro-enterprises with <10 employees and <€2 mio turnover or balance sheet, and (b) lighter regimes for SMEs. See http://ec.europa.eu/governance/impact/key_docs/docs/meg_guidelines.pdf.

Administrative burdens and compliance costs, especially for businesses	
Sufficiently assessed	<input type="checkbox"/> Yes <input type="checkbox"/> No
Based on appropriate data/evidence	<input type="checkbox"/> Yes <input type="checkbox"/> No
If not, please elaborate:	
Digital aspects (including on the development of the Digital Single Market)	
Sufficiently assessed	<input type="checkbox"/> Yes <input type="checkbox"/> No
Based on appropriate data/evidence	<input type="checkbox"/> Yes <input type="checkbox"/> No
If not, please elaborate:	
Futureproofing (degree to which proposal is future proof and innovation-friendly?)	
Sufficiently assessed	<input type="checkbox"/> Yes <input type="checkbox"/> No
Based on appropriate data/evidence	<input type="checkbox"/> Yes <input type="checkbox"/> No
If not, please elaborate:	
b) <u>Social impacts</u>²	
Sufficiently assessed	<input type="checkbox"/> Yes <input type="checkbox"/> No
Based on appropriate data/evidence	<input type="checkbox"/> Yes <input type="checkbox"/> No
If not, please elaborate:	
c) <u>Environmental impacts</u>³	
Sufficiently assessed	<input type="checkbox"/> Yes <input type="checkbox"/> No
Based on appropriate data/evidence	<input type="checkbox"/> Yes <input type="checkbox"/> No
If not, please elaborate:	

² e.g. impacts on employment and labour markets, social inclusion and protection of particular groups, public health and safety, etc.

See also Guidance for assessing Social Impacts within the Commission Impact Assessment system

(http://ec.europa.eu/smart-regulation/impact/key_docs/docs/guidance_for_assessing_social_impacts.pdf)

³ e.g. impacts on climate, air and water quality, use of the renewable or non-renewable resources, the likelihood or scale of environmental risks, use of energy etc.

d) Impacts on individual Member States, regional or local authorities (territorial impacts)	
Sufficiently assessed	<input type="checkbox"/> Yes <input type="checkbox"/> No
Based on appropriate data/evidence	<input type="checkbox"/> Yes <input type="checkbox"/> No
If not, please elaborate:	
9. <u>Opinion of the Regulatory Scrutiny Board⁴ (RSB) of the Commission</u>	
Are the comments and recommendations of the RSB considered in the IA report?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Partly	
Comments:	
10. <u>Monitoring, transposition, compliance</u>	
a)	Will the proposed indicators enable the intended effects to be measured?
	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Partly
	Comments:
b)	Are those responsible for monitoring (and compliance) identified?
	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Partly
	Comments:
c)	Are operational monitoring and evaluation arrangements proposed?
	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Partly
	Comments:
d)	Does the IA address the impact of the proposed transposition deadline for MS ?
	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Partly
	Comments:

⁴ Available by searching by Commission DG and date of publication at the following website
http://ec.europa.eu/governance/impact/ia_carried_out/cia_2012_en.htm

11. Summary

Main issues proposed for discussion during the WP meeting on the Commission's IA:

1.

2.

3.

etc.


