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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés)
N° Cion doc.:	ST 16076/22 + ADD 1-2
Subject:	EMA fees - Impact assessment - Indicative checklist

Based on the Interinstitutional Agreement (IIA) on Better Law-Making of 13 April 2016 and following a Coreper decision on examination of Commission impact assessments (IAs)*, it was agreed that IAs are to be examined at working party level with the help of an indicative checklist.

To this end and with a view to the discussions on the above proposal, delegations will find attached the indicative checklist (doc. 6270/18 EXT 1) which is intended to help delegations prepare their views on the IA as part of their consideration of the Commission's proposal.

Please note that the checklist is purely indicative and non-exhaustive and should be used in a flexible way taking into account what is relevant and appropriate for each legislative file. Delegations are not required to provide written replies but are welcome to do if they wish so.

* For an overall description see doc. 6270/18

Examination of Commission IAs in the Council

in the context of the consideration of Commission proposals

- Indicative Checklist for Working Party Chairs -

Title of proposal	
Lead DG	

1. Context of the IA

a) Is the IA carried out at the initiative of the Commission, the Council, or the European Parliament?

☐ Commission ☐ Council ☐ Parliament

b) Is the policy context explained clearly?

☐ Yes ☐ No ☐ Partly

Comments:

c) Is the legal basis of the initiative clear and appropriate?

☐ Yes ☐ No ☐ Partly

Comments:

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 harmonization**

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.	**Specific aspects included in the IA**
	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	☐ **Yes** ☐ **No**
Based on appropriate data/evidence	☐ **Yes** ☐ **No**
If not, please elaborate:	
Impacts on consumers	
Sufficiently assessed	☐ **Yes** ☐ **No**
Based on appropriate data/evidence	☐ **Yes** ☐ **No**
If not, please elaborate:	
Impacts on competitiveness	
Sufficiently assessed	☐ **Yes** ☐ **No**
Based on appropriate data/evidence	☐ **Yes** ☐ **No**
If not, please elaborate:	

Impacts on Small and Medium Enterprises, including micro-enterprises[1]	
Sufficiently assessed	☐ **Yes** ☐ **No**
Based on appropriate data/evidence	☐ **Yes** ☐ **No**
If not, please elaborate:	
Administrative burdens and compliance costs, especially for businesses	
Sufficiently assessed	☐ **Yes** ☐ **No**
Based on appropriate data/evidence	☐ **Yes** ☐ **No**
If not, please elaborate:	
Digital aspects (including on the development of the Digital Single Market)	
Sufficiently assessed	☐ **Yes** ☐ **No**
Based on appropriate data/evidence	☐ **Yes** ☐ **No**
If not, please elaborate:	
Futureproofing (degree to which proposal is future proof and innovation-friendly?)	
Sufficiently assessed	☐ **Yes** ☐ **No**
Based on appropriate data/evidence	☐ **Yes** ☐ **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.

b) Social impacts[2]	
Sufficiently assessed	☐ **Yes** ☐ **No**
Based on appropriate data/evidence	☐ **Yes** ☐ **No**
If not, please elaborate:	

c) Environmental impacts[3]	
Sufficiently assessed	☐ **Yes** ☐ **No**
Based on appropriate data/evidence	☐ **Yes** ☐ **No**
If not, please elaborate:	

d) Impacts on individual Member States, regional or local authorities (territorial impacts)	
Sufficiently assessed	☐ **Yes** ☐ **No**
Based on appropriate data/evidence	☐ **Yes** ☐ **No**
If not, please elaborate:	

9. Opinion of the Regulatory Scrutiny Board[4] (RSB) of the Commission

Are the comments and recommendations of the RSB considered in the IA report?

☐ **Yes** ☐ **No** ☐ **Partly**

Comments:

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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.

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

10. Monitoring, transposition, compliance

a) Will the proposed indicators enable the intended effects to be measured?

☐ **Yes** ☐ **No** ☐ **Partly**

Comments:

b) Are those responsible for monitoring (and compliance) identified?

☐ **Yes** ☐ **No** ☐ **Partly**

Comments:

c) Are operational monitoring and evaluation arrangements proposed?

☐ **Yes** ☐ **No** ☐ **Partly**

Comments:

d) Does the IA address the impact of the proposed transposition deadline for MS ?

☐ **Yes** ☐ **No** ☐ **Partly**

Comments:

11. Summary

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

1.

2.

3.

etc.