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WORKING PAPER

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CONTRIBUTION

From:	Danish Delegation
To:	Delegations
N° Cion doc.:	ST 9485/18 + ADD1 + ADD2 + ADD3 + ADD4
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products - DK written comments on the impact assessment

Delegations will find attached written comments of the Danish delegation on the impact assessment accompanying the above mentioned Proposal. The comments are inserted in the form of the check list contained in document 6270/18 EXT1.

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: The consequences and scale of the problem is not sufficiently demonstrated. The quantity of generics and biosimilar already produced by European companies outside of Europe is unknown. Therefor there is no sufficient knowledge of how big a problem the lack of a European manufacturing waiver poses for these companies. Furthermore an assessment of the consequences the proposal will have on investments in R&D in the long run is overall lacking.

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: The views of SPC holders are not sufficiently represented.

c) Is any gap in evidence acknowledged?

☐ **Yes** ☐ **No** ☒ **Partly**

Comments: It is clear from the CRA report that only a part of the innovative industry is included in the analysis of the negative impact. Moreover the report does not take into account how disproportionately the proposal will negatively impact countries with primarily innovative industries.

3. Methodology

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

☐ **Yes** ☒ **No** ☐ **Partly**

Comments:

The Impact assessment indicates that, if implemented, the proposal will have a positive effect on the net export and job creation. This conclusion is primarily based on the results of the CRA report of Feb. 2016.

Subsequently, there has been conducted a number of studies, that looks into the results and the underlying assumptions, they find that there is a little or no significant overall effect from the proposal. We are concerned that the CRA report and in particular its assessment of an SPC export exemption, may not provide an appropriate and balanced analysis of the short and long term impact of such exemption provisions.

The main concerns are related to lack of a total overview of the sector, the size of the estimated market share, the short run effect for the innovative industry and the long run effect of on

innovation in society:

The estimated market share can be lower than expected

- The study does not fully consider whether Europe would be globally competitive in generics/ biosimilars since following effects is not taken into account:
  - The production price of generic/biosimilars in Europe will potentially be larger than the production price in third countries, mainly attributed to relatively low wage in third countries.
  - It is uncertain to what degree the new generic/biosimilar production will be placed inside or outside the EU 28, and whether the SPC waiver is sufficient incentive for the European producers to move the production facilities or to establish new facilities in the EU and thereby enhance the European job creation. European headquartered generics have production sites based all over the world, depending primarily on the size of the market and on production costs.
  - Therefore, it is uncertain if European generics and biosimilars producers will place new production facilities and jobs in Europe or place the production outside EU and merely send the products to Europe for repackaging, re-labelling or other less value added activities and thereby competing with the European innovative industry in third countries by having the European brand goodwill advantage.
  - Finally, under the current SPC regime European generic companies are often the first on market in the EU after is expiration date. It is not sufficiently justified that an export waiver would further decrease the time to market.

Consequences for the innovative pharmaceutical industry

- Given the results in the impact assessment studies (CRA, 2016) and (Pugatch, 2017) the negative consequences for the innovative pharmaceutical industry could very well be underestimated, since they do not assess the impact on innovation and factors like:
  - The risk that EU generics may substitute part of EU innovators' exports. As an example the regions without SPC-like protection are currently the innovative industry's highest growth markets. An export waiver risks a declining growth rate in the very markets providing growth – influencing the overall growth of the companies involved.
  - In the Pugatch study (PGU, 2017) the value of the "sales at risk" is estimated at approximately 1.32 billion to 2.27 Billion USD and minimum 4,500 to 7,700 jobs.
  - As mentioned above it can be argued that "generics manufactured in Europe therefore are more likely to compete for market share with the original brands (capitalising on the notion of European brand value), than with low-priced domestically manufactured generic products, with which it would be much harder to compete". In other words, there is a quality issue for patients. European companies are trusted. Thus there is a chance that new European generics can outmatch the need/desire to buy European original brand in third countries. If this is correct, then the estimated losses in sales for originators by the Impact Assessment is probably significantly underestimated

Change in the long run incentives to innovate

- The impact assessment states that overall there would be small or no change in the incentives to innovate if the proposal is implemented. But it is of great concern that the assessment does not look into the long run effect of a weakening of the innovative part of the industry. And the effects of the negative market signal degrading the European SPC protection compared to USA and Japan.
- The CE analysis, commissioned by the Commission, indicates that there is significant positive correlation between the effective protection period and the level of domestic spending on pharmaceutical R&D. Furthermore the analysis states that there is a reduction in domestic investments when IP protection is lowered in the markets where companies sell mostly meaning that the export waiver will have an effect to reduce the protection in markets where innovative sell the most (e.g. US, China) resulting in a reduction of investment domestically (EU).
- It is a possibility that originator companies will change their R&D effort or move it to markets with better protection. Given that there is a positive relationship between the effective protection period and spending on pharmaceutical R&D within EU countries, it could deteriorate the high value of the innovative industry in the EU. Thus it is not sufficiently justified that there would be little or no change in the incentives to innovate.

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:

- It is of great importance to secure the best and most cost effective health care for the European citizens. We do not believe that the proposal will support that objective as it will potentially water down the delicate balance of protection for patented products and harm the innovative industry in the long run.
- Generics and biosimilars, already have an easy and fast entry to the European market after SPC expiration.
- Furthermore the impact assessment's estimates for the possible new market share is possibly overestimated as the study does not consider whether Europe would be globally competitive in generics/ biosimilars since it is not taken into account that the production costs of generic/ biosimilars in Europe will most likely be larger than the production costs in third countries, mainly due to relatively low wage levels in third countries.

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

☐ **Yes** ☒ **No** ☐ **Partly**

Comments: We believe the proposal undermines the EU's goal of transforming the European countries into innovative and knowledge based economies.

d) Are the objectives linked to measurable monitoring indicators?

☐ **Yes** ☒ **No** ☐ **Partly**

Comments: As an example there is not a proven link between European job creation in the generics industry and the SPC.

5. Subsidiarity & Proportionality

a) Is the Union's competence clearly established?

☒ **Yes** ☐ **No** ☐ **Partly**

Comments:

b) Does the IA analys 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:

- We are not convinced that there is a need to introduce an export waiver. We are concerned that it may hamper the incentives for continued investments into the research and innovation of medicines, and thereby affect the European goal of fostering a knowledge based economy negatively.

- The balance between rights for the innovative industry and the generic industry is very delicate and we believe that our current legislation is an effective solution. A solution that makes sure that we also can benefit from the generics after the termination of the SPC, and also support the desire and possibility of innovation and life science at the same time
- A well-functioning generic market should be maintained without weakening innovation and the strong life science sector in the EU.
- The lack of a unitary SPC hinder the potential added value of an EU action in this area.

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: The commission is currently conducting a wider review of IP incentives in the pharmaceutical sector. In particular an evidence-based analysis of the impact of EU pharmaceutical incentives on innovation, availability and accessibility of medicinal products, including on pricing strategies where particular attention is given to SPCs. A proposal concerning the SPC should await the conclusions of such a review, and not target an expected “patent cliff” in 2020.

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: Yes, however we find it very critical, that it is not considered how this will disproportionately negatively impact small economies with mostly innovative industry.

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: As stated above it is not to a satisfying degree analysed what long-term effects it will have for the European economy to displace high value added jobs with lower value added jobs and how much it will impact the economy, that there will be less incentive to innovate in Europe in the long-term.

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

☐ **Yes** ☒ **No** ☐ **Partly**

Comments: As stated we do not believe the impact for the originators and the countries with a mostly innovative industry is clearly analysed.

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: As stated above, we do not believe that the competition aspect is sufficiently assessed. We believe the European brand value will mean crowding out of innovative products exports to third countries rather than directly compete with far cheaper local generics.

Impacts on consumers

Sufficiently assessed	☐ **Yes** ☒ **No**
Based on appropriate data/evidence	☐ **Yes** ☒ **No**

If not, please elaborate: We do not believe that European consumers will benefit from the measure as is one of the goals of the initiative, especially if the waiver will have a negative impact on investments into R&D of new innovative medicines. European generics are already among the first to enter the European market after SPC expiry.

Impacts on competitiveness

Sufficiently assessed	☐ **Yes** ☒ **No**
Based on appropriate data/evidence	☐ **Yes** ☒ **No**

If not, please elaborate: Globally, the pharmaceutical industry is highly competitive; in countries like USA and Japan, which are in strong competition with the European innovative industry, they do not have an SPC export waiver, which means that a export waiver solely for European producers will be a comparatively disadvantage for the European innovative industry.

Furthermore the crowding out of higher value added products to the benefit of generics will also hurt EU competitiveness. We do not believe these aspects are sufficiently assessed.

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: It's a risk that the export waiver will add further complexity to the existing SPC system, which is an already complex and fragmented system. Also the IA states that SMEs are mostly generics. Many SMEs are biotech too, the IA doesn't provide an adequate assessment on the impact that the waiver could have on the part of SME's that are biotech.

Administrative burdens and compliance costs, especially for businesses

Sufficiently assessed ☐ **Yes** ☒ **No**

Based on appropriate data/evidence ☒ **Yes** ☐ **No**

If not, please elaborate: There is no clear assessment of the expected administrative burdens for generics that wish to enter the market, as an example: It is not clear in the proposal whether the publication is an essential condition to start exporting. Does the waiver take effect when the company *notifies* the patent office or when the patent office *publishes* the notification? For example if a patent office does not publish timely (within 28days) the received notification, does that entail that the producer of generic can start exporting?

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: It's unclear if a potential new solution will be digital and easy accessible

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: The future development of pharmaceuticals will be even more costly and lengthy and the return on R&D is decreasing. A loosening of the current European SPC regime is not good for this development and is neither future proof nor innovation-friendly.

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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: As stated above, there is no consideration for the disproportionate negative impacts on smaller MS with innovative industries. For Denmark, the proposal is of great significance, as the innovative industry constitute a large share of the economy, life science alone accounts for 17 pct. of the export in goods, and a quarter of the value added in the Danish industry.

The Innovative industry is of great significance to the knowledge-based economy that Denmark and EU relies heavily on. One third of the private investments in R&D in Denmark come from the pharmaceutical innovative industry. An export waiver, and the market signal that the EU will send with the exception, can potentially harm the innovative industry in Denmark. Any change in the framework conditions for this industry can thus potentially have enormous negative consequences for the Danish economy.

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. *The estimated market share can be lower than expected*
2. *The lack of short term and long term consequences for the innovative pharmaceutical industry*
3. *The lack of impact assessment on individual MS*

etc.