

ANNEX 1

10 principles of Better Regulation the Commission has failed to respect in the review of EU rules on supplementary protection certificates (SPCs)

1. Thorough analysis of consultation feedback

“An impact assessment should be...open to stakeholders’ views...”

Better Regulation Guidelines, page 17

“...the input for each consultation needs to be thoroughly analysed...”

Better Regulation Guidelines, page 85

- The public consultation on possible reform of SPCs opened on 12 October 2017 and closed on 4 January 2018. Over 100 submissions from various stakeholders were submitted, many of which provided substantial evidence demonstrating the potentially negative impact of a manufacturing waiver on the broader system of intellectual property (IP) protection.
- Analysing the data and input provided by stakeholders must be done thoroughly and this requires time. Nevertheless the Commission seem to be contemplating a legislative revision that could be initiated with a legislative proposal relatively soon. This jeopardises any full-fledged and thorough analysis of contributions regarding an issue that has substantial social, trade, economic and legal repercussions and could fundamentally restructure IPR rules. This approach goes against the letter and the spirit of the Better Regulation Guidelines.

2. Consideration of all regulatory options

“It is important to consult widely about alternatives, think outside the box and give due consideration to all different options. This is one of the key functions of an impact assessment process... When done badly, it...significantly undermines the credibility of the whole exercise and its usefulness for political decision-making.”

“Start by considering the widest possible range of policy alternatives both in terms of content and instruments. Consider regulatory and non-regulatory means, less or more prescriptive measures, actions at national, EU and international level.”

“When designing the policy options, always consider: Alternative policy instruments e.g. non-regulatory alternatives; self-regulation or co-regulation...”

- In the area of SPCs, alternative non-regulatory approaches have been implemented within certain EU Member States. For example, an industry self-regulation model for a manufacturing waiver was introduced in France in 2015, and has functioned quite successfully.
- However, the Commission has not given any consideration to the non-regulatory ‘soft law’ option, either in its Inception Impact Assessment of February 2017 or in the public consultation held between October 2017 and January 2018 (which did not contain a single question on the possibility of a self-regulation model).
- Indeed, in the Commission’s own Better Regulation Toolbox, the benefits of self-regulation as a policy instrument are explicitly recognised: *“Self-regulation by the relevant industry can in suitable cases deliver the policy objectives faster or in a more cost-effective manner compared to mandatory requirements. They also allow greater flexibility to adapt to technological change (e.g. in the ICT-related areas of activity) and market sensitivities.”* (page 109)
- Furthermore, a soft law approach can deliver results much more rapidly. A legislative revision, even limited in scope, takes time and will inevitably collide with a more substantial revision of the legislative framework which is in any case required in the context of the Unitary Patent.
- **In failing to consider the widest possible range of alternative policy instruments (including Member State action) as required under the Better Regulation Guidelines, the Commission is undermining the very credibility of its actions.**

3. An objective and unbiased impact assessment

“Impact assessment is a tool to help structure reflection and conduct analyses informing policy design. It is not a list of tasks to tick off... An impact assessment should be comprehensive, proportionate, evidence-based, open to stakeholders’ views, unbiased, prepared collectively

with relevant Commission services, embedded in the policy cycle, transparent and be of a high quality.”

Better Regulation Guidelines, page 17

“Keeping an open mind is important even if, in many cases, the IA analysis may start from an idea, stakeholder view or political statement, about what a policy proposal may look like.”

Better Regulation Guidelines, page 21

- Based on the required procedural steps, the European Commission is currently performing an impact assessment. The objective of an impact assessment is to assess the various impacts an EU action may have prior to deciding on the best policy option to pursue.
- Based on statements, DG GROW seems to already have chosen the path forward and is therefore in effect pre-empting the outcome of the impact assessment. It is treating the assessment and consultation as boxes to be ticked, as tools to validate a pre-determined position. Therefore it is not an objective, evidence-based and unbiased impact assessment in conformity with the Better Regulation Guidelines.

4. Identification and analysis of all potential economic impacts

“A wide range of possible impacts should be reviewed across the economic, social and environmental policy areas, going beyond the most obvious consequences of the proposed policy. All potentially important impacts should be identified regardless of whether or not it will be possible to assess them precisely. Failure to identify a significant impact may affect the overall comparison of options or weaken the case for the Commission's proposal...”

“Potentially important indirect impacts should also be considered...A positive impact for one party can be negative for another. It is therefore important to identify who would be specifically affected by each impact.”

Better Regulation Guidelines, page 24

“All relevant impacts should be assessed qualitatively and quantitatively whenever possible.”

Better Regulation Guidelines, page 27

- The Commission’s analysis of the potential impacts of introducing a manufacturing waiver neglects important elements.

- In particular, the ‘CRA report’ on which the Commission has based much of its analysis speaks a lot about the possible impacts on the innovative and generic industries, but at no point does that report analyse the impact, either quantitative or qualitative, of a manufacturing waiver on the research sector. Weakening the SPC regime might reduce the attractiveness of investing in research in key areas such as neuroscience.
- There is also a failure to address the impact on companies doing research in the field of veterinary medicines. Given that these veterinary medicines companies have fewer IP incentives available than the pharmaceutical sector active in research for medicines for human use (e.g. incentives for pediatrics or orphan drugs), SPCs are of fundamental importance to their business plan.
- **By not assessing the broader indirect impacts of reforming the SPC regime, the Commission is undermining the core of its impact assessment and failing to respect the rules set down in the Better Regulation Guidelines.**

5. Identification and analysis of potential social impacts

“IAs must compare the policy options on the basis of their economic, social and environmental impacts (quantified costs and benefits whenever possible)...”

Better Regulation Guidelines, page 14

“Both positive impacts (i.e. the benefits) as well as negative impacts (i.e. the costs or adverse environmental and social impacts) should be identified.”

Better Regulation Guidelines, page 24

- In its analysis of the impact of introducing a manufacturing waiver for SPCs, the Commission appears to be disregarding a crucial difference between generic and innovative companies, namely that innovative companies invest about 15% of their revenues into entirely new medicines.
- Over 7,000 products are currently in development, many aiming to treat rare diseases and meet the medical needs of ageing societies. A weakening of the SPC framework could reduce the attractiveness of investment in developing these new medicines, which might have important knock-on implications for patient health and access to new treatments.

- **By failing sufficiently to analyse these key social impacts, the Commission is not conforming to the minimum standards of impact assessment set down in the Better Regulation Guidelines.**

6. Clear, effective legislation that ensures certainty and predictability

“Legislation should do what it is intended to do, it should be easy to implement, provide certainty and predictability and it should avoid any unnecessary burden. Sensible, realistic rules, properly implemented and enforced across the EU.”

Better Regulation Communication 2015, page 4

“The three Institutions recognise their joint responsibility in delivering high-quality Union legislation and in ensuring that such legislation focuses on areas where it has the greatest added value for European citizens, is as efficient and effective as possible in delivering the common policy objectives of the Union, is as simple and as clear as possible, avoids overregulation and administrative burdens for citizens, administrations and businesses, especially small and medium-sized enterprises ("SMEs"), and is designed with a view to...strengthening the competitiveness and sustainability of the Union economy.”

Inter-institutional Agreement on Better Law-making 2016, recital 3

- The Commission appears to be planning a partial and targeted legislative amendment to the EU framework on SPCs. However, there is risk that by making a limited legislative change (in particular a change whose alleged positive impacts are disputed), the Commission could throw the entire regulatory framework off balance.
- This would be compounded by the fact that the Commission also plans to take legislative action on a unitary SPC. How can it reconcile action that simultaneously strengthens and weakens the EU framework on SPCs? Proceeding in this manner would threaten the certainty and predictability that is the cornerstone of the EU system of IP incentives.
- **Therefore, by proposing (potentially harmful) changes to one part of the regulatory framework, the Commission might call into question the effectiveness, certainty and predictability of the entire framework, ultimately harming the competitiveness and sustainability of the EU economy in the long term. This is clearly inconsistent with the goals of Better Regulation and Better Law-making.**

7. Policy coherence

“The IA...should attempt objectively to compare the options against common criteria, in particular: ...The coherence of each option with the overarching objectives of EU policies.”

Better Regulation Guidelines, page 28

- Beyond coherent action in a given policy field, the principle of policy coherence is important in two others ways that feature quite prominently throughout the Better Regulation agenda:

- **Coherence with the broad over-arching policy objectives.** One of the key messages the Juncker Commission has set out since the start of its mandate, is that it wishes to be “big on big things”.

If we apply this to the current discussion on SPCs and more specifically the manufacturing waiver, it would only make sense to address the SPC framework in the context of the Unitary Patent by creating a Unitary SPC. The latter will indeed be a key driver for among others the biotechnology, plant protection and pharmaceutical sectors and drive competitiveness, investments, growth and jobs.

Addressing the limited aspect of the manufacturing waiver (which in all likelihood will result in only limited job creation, if any) would mean going against the over-arching policy objective of the current Commission.

- **Coherence between policy areas.** A manufacturing waiver would also go against EU trade policy. The EU is trying to enforce its IP standards in a global economy. For example, DG TRADE is promoting SPCs in its on-going trade discussions with Mexico. And the Commission introduced and won a WTO case against a stockpiling exemption in Canada. **This is inconsistent with the potential introduction of a SPC manufacturing waiver (or stockpiling exemptions) and therefore, once again, goes against the Commission’s own Better Regulation principles.**

8. Analysis of SME impacts

“Certain elements must be included in the final IA report. These include: ...(iii) impacts on SMEs following the ‘SME test’ in the Toolbox;”

Better Regulation Guidelines, page 14

“The Commission aims to improve the overall approach to entrepreneurship, permanently anchor the "Think Small First" principle in policymaking and to promote growth of SMEs (and start-ups in particular) by helping them tackle the remaining problems which hamper their scaling-up. Legislation, administrative rules and procedures should be simple, easy to understand and to apply. SMEs' interests should be taken into account at the very early stages of policymaking in order to make legislation more SME friendly.”

Better Regulation Toolbox, page 155

- The role of small and medium-sized enterprises (SMEs) in the pharmaceutical and sector is significant. In particular, SMEs develop 27% of all new medicines and 61% of innovative orphan medicinal products.
- They have an especially important role in the context of neuroscience research, where biotech funds are currently investing in around 100 start-ups to advance the research into diseases like Alzheimer's, Parkinson's and MS.
- **Given that SMEs, notably start-ups investing highly on innovation would be particularly affected by any weakening of the EU system of IP incentives, the Commission should take care to ensure a full analysis of the quantitative and qualitative impacts of a manufacturing waiver on these stakeholders. However, as mentioned above, the CRA report does not look at the implications for the research sector in general.**

Two fundamental and over-arching principles of EU action:

subsidiarity and proportionality

- Within the Better Regulation Guidelines, but even more fundamentally as a general principle in the EU legal framework, the principles of subsidiarity and proportionality are the cornerstone of any EU action, big or small. The principles are crucial in the context of undertaking impact assessments.
- Questions can be raised whether these two fundamental principles have sufficiently been taken into account in the Commission's review of the SPC framework.

9. Subsidiarity: is EU action required?

“In areas outside its exclusive competence, the IA should verify whether EU action is compatible with the principle of subsidiarity. This is not to be taken for granted...”

Better Regulation Guidelines, page 19

- By not considering the effectiveness of self-regulatory action taken at national level in France (see point 2 above), questions can be raised about whether the Commission is respecting the fundamental principle of subsidiarity. In other words, could Member States resolve this issue more effectively?
- Although for the existing legal framework on SPCs, the principle of subsidiarity was evaluated and found to be respected, this does not mean that this is automatically the case for any adaptation regarding a manufacturing waiver. **The Commission must ensure the question of subsidiarity is fully addressed in the current analysis.**

10. Proportionality: is the contemplated action suitable and necessary and could less onerous routes be more appropriate?

“The compliance of the options with the proportionality principle, and in particular of any preferred option, should also be considered...”

Better Regulation Guidelines, page 28

- The Commission has not given the principle of proportionality sufficient consideration. The proportionality test must assess the following principles:
 - There must be a legitimate aim for a measure,
 - The measure must be suitable to achieve the aim (potentially with a requirement of evidence to show it will have that effect),
 - The measure must be necessary to achieve the aim, and there cannot be any less onerous way of doing it,
 - The measure must be reasonable, considering the competing interests of different groups in question.
- By not giving serious thought to the ‘soft law’ option, the Commission seems to be disregarding key elements of this proportionality test, in particular aspects regarding suitability, the necessity of the measure to achieve the desired objective, and assessing whether there is not a less onerous way of taking action. **The Commission should carry out a full proportionality analysis on the subject of an SPC manufacturing waiver.**