

ANNEX 2

Questions the Commission has yet to answer on SPCs

- 1) Has the Commission considered the potential impact a legislative change would have on the research and development of new medicines?**
 - Only recently Commissioner Malmström for Trade said that “the EU takes very seriously the balance of interests of European innovative companies that produce modern medicines and the objective of facilitating access to the greatest number of persons to the most effective treatment available.” In moving forward with a potential proposal, the Commission is threatening to knock this ‘balance’ off course, demotivating areas of medical research at the margin of investment decisions. A reduction in IP-related incentives would particularly threaten research into neuroscience, leading to an investment shift to disease areas where R&D risks are much lower. Such trends are already visible, with Pfizer’s recent decision to pull out of Alzheimer’s research, or the lack of innovative antibiotics. Any reduction in incentives would see more companies moving away from high-risk R&D activities, leaving tens of thousands of European citizens without treatments or cures.
 - The link between innovation and incentives is clearly shown in the case of antibiotics. We do not have new antibiotics mainly because there is not a sufficiently strong incentive system to support such research. The risk is too high for the reward. This has led to the rise of superbugs that are resistant to antibiotics, or AMR. The consequences of tinkering with incentives only become clear many years later. With AMR, this is not in the way this is created a particularly acute health threat.
 - Much good can be done with the right incentives. In the area of rare diseases, for example, a positive incentive change has led to a wealth of new innovative treatments that have transformed patient lives. Before the Regulation on Orphan Medicinal Products entered into force there were only few medicines available for rare diseases in the EU. Now, there are well over 140 and many more being researched. Therefore, any changes to the incentives system have to be considered with utmost diligence in order to avoid a negative impact on the discovery and patients’ access to new life-changing medicines.
- 2) Has the increased revenue for European generics been overestimated?**
 - One of the main points raised in this debate is that an SPC manufacturing waiver would increase the competitiveness of European generics companies, as well as increasing EU exports to third countries.
 - This argument is echoed by the Charles Rivers Associates (CRA) report, which estimates that a SPC manufacturing waiver could bring 33bn EUR additional revenue to European generics companies, due to the fact that they would be able to manufacture treatments in Europe and export them to third-countries whilst European patents are still in place. However, alternative reports prepared by independent economic experts show that

findings and conclusions vary wildly based upon the data used. The CRA report relies heavily on data from treatments with US patent extension terms. Of their sample, 92% of treatments have an earlier patent expiration date in Europe than they do in key third countries. This means that under the existing regulation, European generics would still be able to manufacture products earlier than their third-country counterparts in the large majority of cases, allowing them to compete on an equal (if not better) footing from a timing perspective.

- Changing the SPC Manufacturing Waiver would therefore only bring slight differences to European generics revenue, far below the estimates provided in the CRA report. For example, economic experts commissioned by our industry estimate that a new legislative proposal on SPC waiver could impact only 4% of EU generics products, creating an additional revenue of only 2bn EUR, versus the 33bn EUR stated in the CRA report. Such drastic differences in figures impact all other economic estimates made in the report, such as the potential for increases in EU exports of medicinal products, the general increase in sales for the pharmaceutical industry, generics competitiveness and so forth.
- This demonstrates data flaws in the CRA report, and as a consequence undermines the arguments and assumptions given.

3) Can the Commission justify the speed at which it has reviewed the SPC Regulation, given the lack of currently available information and the disproportionately wide-ranging impacts of regulatory change?

- The Commission has moved quickly in relation to evaluating the “policy options for an optimisation of the European SPC legislation.” The public consultation closed on 4 January, and within less than four weeks we hear that the Commission is busy preparing a proposal on the SPC manufacturing waiver.
- Given this short time frame, we are concerned that not all arguments and inputs have been properly considered. Such a short timeframe suggests that stakeholder inputs was sought as a formalistic exercise, and that the decision to put forward a legislative proposal was a foregone conclusion. So far, stakeholders, including Industry, have not been notified of the results of the public consultation, nor have the results been made publicly available. This all sends a strong signal to us that, so far, stakeholder inputs have not been fully processed.
- Similarly, there are two pending commission-sponsored expert reports on SPCs and pharmaceutical incentives which are yet to be published in the first half of 2018. Given the speed that the Commission are proceeding with the legislative proposal on SPCs ahead of publication of these reports, we are concerned that these reports will not be given proper consideration or be integrated into any legislative proposal. Is this not undue haste?

4) Will the Commission give proper time to consider counter evidence by other experts aside from the CRA report?

- Currently, the Commission is basing its examination and decision on a potential legislative proposal solely on the CRA report.
- The report is based upon largely confidential data provided by Medicines for Europe and a generics company. Such confidentiality makes the robustness of the data and the validity of the study impossible to replicate and verify.
- The data in itself has significant gaps and CRA has failed to consider many important arguments, according to several independent economic experts who have examined the report. As this is the only Commission-sponsored report currently available, we are concerned that the Commission is basing its assessment of this hugely important legislation largely on flawed data.
- The Commission has sponsored two other expert reports from Copenhagen Economics and the Max Planck Institute, the results of which are expected to be published in first half of 2018. Given such substantial concerns around the Commission's timeline and the CRA report's credibility, it would be prudent for the Commission to wait for the publication of the pending Commission-sponsored reports and to postpone any immediate legislative proposal until all evidence has been considered. This is particularly important for the Max Planck Institute report, which focuses on SPCs.
- Our Recommendation is to wait for the publication of these two reports because they are likely to show that the CRA report is not robust in some key areas.

5) Given that there is no immediate urgency, will the Commission consider taking the appropriate time to assess all available data and arguments before deciding whether to move forward with a legislative proposal?

- Aside from the political expediency of legislating before the end of the current Commission mandate, one possible explanation for the undue speed at which the Commission has examined this issue derives from a successful lobbying campaign run by parts of the industry based on some specific product examples.
- Does the Commission want to undermine the European legislative process and move forward with a legislation that would have an impact on patients, economy and research & development on the basis of the patent expiry of some specific medicines?

6) Has the Commission fully considered the impact regulatory change might have on employment in Europe?

- The impact on jobs has not been fully considered. The report commissioned by CRA on this topic omits key details and considerations.

For example, any increase in generics jobs would likely be offset by some employment losses in the high-value innovative industry, which are based mostly in Western Europe. New generics jobs will be mostly based in Central and Eastern Europe. From a jobs point of view, the result may just be a geographical displacement, and creation of lower value jobs in place of higher value ones.

- Does the Commission believe it is within its competency to geographically displace employment from Western to Eastern Europe? Has the Commission notified its Member States of the impact a change in the legislation may have on the employment market?

6) Has the Commission considered the competitiveness of third-country generics vs European generics?

- Even if a SPC manufacturing waiver enabled EU generics to manufacture products within the EU, this would not necessarily mean that EU generics could compete on the same level with third-country generics (e.g. China and India), especially on pricing. Success in the generics market is determined mainly by price, a factor which seems to have been overlooked in the CRA report.
- Future market share between Europe and other parts of the world in generics manufacturing will be dictated by a race to the bottom in terms of manufacturing cost. It seems strange when much economic analysis say it's a forlorn hope, and yet risks undermining a successful SME part of the industry that is highly successful.

7) Is the Commission prepared for the SPC Regulation to be opened up beyond the limited scope foreseen by a potential recast? Has the Commission prepared for this eventuality?

- This issue has and will continue to attract a huge amount of lobbying, to both the Parliament and Council. There could be a significant amount of political pressure to open this issue further, which would have huge impacts on Industry. Such impacts have not been properly considered within the scope of a recast.
- The negotiations are likely to be detailed, fraught and time-consuming, which may see the Commission come to the end of its current mandate before the Ordinary Legislative Procedure is concluded. Would it not be better for the Commission to take the extra time to consider the SPC Regulation, to prepare for the eventuality that it is opened up more broadly during negotiations?