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European Confederation of Pharmaceutical Entrepreneurs AISBL

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European Commission
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Date: 24 January 2018

The European Commission's work on the SPC legislation

Dear Commissioner Bieńkowska,

I am writing to you on behalf of the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE). A group that represents, *inter alia*, small and mid-sized companies in the early phases of drug discovery and device innovation.

We would like to express our mounting concerns regarding possible changes to the Supplementary Protection Certificates (SPC) Regulation (EC) No 469/2009. We understand that the Commission is expected to publish a proposal to legislate on an SPC manufacturing waiver under the current mandate. Assuming this is the case, in this letter we outline both procedural and materially important concerns that have not been adequately answered.

IP-intensive sectors account for around 42% of EU GDP, generate 38% of all jobs, and contribute to as much as 90% of EU exports. With so much at stake, we believe it is vital that the issues outlined below are addressed before such a proposal is made.

Procedurally Important Concerns

As observers of EU policy-making and participants in the consultation process, we have strong concerns on whether the Commission's process in relation to the optimisation of the SPC legislation is entirely in line with the spirit of Better Regulation.

Better Regulation

The 'Juncker era' has been characterised by a reduced tendency to legislate at the EU level, acting only where there is a clear balance of evidence in favour of action. In this penultimate year for the Commission, we are concerned that elements of the Commission appear to be deviating from this successful, tried and tested approach. Before proposing legislation, we as an industry, urge the Commission to take a step back, in favour of examining previous examples of successful voluntary industry agreements that achieve equal aims, using soft law instruments. Given no questions were asked in the stakeholder consultation on soft law instruments, other than on consistent interpretation (question 37), we would like to engage further with the Commission to explore this option. Furthermore, soft law options regarding a potential SPC manufacturing waiver were explicitly excluded from the Inception Impact Assessment from the very beginning. Our expanded concerns related to better regulation are affixed in Annex 1 "Better Regulation 24.01.2018".

Undue Rush

The Commission's public consultation, to which we responded in good faith, closed on 4 January of this year. We are now very concerned that less than four weeks later, DG GROW indicated to Commission colleagues

a concrete plan to put forward a proposal on the SPC manufacturing waver by April 2018. This is a remarkably short turnaround for such a complex issue. Was the decision to put forward a legislative proposal a foregone conclusion? We fear that this is the case, and key stakeholder input has therefore not been given the proper weight of consideration required.

Under pressure

It is possible, given the speed with which the Commission is moving forward, that undue pressure is being exerted by some Member States with state ownership in certain industrial sectors and a well-orchestrated campaign from the generic industry subsector with a clear commercial interest in the waiver. We are informed of an "urgent need to act" but receive little information about the concrete arguments underlying the urgency. One example being mentioned is the expiry of patents of specific products. While it would be politically expedient to legislate within the current mandate, we urge for caution against moving ahead so quickly. Waiting for the publication of further evidence, allowing sufficient time to examine stakeholder input and coming forward with a comprehensive, coordinated IP package, would seem like a prudent holistic approach. Rushing through a single change on a small area of IP before 2019 could lead to many unintended consequences.

Materially Concerns

Not only are we concerned with the process, we are also concerned about the knock-on and secondary impacts to the overall incentives framework for new medicines. It is possible this change will fundamentally unbalance a proven system that is delivering new life changing medicines year-on-year. Our members' role is to find new medicines for patients with life altering and life-threatening diseases. They take on this challenge knowing that every new medicine they find has untold positive impacts for the patients concerned. Weakening IP incentives for innovative small and mid-sized companies also weakens Europe's ability to deliver new medicines and globally compete on innovation.

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. However, 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 EU Regulation on Orphan Medicinal Products[1] entered into force there were only very few medicines 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.

Taking on the Complex Research

Of top concern is that investment in high-risk, high-failure areas of medicine could suffer under a change in existing legislation. A reduction in IP-related incentives would see investments shift to disease areas where R&D risks are lower. Such trends can already be seen under the existing system: Pfizer's recent decision to pull out of Alzheimer's research worried many patient groups. While 'big pharma' can divest away from high-risk disease areas to adapt to new regulatory regimes, smaller companies and start-up biotechs may no longer gain the capital needed to get their operations off the ground. In the discovery business, small and mid-sized companies are responsible for a high percentage of new molecules developed, which are then commercialized by larger companies. Any weakening of incentives would further see companies moving away from high-risk R&D activities, leaving tens of thousands of European citizens without treatments or cures.

[1] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02000R0141-20090807&qid=1516802283081&from=DE

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Displacement, not Creation of Jobs

The impact on jobs has not been fully considered. The report commissioned by Charles River Associates (CRA)[2] 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. From a jobs point of view, the result may at best just be a geographical displacement, and creation of lower value jobs in place of higher value ones.

Overstated Benefits

Finally, the CRA report may also overstate the benefits a legislative change in the Regulation would bring to the EU generics industry. This is true for both the ability of European generics manufacturers to compete with developing-country producers and the estimated savings for European governments. The report's assumption that a 6-month delay in generics entry to market is directly attributable to the SPC Regulation is unfounded, neglecting to consider delays caused by producers' profit estimates, pricing and reimbursement negotiations and other such causes which would persist regardless. Moreover, the reality is that much of the generics manufacturing base is moving to developing countries. This legislation might simply hasten this trend.

It is difficult to see how European generics companies will compete on the global market with growing power-houses like India taking more and more of this industry. Future generics market share between Europe and other parts of the world will be largely be dictated by manufacturing cost. It seems strange to pursue a stronger European generics industry when much economic analysis suggests questions its long-term global competitiveness, while at the same time risking a successful SME part of the industry.

We have outlined the most important procedural and material concerns above. If there was a robust argument for making changes that did not decrease the discovery of new medicines and which supported small and mid-sized companies in Europe we would support it.

But this debate is not yet robust. This rushed, evidence-light and politically driven process is not in the right spirit, nor does it have the weight of facts on its side. We strongly urge you to think through the questions which elaborate on all of the above in Annex 2 'Key questions the Commission has yet to answer on SPCs 24.01.2018' before moving ahead.

Yours sincerely

Dr. Alexander Natz
Secretary General

Cc: First Vice President Frans Timmermans,
Vice President Jyrki Katainen
Commissioner Vytenis Andriukaitis
Commissioner Cecilia Malmström

[2] https://publications.europa.eu/en/publication-detail/-/publication/6e4ce9f8-aa41-11e7-837e-01aa75ed71a1/language-en