[redacted]

From: [redacted] (SANTE)
Sent: mardi 6 mars 2018 11:42
To: [redacted]
Subject: Re: Meeting request re: SPC Waiver - AbbVie

Our reference: sante.ddg1.b.5(2018)1383384

Dear Mr [redacted],

Thank you for your email addressed to Mr Prats-Monné dated 2 March 2018, requesting a meeting to discuss the potential introduction of a SPC manufacturing waiver.

Due to a heavy schedule, Mr Prats-Monné will unfortunately not be able to meet with the company Abbvie in the coming weeks. Furthermore, considering that DG GROW is responsible for the issue of the SPC manufacturing waiver, DG SANTE Unit on pharmaceuticals will not be in a position to organise a meeting with the company.

With best regards,

Unit "Medicines: policy, authorisation and monitoring"

European Commission
DG Health and Food Safety

From: [redacted]
Sent: Friday, March 02, 2018 11:39 AM
To: SANTE DG
Subject: Meeting request re: SPC Waiver - AbbVie

Dear Mr Prats Monné,

My name is [redacted] and I work for the public affairs agency GPLUS in Brussels.

We represent the US healthcare company AbbVie which, in close coordination with the EU pharmaceuticals association EFPIA, would like to flag immediate concerns about a legislative initiative which we believe could durably damage the European Union intellectual property framework for the European research-based pharmaceutical industry – the potential introduction of the "SPC Waiver".

We would be delighted if you were available for a meeting with AbbVie in the coming weeks to discuss the matter in person.

Following the publication of an inception impact assessment at the beginning of 2017 and a public consultation, we understand the Commission is seriously considering proposing a legislative initiative in the coming weeks or months to introduce an exemption to the intellectual property rights granted by the Supplementary Protection Certificate (Regulation (EC) no 469/2009), also known as the "SPC waiver".

We understand that, in essence, the initiative would aim to overcome market access issues that the EU generics industry may face by weakening EU intellectual property rights for the EU research-driven industry. We believe, however, that this approach unnecessarily pitches European healthcare industries against each other in a way that will prove to be both ineffective and counter-productive, for a number of reasons:

1. **Wrong instrument and unclear benefits:**

   (a) Inside the EU, we have serious doubts that an SPC waiver would improve access to generics, as there currently is no market failure. According to Medicines for Europe, the generic medicines industry is the main provider of medicines in the EU, accounting for 56% of dispensed medicines. By 2020, generic medicines are even expected to make up 70-80% of the medicines used in Europe, and research shows that EU generic manufacturers are often first to market under the current set-up and therewith in a good position to compete for the European market with international peers (c.f. Point C: https://www.efpia.eu/media/288516/efpia-spc-report_120917_v3_10217-002.pdf).

   (b) Outside the EU, an SPC waiver would not help gain access to any important market which is currently closed to EU generics manufacturers. If low market penetration was caused by IPR-related hurdles, one would expect a large number of unsuccessful attempts by EU generic manufacturers to obtain licenses for export. We are not aware of this. However, it is known that a number of export markets have put in place trade barriers, such as localisation requirements, and often sport significant local production capacities for generics (e.g. Brazil: 90%, China: over 56% etc.) SPC waivers would not help overcome either of these challenges. We are therefore confident that a thorough assessment of policy options to enhance generic penetration in third markets would generate alternative measures which yield more benefits for EU generics manufacturers while being less intrusive for EU research-based industries.

   (c) Overall, it remains highly doubtful that the proposed measure would generate net economic benefits for Europe.

2. **Inconsistent with established trade policy and possible counter-measures:** The introduction of an SPC waiver would be incompatible with a number of EU FTAs which provide for a patent extension mechanism that shall confer the same rights as the original patent. It would also undermine the well-established EU trade position which speaks out in favour of IPR and against localisation policies. It is worth noting that the draft proposal already raised concerns in the United States, triggering deliberations about Section 301 measures.

3. **Downside risks of incomplete impact assessments:** A weakening of Intellectual Property Rights could potentially undermine EU research-based jobs and investments as well as patient access to new therapies. From a procedural perspective, it is worth recalling that the European Commission is preparing a comprehensive review of the incentives for European pharmaceutical industry. In line with better regulation principles, we feel this review should be thoroughly completed, rather than isolating individual measures for what be a hastened, ill-prepared and surely controversial, political debate before the end of this term.

I attach some materials for your perusal in case this is of interest. Thank you in advance for your kind response.

Kind regards,

[redacted]

g+(r)

[redacted]
partner

g+europe

[redacted]

[redacted]

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