

Press Release

US interference unacceptable in EU legislative proposal for an SPC manufacturing waiver

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The US patent and trademark office (USPTO), together with the US Trade Office (USTR) and the US Department of Commerce, is holding this week a dedicated, Government official only briefing on the EU legislative proposal for a Supplementary Protection Certificate (SPC) manufacturing waiver. The meeting, which will be conducted under Chatham house rules, will take Tuesday, October 23rd in Brussels.

The aim of the meeting is to convey the position of the US commercial bodies and representatives to EU officials on the introduction of an SPC manufacturing waiver in Europe, and influence the outcome of this EU legislative proposal. This is in line with consistent efforts from US commercial interests to close the US healthcare market to biosimilar medicines. Unfortunately the organisers have had no regard for transparency about the details of the meeting, the participants, nor the agenda.

As has been highlighted by numerous independent studies on the matter, the introduction of an SPC manufacturing waiver in Europe, if done so correctly, can deliver vast benefits for patients, EU healthcare budgets and investments in manufacturing of medicines.

The US is interfering in an EU domestic policy matter by trying to manipulate and influence the current debate, in order to defend non-better-specified interests.

Commenting on the meeting, Adrian van den Hoven, Director General at Medicines for Europe stated "We are surprised to hear that the US is openly interfering in an EU domestic affair in an extremely delicate moment of the legislative process on the SPC manufacturing waiver. The EU, as an entity of 28 sovereign Member States, does not need and cannot accept such external pressure, let alone when it comes to the health of patients and investments in medicines' development. Europe cannot be intimidated and will not capitulate before the defence of the economic concerns of US commercial interests!"

Medicines for Europe

Medicines for Europe represents the generic, biosimilar and value added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members employ 160,000 people at over 350 manufacturing and R&D sites in Europe, and invest up to 17% of their turnover in medical innovation. Medicines for Europe member companies across Europe are both increasing access to medicines and driving improved health outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high quality, effective generic medicines, whilst also innovating to create new biosimilar medicines and bringing to market value added medicines, which deliver better health outcomes, greater efficiency and/or improved safety in the hospital setting for patients. For more information please follow us at www.medicinesforeurope.com and on Twitter @medicinesforEU.