# Legislative breakthrough: SPC manufacturing waiver to be introduced for export and stockpiling

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The introduction of an SPC manufacturing waiver in the European Union is now all but a done deal.
Following the European Commission's initial proposal for a regulation amending Regulation (EC) 469/2009 on SPCs for medicinal products (COM(2018) 317 final) issued on 28 May 2018, the European Parliament's Committee on Legal Affairs (JURI) adopted its final report and decided to open the inter-institutional "trilogue" negotiations between Parliament, Council and Commission at the end of January 2019, while the Council in parallel agreed its own negotiating mandate on 16 January 2019, as previously reported on this blog.

Under the pressure of the fast approaching European elections scheduled for May 2019, the European institutions reached a compromise in their trilogue meeting on 14 February 2019, which was presented in the Committee on Legal Affairs on 19 February 2019.

Under the compromise reached, the scope of the manufacturing waiver, which was originally devised to allow the production of SPC-protected medicinal products for the exclusive purpose of export to non-EU countries, has been broadened to cover also the production and stockpiling of medicinal products for "day-1 entry" to the EU market immediately after SPC expiry. Such stockpiling, in contrast to the manufacturing for export, will be allowed only during the final six months of the SPC lifetime, which is considerably shorter than the two-year period previously endorsed in the final report of the Committee on Legal Affairs.

Nevertheless, the extension of the manufacturing waiver to allow stockpiling is a clear victory for the European generics and biosimilar industry, and as such has received enthusiastic acclaim from the industry's lobby group Medicines for Europe.

Yet, Medicines for Europe also expressed "deep regret" in view of the safeguards provided for SPC holders, most notably the requirement to directly inform the SPC holder (in addition to notifying the competent national patent office) at least three months before the start of production under the manufacturing waiver, which the organization denounced as "unnecessary and redundant".

While the provisional agreement reached in the trilogue negotiations between the European Parliament, the Council and the Commission must still be formally approved by the Parliament and the Council, it can be expected that the legislation introducing the SPC manufacturing waiver will be promptly adopted, presumably on its first reading in the European Parliament, which is tentatively foreseen to take place on 3 April 2019.

Alas, the details of the compromise reached in the trilogue negotiations have not yet been fully revealed, and any documentation of trilogue meetings is notoriously difficult to obtain.

**UPDATE #1**: The compromise text agreed in the trilogue negotiations has just today been approved and published by the Permanent Representatives Committee (COREPER) of the Council on 20 February 2019, thus taking the SPC manufacturing waiver a further step towards adoption. All details of the provisional agreement can be found in this document.

**UPDATE #2**: An extraordinary meeting of the European Parliament's Committee on Legal Affairs has now been scheduled for 26 February 2019 in order to vote on the provisional agreement reached in the trilogue negotiations. Assuming that the provisional agreement will be confirmed, this will allow the European Parliament to adopt the agreement in plenum.

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