

[ESMA updates Q&A on Short-Selling Regulation](#)

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The purpose of this Q&A is to promote common supervisory approaches and practices in the application of SSR. It aims at providing investors and other market participants with clarifications on the applicable requirements.

ESMA will periodically review these Q&A and update them where required.

[Opening remarks by Vice-President Katainen and Commissioner Bieńkowska on the Commission's proposal on Supplementary Protection Certificates](#)

Vice-President Katainen

Today Elżbieta and I are here to present a new legislative proposal that has been designed to help EU-based companies tap into fast-growing global markets on pharmaceuticals.

Our proposal amends existing legislation on the protection of intellectual property rights covering pharmaceuticals, more specifically in the area of Supplementary Protection Certificates, or SPCs.

This subject matters. It matters because patents and SPCs support and sustain the world-class innovation capacity of the EU pharmaceutical industry. A sector that provides 570.000 jobs in the Union, invests €27 billion in Research and Development, and exports worth of €220 billion annually.

Our SPC rules are the strongest in the world, and for a good reason: to reward investment in innovation and protect intellectual property in the EU.

Pharmaceutical SPCs aim to offset the loss of patent protection for medicines that occurs due to the lengthy testing and clinical trials these products require prior to obtaining regulatory marketing approval. An SPC can extend a patent right in the EU for a maximum of five years.

That is the baseline and that will not change.

Let me briefly explain what the issue is right now, and Elżbieta will then present the initiative we are proposing.

EU and global pharmaceutical markets have changed dramatically since the SPC was introduced back in 1992. Global demand for medicines has increased massively, reaching €1.1 trillion in 2017. In this growing market, generics and biosimilars now represent an important part of the future. That was not the case in 1992 when our rules were first framed.

Today, the EU plays a pioneering role both in pharmaceutical research and in manufacturing of generic medicines and biosimilars.

However, Europe's trading partners are increasingly involved in manufacturing for the quickly expanding market of generics and biosimilars.

This is why it is urgent to act now to maintain our leadership position in pharmaceuticals.

We are proposing a very limited and targeted change to the current regime to remove a legal barrier that was preventing our companies from competing on equal terms with our global competitors on non-EU markets.

Why? Because during the SPC period of protection of the product in the EU, EU-based generics and biomilars manufacturers cannot produce for any purpose. Not even for the sole purpose of exporting outside the EU to countries where SPC protection has expired or does not exist.

This puts our generics and biosimilar manufacturers in a clear competitive disadvantage as regards our global competitors.

What are the risks? Delocalisation of manufacturing out of Europe. Loss of investment in Europe. Loss of export markets. And, in addition, delays in new generics and biosimilars reaching the EU market.

So we need to act now. We will continue the top class protection of European innovators in the pharmaceuticals sector, but at the same we want our companies to be able to compete globally, whilst maintaining production in Europe.

Elżbieta will now tell you what we are proposing.

Commissioner Bieńkowska

Thank you Jyrki.

As you explained, we are acting today to remove an unintended competitive disadvantage for the EU-based generics and biosimilar when they go on the export markets.

The global pharmaceutical market is changing fast:

- The total spending on medicines is to increase from €950m in 2012, to €1.1 trillion in 2017.
- There is a shift towards ever-greater market share by generics and biosimilars, which could represent 80% of medicines by volume by 2020.

But today, our own legislative framework does not allow these generics and biosimilars to compete on export markets on an equal basis with non EU based companies.

And this has also an impact on their capacity to access our own EU market once the protection in the Single Market is over.

This is a paradoxical situation, especially at a moment when we expect a patent cliff by 2020, i.e. that a lot of medicinal products going off patent progressively as of 2020. In clear, there is a potential opening of a market of €95bn worldwide.

We therefore want to be sure that our EU based generics and biosimilar are in position to compete, from the EU, on equal terms, in order to capture part of this expected growth in the market.

Failing to do so, at a moment when these companies are making their investment decisions, we are running the risk of increased delocalisation, loss of export opportunities and loss of competitiveness of EU pharmaceutical industry as a whole.

So we have to act now.

We have listened carefully to all sides of industry. To their concerns and their expectations.

On that basis, today we are proposing a balanced, proportionate and well-calibrated exception to the current SPC system in the form of a "manufacturing waiver".

We are not changing the core or length of intellectual property protection of pharmaceuticals. We are not changing the overall SPC system. We remain committed to strong IPR and SPC protection and enforcement in the Single Market and beyond. The IPR protection in Europe is the strongest in the world, and it will remain so with this proposal.

What we propose is to allow EU-based companies to manufacture a generic or biosimilar version of an SPC-protected medicine if they do so exclusively for the purpose of export to a non-EU market where protection has expired or never existed.

This will boost investment and job creation in Europe:

- Up to 25.000 new and high-skilled jobs over the next 10 years could be generated in the EU;
- with possible export gains for EU companies of €1 billion per year;
- It will particularly benefit the many small and medium-sized enterprises in the field.

We will also re-affirm Europe's position as a hub for pharmaceutical R&D and manufacturing.

Let me clear however. This proposal is not about rewarding one side of the industry – the generics and biosimilar industry – to the detriment of the other side – the originators.

This proposal is therefore accompanied with strong safeguards to ensure that the intellectual property protection in Europe is not undermined:

- A notification procedure to competent authorities for using the waiver ensuring transparency;
- A labelling obligation to ensure that what is produced for the export markets, is not diverted back towards the EU market;
- A due diligence requirement on generics and supply chain to ensure that their supply chain apply the rules correctly.

So all sides stand to gain from this proposal.

This is good for the competitiveness of the overall EU pharmaceutical sector, it will improve patients' access to medicine and help national health budget.

We therefore call on the European Parliament and the Council to adopt the Regulation swiftly in this legislative term, by next spring.

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[Press release – Pharmaceuticals: Commission refines intellectual property rules](#)

[Frequently Asked Questions \(FAQs\) – Supplementary protection certificate for medicinal products](#)

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[Letter to EFRAG on DP Equity instruments impairment and recycling](#)

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[EESC 9th civil society days: The digital era needs human skills and a proper legal environment](#)

Citizenship, Democracy and Culture in a digitalised Europe was the motto of the 2018 Civil Society Days, organised by the Liaison Group at the European Economic and Social Committee (EESC) on 24 and 25 May in Brussels. In six workshops, participants discussed living together in a digital Europe in the future and concluded with the adoption of seven [key recommendations](#). Panels focused on culture and education, identities and polarisation, cybersecurity and data protection, digital democracy and citizen participation, overcoming the digital divide and artificial intelligence as a common good.

In his opening address, EESC President **Luca Jahier** stressed the importance of the Civil Society Days – which is why he had proposed organising this event on the very same day as the EESC’s 60th anniversary celebration. “We represent Europe at work. This has given the EESC the authority to advise the other institutions for the past 60 years. You can be assured that the recommendations you are drafting today will not remain on paper only but feed in the European policy work.”

He also highlighted the fact that for the first time civil society organisations were joining forces to debate the complex issue of digitalisation in a comprehensive way and that they were here to help shaping the digital world we are living in by asking the right questions and proposing answers for the common good.

In his keynote speech, **Andrea Renda**, Chair in Digital Innovation at the College of Europe, underlined the key role civil society has to play in shaping Europe’s future: “We need to put our strength and resources together and craft our future in a sustainable way”, he said. For the medium term, he predicted a lot of destruction accompanying digitalisation, not least because of the tremendous speed of change. However, in the long run he was convinced that: “We will work less and differently, with better subjective well-being. In the future work will be more rewarding”.

MEP Ana Gomes stressed the importance of steering digitalisation at European level and referred to the key role of education: “Nothing replaces human sensitivity; we need to continue to invest in human education”.

According to **Ray Pinto**, policy director at DIGITALEUROPE, access to the internet should be a fundamental right. Digitalisation, if used properly, could help create a unified democratic, transparent, digital Europe, where citizens can voice their views and take a more active role in decision-making.

But technologies and artificial intelligence (AI) needed experts to handle them. In Europe there was a shortage of around half a million experts. Only 16.7% of ICT experts were women, while 83.3% were men (compared with 54% men/46% women in the workforce as a whole).

Furthermore, while the US and China were registering huge increases in AI patents, Europe was lagging behind. 83% of external investment in AI was being absorbed by the US and China.

Maarit Palovirta from the Internet Society whose mission is to keep the internet open and neutral, globally connected, secure, trustworthy and accessible for everyone acknowledged that this mission had been challenged by incidents such as online crime episodes, fake news, etc. She said: “We cannot ignore this, but no business and no government can tackle these problems alone. As internet users, as civil society we need to use our power to influence policies and take responsibility for the future of the internet. Our job is to bring back a positive approach towards the internet, including transparency and ethics”.

Dr Beate Wagner, managing director of the Global Young Academy, belongs to a group of 27 people who are promoting a Digital Charter for the EU. “It is not about inventing new fundamental rights but rather of reformulating rights partly in the light of the digital era”, she explained. The goal was to commit state and non-state actors. Since Facebook, Twitter, Instagram and others form a public space it was in the group’s view necessary to address this challenge accordingly. “When it comes to automated decision-making, it needs human beings to take the responsibility”, Dr Wagner emphasised.

Also **Alessandro Mantelero**, Professor of Law at the Polytechnic University of Turin, emphasised the huge impact of algorithms on decision-making and recommended a particular focus on risk management. “When it comes to artificial intelligence, we don’t need to consider just whether it is legally compliant but also whether it is socially compliant”, he said. The General Data Protection Regulation (GDPR) must contribute to creating a digital environment which is not a mere data ecosystem but primarily a rights-based, value-oriented and participatory environment.

In his conclusions, Secretary General of SOLIDAR and co-chair of the liaison group **Conny Reuter**, who moderated the event referred to the great European philosophers Kant, Hegel and Rousseau, stressing that digitalisation is also about ethics and the social contract of our society and honoured those member organisations of the EESC Liaison Group which had organised the six

interactive workshops.

The Civil Society Days, which the EESC organised this year for the 9th time, are intended to highlight and foster the important role that civil society plays in building a European Union which is more in tune with citizens' aspirations – a European Union that people can make their own.

More on the speeches and presentation as well as the recommendations of these workshops can be found on the EESC's webpage.