



# EURACTIV

## PHARMA INNOVATION

SPECIAL REPORT | 9 - 13 OCTOBER 2017  
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# Andriukaitis: Supporting drug innovation is 'the only way'

By Sarantis Michalopoulos



Expert: "The IP aims to give certain exclusivity rights, it's a stimulus to innovate and develop new products and the basic idea is that you can get a good financial return on innovation efforts." [European Commission]

**B**acking innovation in the pharmaceutical market and developing new evidence-based economic models is the only way forward for future healthcare, according to EU Commissioner for Health and Food Safety Vytenis Andriukaitis.

*EURACTIV.com reports from Austria.*

Hit hard by austerity, the health systems of EU member states are under huge pressure. Combined with an ageing population and the alarming burden of chronic illnesses, EU

member states have targeted specific aspects of the incentives granted to the pharma industry in order to decrease drug prices.

On the other hand, many suggest that such an approach would have a detrimental impact on innovation in the pharma sector. Instead, they claim policymakers should focus on other healthcare fields to save costs, considering that the pharmaceutical expenditure has remained stable in recent years.

**INCENTIVISING  
INNOVATION**

Member states have the full competence to decide which medicinal products are reimbursed and at what price, while the European Commission is exclusively responsible for the competition of medicinal products on the EU market.

In June 2016, EU health ministers called on the European Commission to perform an overview of the current EU legislative tools and incentives that aim to facilitate investment in the development of medicinal products.

One of these incentives is the

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supplementary protection certificates (SPCs), an intellectual property right that serves as an extension of a patent right. The regular patent for a pharmaceutical product in the EU is 20 years. An SPC can extend this patent right for a maximum of five years.

Specifically, SPCs aim to offset the loss of patent protection for pharmaceutical products that occurs due to the compulsory lengthy testing and clinical trials these products require prior to obtaining regulatory marketing approval. This period can last 12 years.

Speaking to EURACTIV on the sidelines of the European Health Forum Gastein (EHFG) in Austria last week (4-6 October) Andriukaitis said there was a need to understand innovation.

"It's a very broad understanding as we have a lot of different innovations that we need to develop new economic models," he said.

Asked whether a shift in incentives should still support innovation he replied, "No doubt. We need to discuss issues in complexity. Some incentives are old; some mechanisms need to be developed."

"There is only one way, to support innovations and use evidence-based economic models," Andriukaitis said, adding that "justice" is needed in the revision of patent issues and SPCs.

The EU health chief stressed that the executive was open on how to move forward collecting all data and pointed out that next year would be a good opportunity to debate different ideas.

### **WITHOUT INCENTIVES, INNOVATION STOPS**

In a separate interview with EURACTIV, Nathalie Moll, director-general at the European Federation of Pharmaceutical Industries and Associations (EFPIA), said incentives

are the "foundation" on which all medical innovation is based.

"It's what gives investors and innovators the confidence to take that moonshot, open up a new treatment pathway, deliver the next piece of incremental innovation then navigate the long, complex and risky road to bring a new treatment to patients," she said.

"Without incentives, innovation stops," she warned, adding that a possible devaluation could lead to €33 billion investment in research and development moving away from Europe.

Asked about SPCs, Moll noted that the European framework of incentives is an interlinked package of measures that work together.

"Devalue any aspects of the framework and it has a negative impact on innovation and makes Europe a less attractive place to innovate," she said, adding that SPCs were created to make up for the incredibly long development and regulatory processes medicines go through.

### **DON'T ATTACK THE INNOVATION SYSTEM**

Peter Bogaert, a specialist in life sciences and partner with the law firm Covington & Burling, shares a similar view.

"The incentives which are built in the pharmaceutical regime and especially the SPCs and the regulatory exclusivity aim to work as a stimulus to develop new products in order to basically continue the innovation in the long term," he told EURACTIV.

Bogaert admitted that there might be models where one has a more fine-tuned approach to the prices but one should not attack the innovation system purely in order to get cheaper products because then "you are undermining the incentives for new products and this reduces the level of innovation in the industry".

"The IP aims to give certain

exclusivity rights, it's a stimulus to innovate and develop new products and the basic idea is that you can get a good financial return on innovation efforts," he emphasised.

In addition, there are voices suggesting a moderate solution that will ultimately favour public health. An EU diplomat told EURACTIV in Brussels that a "consensus" was possible considering that all stakeholders on the table will have their ears open.

"We neither can fully accept the public health NGOs arguments about incentives nor fully disregard the pharma industry concerns about innovation [...] practically we are talking about patients and it's their life at stake," the diplomat explained, adding that the pharma industry should "no way" be discouraged from innovating.

### **IP NOT LINKED TO INNOVATION**

Following a request by the EU Council, the European Commission is currently doing a review of the incentives and by the end of this year or in the beginning of next year it's expected to come up with a study.

Clemens Martin Auer, EHFG President and Director General at the Austrian Federal Ministry of Health and Women's Affairs, said it was unprecedented that the EU health ministers should ask the Commission to do something like that.

"Because the ministers are concerned that there might be disincentives in the market regarding certain aspects of the IP (intellectual property) regulation, not the IP regulation in general. This is a misunderstanding in the public discussion that some pharmaceutical representatives are doing, maybe on purpose," he said.

Auer added that not only the

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Commission but OECD and WHO are doing it as well

“Because if one looks deeply into this issue, one will find out that IP, in general, is not always linked to innovation. IP is about granting market exclusivity and this is a totally different topic than innovation. It has to be a balanced approach,” he emphasised.

### **‘WE NEED AFFORDABILITY AT THE END OF THE DAY’**

Dr Suerie Moon, a Research Director and Co-Chair of the Forum on Global Governance for Health at the Harvard Global Health Institute, does not share the pharma industry’s concerns.

Dr Moon highlighted the “fear” of policymakers to touch on IP systems, claiming that if a system is not delivering the outcomes society wants,

then that policy needs to change.

She told EURACTIV that the current tools, including the IP system, were very “blunt, not well calibrated to get certain types of innovation”.

“That’s, for example, why we don’t have any new classes of antibiotics,” she stated, adding that policymakers need to figure out the right mix of incentives and regulations that would generate both the innovations that society needs as well as ensuring that they are affordable.

For Dr Moon, patents can be licensed to multiple suppliers, so it is not a question of patents or no patents. “But if a firm has a patent on a medicine, the government could conduct a patent buy out – the idea is that the government gives a prize to the firm, because the firm has developed a useful new product, and in exchange the government is able to purchase the medicine at the generic price,” she noted citing as an example Australia with hepatitis C.

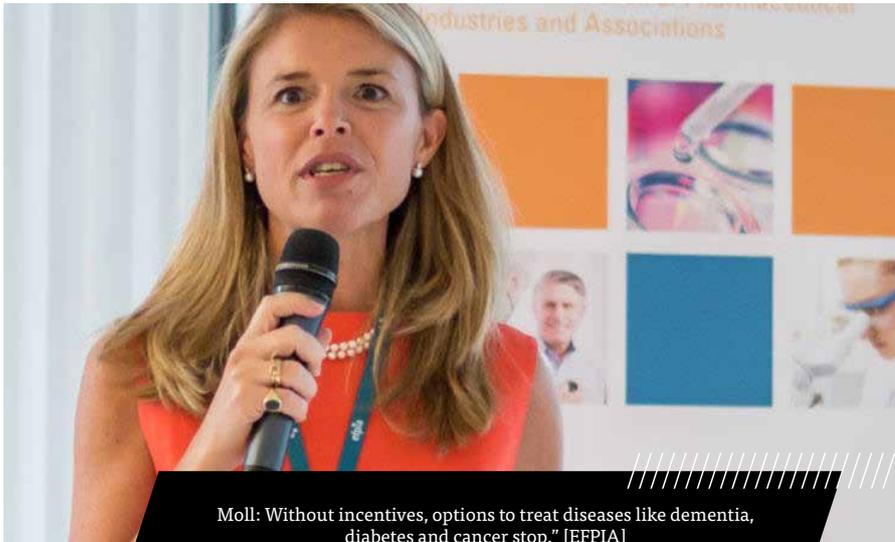


INTERVIEW

# Pharma boss: Targeting drugs won't make healthcare systems more sustainable



By Sarantis Michalopoulos



Moll: Without incentives, options to treat diseases like dementia, diabetes and cancer stop." [EFPIA]

Michalopoulos on the sidelines of the European Health Forum in Gastein.

**Last June EU health ministers asked the Commission to come up with a report regarding the reexamination of incentives for the pharma industry. Could this impose a potential threat to innovation in the pharmaceuticals sector?**

Incentives are the foundation on which all medical innovation is based. It's what gives investors and innovators the confidence to take that moonshot, open up a new treatment pathway, deliver the next piece of incremental innovation then navigate the long, complex and risky road to bring a new treatment to patients.

It's about giving assurance to innovators that their often huge investment in developing a new treatment is protected. That their innovation can't be copied by people that have undertaken none of the risks, none of the years of research, none of

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“Salami-slicing” the cost of medicines, which represent almost one-fifth of health system budgets and are subject to rigorous value assessments, won't make healthcare systems more sustainable in the future, Nathalie Moll told EURACTIV.com in an interview.

Instead, healthcare systems, which are under pressure from an ageing

population and increased prevalence of chronic disease, should be re-oriented towards delivering health outcomes rather than interventions, Moll added.

*Nathalie Moll is the Director General of the European Federation of Pharmaceutical Industries and Associations (EFPIA).*

*She spoke with EURACTIV's Sarantis*

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the frustrations and failures along the way to develop a new treatment.

Without incentives, innovations stop. New options to treat diseases like dementia, diabetes and cancer stop. De-value it and you risk the 33 billion investment in research and development moving away from Europe to regions that value, and are competing for, the knowledge-based economy.

***Policymakers aim to change some aspects of the intellectual property, such as the Supplementary protection certificates (SPCs). Even one month more of IP protection is crucial for the pharma industry, but it's crucial for policymakers as well.***

The European framework of incentives is an interlinked, package of measures that work together to protect innovation and drive research to areas of unmet medical need. Devalue any aspects of the framework and it has a negative impact on innovation and makes Europe a less attractive place to innovate.

For example, SPCs were created to make up for the incredibly long development and regulatory processes medicines go through. Out of the 20 years patent protection, less than half of that will be with your medicine actually on the market. The SPC is an attempt to replace some of that time lost up to a maximum of 5 years. It is a tool that is delivered on a case by case basis in a very careful manner and that

can be challenged and is challenged on occasions. It is not just an automatic system. As we see other countries and regions adopting SPCs and strengthening incentives, it says to me that the importance of incentives in protecting innovation and attracting research is well recognised.

***What is your opinion about the generics' claims about the manufacturing waiver?***

An SPC manufacturing waiver would be detrimental to innovation, to research and development in Europe and to the economy as a whole.

It would be sending a concerning signal about the EU's respect for and seriousness about building a knowledge-based economy. This would also be at odds with the block's trade policy, in which the EU has consistently argued against localisation policies and in particular against using IP tools to favour domestic production. There are also potential export losses to European originator companies resulting in a drop in export value for the EU.

Several studies have shown that any potential benefits to European generic manufacturers are minimal. The window of opportunity for exporting European generics to non-European markets prior to European SPC/patent expiry is often quite limited, as loss of exclusivity would either be earlier or not significantly later than SPC expiry in European markets.

In contrast to the development of a knowledge-based economy, any

potential benefits are also likely to be short-lived, as an SPC waiver would certainly encourage other 3rd/ potentially importing countries, which are more competitive from a manufacturing perspective, to take similar measures, negating any benefit for generic manufacturers and the economy in Europe.

If you are manufacturing for export into less developed countries, say India or China, the experience even our smaller companies have had is that they don't stand a chance because the local producers are in that market at very competitive prices. So we need to carefully examine all the claims to see who a waiver would really benefit.

***As a representative of the pharmaceuticals sector, what would you advise EU countries to do in order to save costs, instead of focusing on drugs pricing?***

According to OECD figures, medicines costs represent around one-fifth of health system budgets and salami-slicing one of the only elements of healthcare budgets that are subject to rigorous value assessments is not going to make healthcare systems under pressure from an ageing population and increased prevalence of chronic disease more sustainable in the future.

By re-orienting healthcare systems on delivering health outcomes, rather than on delivering interventions, many stakeholders, including EFPIA, believe

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that we can put healthcare systems in Europe on a more sustainable path.

By determining exactly what type of intervention brings the best health outcome for each patient, and directing our resources to those specific measures facilitates better health outcomes and quality of life for patients. By eliminating spending on ineffective interventions, a focus on outcomes can free up the resources required to address the healthcare needs of an ageing population and fund those innovations that deliver positive results for patients and value for systems.

The potential for waste reduction is significant. It is estimated that 20% of healthcare spending is currently wasted on ineffective interventions. Again, it requires new ways of working, greater collaboration and is predicated on a data infrastructure that can capture and analyse healthcare data to help identify waste. System-wide change takes time but there are many fantastic examples of this happening across Europe.

Here in Gastein, we were calling for a conversation across all actors in European health care to look at healthcare spending as a whole, to optimise who we use our resources to deliver the most we can for patients.

**Considering the complicated decision-making procedures that currently exist at EU level, what should be done in order for eHealth solutions to take centre stage in the discussion? How**

**can it be taken from theory to practice?**

There is a lot that can be done to help Europe realise the potential of eHealth and healthcare data both in terms of research and shaping patient care. Standardising definitions of outcomes, developing standards for collection of data, ensuring interoperability of systems and consistent implementation of the data privacy legislation across member states to name a few. There are a number of very practical examples where EFPIA and its members are engaged in helping create the infrastructure to help realise the potential such as the IMI Big Data for Better Outcomes project or the European health data network that brings together secondary care sites across Europe to work together and pool their data in a standardised way so it can be analysed.

**But the point is that this value-based approach using real data, the industry is trying to push for it in order to justify its innovation. But can the member states play a role in this?**

Developing value-based approaches to healthcare that deliver more for patients and realising the potential of healthcare data are not industry initiatives. They are critical for the whole healthcare community as we try and address the challenges presented by an ageing population.

Member states and the EU can play a vital role. For example, EU structural funds that are focussed on

innovation could be used in countries to make sure the data collection capacities in hospitals and other places are geared towards collecting real-world evidence. Many member states are driving the change to a more patient outcomes-focused approach predicated on the use of healthcare data.

As an industry, we are part of this dialogue and are keen to play our part. But really this is about system-wide change, learning from the fantastic examples of best practice we see emerging across Europe.

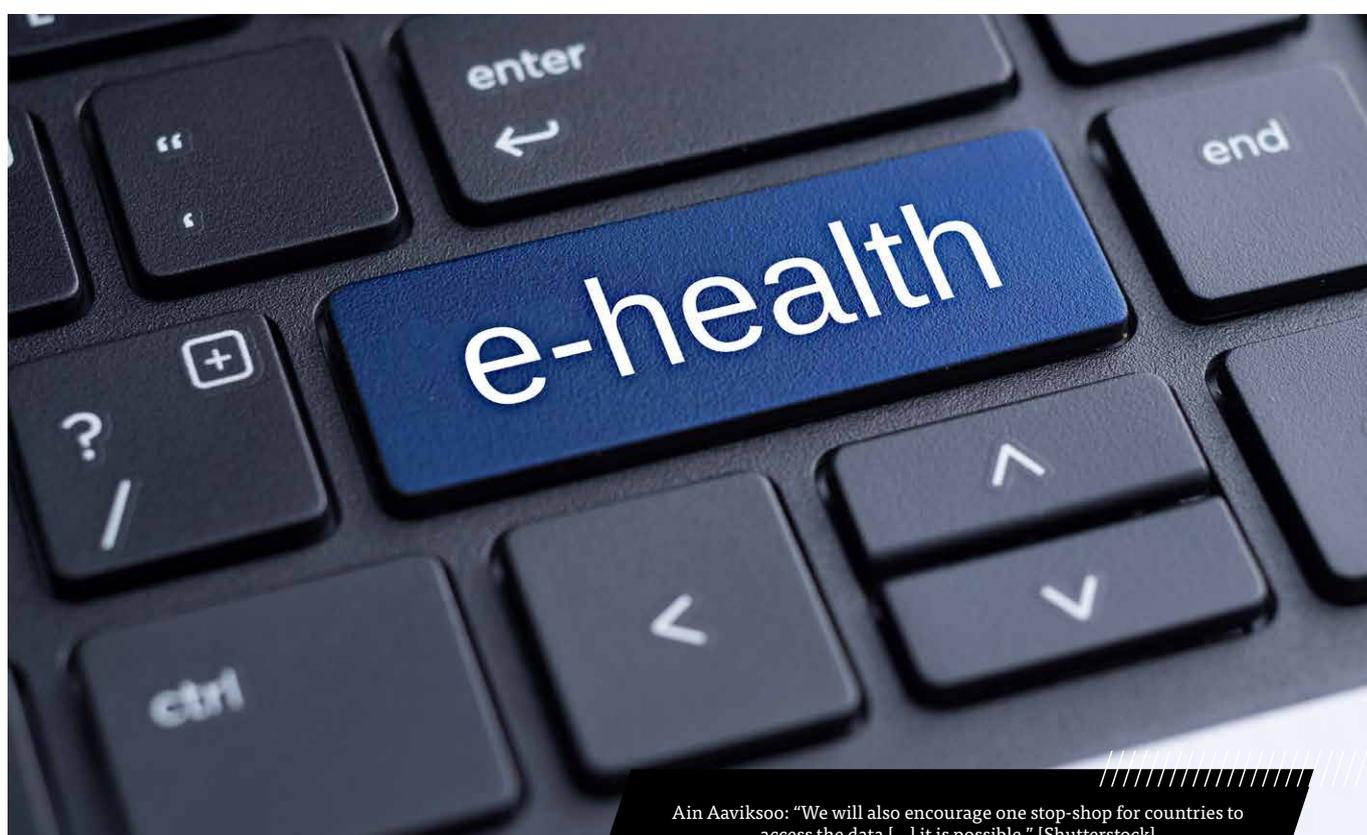
**One last question about the EMA relocation. The European Commission has made its assessment regarding the different needs, now it is up to the member states to decide. This could result in a political decision as well. Do you fear that a political decision would disrupt the drugs market in Europe?**

You are right, the future location of the EMA is a decision for the member states to make. It has to be based on supporting the continuity of the Agency's critical functions, its ability to retain staff and access to expert networks. Basing the decision on right criteria is vital for the EMA and for the public health of citizens across Europe.

# Estonian official: Coalition of the willing can 'drive' healthcare data in Europe

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By Sarantis Michalopoulos



Ain Aaviksoo: "We will also encourage one stop-shop for countries to access the data [...] it is possible." [Shutterstock]

**A**s long as the political will exists, a coalition of EU member states can speed up healthcare data mobility in Europe and start showing cross-border results in order to encourage others to join, an Estonian government official told EURACTIV.com.

Speaking on the sidelines of

the European Health Forum in Gastein last week (4-6 October), Ain Aaviksoo, who is responsible for e-services and innovation in Estonia's Ministry of Social Affairs, talked about the importance of healthcare digitalisation and the efforts that his country has made during its EU presidency to speed up the adoption of digital procedures.

He stressed that technology by itself is powerless but said it has a huge potential if applied correctly.

"We can gain efficiency, we can get a more targeted, more precise approach, we can personalise, we can get quicker diagnoses. So if we apply it at the right place to the right people, it

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can also provide savings.”

### DATA MOBILITY: THE 5TH FREEDOM

Speaking about his country’s EU presidency focus, Aaviksoo said making advances in digital in all policy areas was important. “The mobility of data is the potential 5th freedom in Europe,” he said.

The cross-border flow of data has taken centre stage in the discussion in Brussels. When citizens move to another EU member state, their healthcare data is in fact simply “lost”.

“People move and their data doesn’t follow them. And they are therefore missing out on good solutions,” Aaviksoo said, stressing that the main reason is the market fragmentation caused by data protection barriers.

The official cited an eHealth solution that offers crowd-based services for stroke rehabilitation services, but which is only available in Estonia. “There are limited applications in Germany, but for that, this company needs to open different offices in other regions in addition to Estonia,” he said.

He added that it’s more a question of implementation hurdles than actual legal barriers, as different member states have different limitations. But in reality, even where the law would allow for the offering of services, other countries are still hesitant.

“Therefore we want to proceed with our presidency to encourage those member states that are willing and able to share the data to do it, and to show the way to those others who may need to change,” the Estonian official emphasised.

“So the political will is there. Now the implementation can start with those who are capable of going ahead first and show results in a cross-border manner on a European scale pretty soon.”

Estonia has not proposed any new legal initiatives, but according to Aaviksoo, Tallin is proposing a coalition of the willing consisting of member states that are backing it with their own national investment. “But also we have very good collaboration with the Commission, who is seconding that, and also the private sector is coming.”

“By the end of this year, we hope to collect as many signatures as possible to what we call a letter of intent.”

### HOW DO WE SOLVE DATA PROTECTION?

According to the government official, member states can apply internal additional measures when it comes to health data. The coalition of the willing enables, at a minimum, implementation of the EU’s data protection regulation.

“We have very strong reasons to believe there is actually an increased consensus among many member states that the combination of what we call technology, legal framework and data governance is what needs to be adjusted in specific countries. So it is not specific laws, but really how you apply that,” he said.

He also pointed out that secondary use of medical data for research purposes has to be there.

“We will also encourage a one-stop-shop for countries to access the data, [...] it is possible.”

### THE “BLACK BOX”

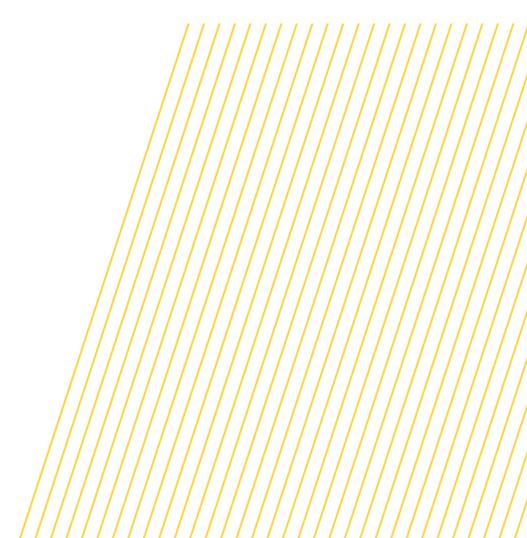
Clemens Martin Auer, EHFG president and director-general at the Austrian Federal Ministry of Health and Women’s Affairs agreed that the biggest challenge was that there is a broad consensus at the policy level that ITC and health, or eHealth, is one of the most important innovative drivers in the healthcare sector.

“And especially for organising the continuous care in the fragmented

world of healthcare services,” he said.

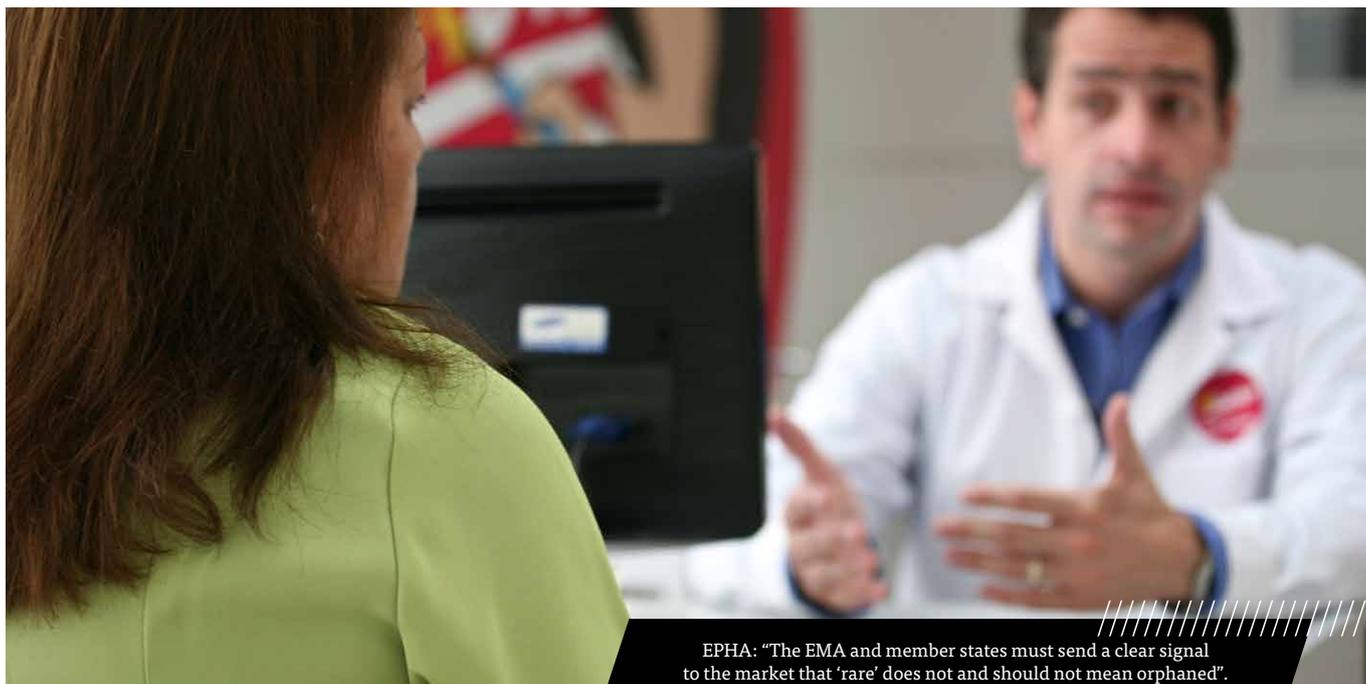
He noted that a coalition of the willing to a certain extent is true but the largest countries, such as Germany, are a “black box”.

“Continuity of care is about transferable data. So we have to organise interoperability. But in a fragmented world to organise interoperability is a challenge. So there we are. Can we agree on a European coding system? No, we can’t, because certain member states have certain approaches to this ontology, this coding system. We are getting there, but these processes are slow and need a lot of conviction and convincing people.”



# Patients: 'Think carefully' before questioning orphan drugs' incentives

By Sarantis Michalopoulos



EPHA: "The EMA and member states must send a clear signal to the market that 'rare' does not and should not mean orphaned".  
[Alex Proimos/Flickr]

Organisations of patients with rare diseases have warned EU policymakers to "think carefully" before reviewing the incentives in the orphan drugs regulation, claiming that the pharma industry should not be discouraged from investing in new therapies.

With national health budgets under pressure by austerity, health ministries are seeking ways to cut drug spending by focusing on industry incentives.

Pharmaceutical companies, for their part, cite OECD figures pointing that drug expenditure has remained stable at 15% over the past years. They

also claim that cutting spending could pose a threat to innovation and that there are other ways of cutting costs in the healthcare sector.

In June 2016, EU health ministers called on the European Commission to perform an overview of the current EU legislative tools and incentives that aim to facilitate investment in the development of medicinal products.

The 2000 orphan drug regulation could be part of that review. The regulation includes special incentives (market exclusivity, regulatory data protection) for the industry and orphan drugs, which are used for rare diseases and are marketed at high prices.

The European Commission should consider a "revision of the regulatory framework on orphan medicinal products without discouraging the development of medicinal products needed for the treatment of rare diseases," the EU ministers said in their 2016 conclusions.

However, the fine line between the need for pharma innovation, affordability and patients' safety in practice proves hard to identify.

**'EXCEPTION BECOMING THE RULE'**

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Yannis Natsis, Policy Manager at the European Public Health Alliance (EPHA), said the problem with orphan drugs is the growing number of medicines obtaining the orphan drug designation.

“So, the exception seems to be becoming the rule,” Natsis told EURACTIV.com at the European Health Forum Gastein last week (4-6 October).

Another issue is that orphan drugs often come to the market with very limited and incomplete data. “They are supposed to be for very limited sub patients’ groups but they reach the blockbuster status very quickly,” Natsis said.

“This is why the companies see a business opportunity – every drug wants to be an orphan drug.”

Natsis admitted that the 2000 orphan drug regulation has encouraged many good drugs to be placed on the market. But he believes that incentives have been used more for profit maximisation rather than genuine innovation.

“We need to have an extensive review of the system. There is nothing wrong with looking back and learning from our mistakes.”

The European Medicines Agency (EMA) said policymakers should fully exploit the legal possibilities to reduce protection periods for orphan medicines that do not meet the criteria.

Orphan drugs enjoy a 10-year market exclusivity but according to the regulation, this period could be reduced to six years when there is sufficient evidence that the product is profitable at the end of the fifth year.

“The EMA and member states must send a clear signal to the market that ‘rare’ does not and should not mean ‘orphaned’. We need to uphold the spirit of the orphan legislation but not encourage the abuse of the incentives,” Natsis emphasised.

## ORPHAN DRUG REGULATION IS A SUCCESS

Patients with rare diseases would be directly impacted by a review of the orphan drug regulation incentives considering that they are already faced with accessibility issues, delays, or absence of medicines.

Simone Boselli, Public Affairs Director of Rare Diseases Europe (EURORDIS), which represents patients with rare diseases, agrees with EMA’s proposal to eventually reduce protection periods for orphan medicines that do not meet the criteria over time.

But he insisted that, contrary to what many believe, the orphan status of a product is not easy to obtain in Europe, and is not meant to last forever.

From all orphan designation applications submitted to the EMA, only 72% receive a positive opinion for designation, he pointed out. And 27% more will be losing their orphan status at the time of receiving their marketing authorisation.

“This shows that the evaluation of the orphan status is strict and only for therapies addressing unmet medical needs or non-satisfactory treatments,” Boselli said.

However, EURORDIS is fully against a review of incentives in the orphan drugs regulation, a move supported by the European Public Health Alliance (EPHA), a grouping of health NGOs.

The patient organisation claims that the orphan regulation has succeeded in fulfilling its primary goal of attracting investment in the development of therapies for life-threatening or debilitating diseases for millions of people who have today either no treatment at all or no satisfactory treatment. This success should be attributed to the incentives granted by the regulation, they claim.

“To date, 143 products have been approved under the EU Orphan Drug

Regulation since its adoption, 97 of which are still currently holding orphan status after their period of market exclusivity, hence open to head-to-head competition. This is a genuine success, and one that should be celebrated proudly by all,” Boselli told EURACTIV.

As far as the high prices argument is concerned, Boselli highlighted that amongst 70+ orphan medicines approved by EMA up to April 2014, 24% of them had an annual cost below €11,000, and only 18% of them an annual cost higher than €111,000.

“It is also fair to point out that most orphan drugs are to treat cancers and prices of orphan medicines in cancer are not more expensive on average than other new cancer therapies. Simply put, some innovations are expensive, but it is not just orphan products,” Boselli stressed.

## TURNING INVESTORS ELSEWHERE

EURORDIS also believes that without the current incentives, investments that have been encouraged by the legislation will most likely be channelled to other segments of the economy offering higher returns, rather than health and pharmaceutical research for rare diseases.

“We should think carefully about the long-term consequences of criticising current incentives, which could very quickly create sufficient concern or unpredictability to deter investors, pharmaceutical and biotech companies from investing their resources into the research and discovery of new rare disease medicines,” Boselli said.

“In order to link innovative science with the economy and the real therapeutic added value with value for money, we need to not challenge the EU Orphan Drug Regulation,” Boselli concluded.

# New Commission study fuels generic drugs industry 'manufacturing dispute'

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By Sarantis Michalopoulos



EFPIA: "An SPC manufacturing waiver would be detrimental to innovation, to research and development in Europe." [Tom Small/Flickr]

The European Commission launched on Thursday (12 October) a public consultation on supplementary protection certificates for pharmaceutical products and the so-called Bolar patent research exemption.

Global medicines spending is expected to shift toward generic drugs, with an expected rise from 27% in 2012 to 36% of total sales by 2017, according to a Commission staff working document that accompanied the EU executive's 2015 Single Market Strategy Communication.

"Generics and biosimilars could represent 80% of the volume of medicines by 2020," the document reads.

The Commission announced its intention to add a manufacturing waiver to supplementary protection certificates (SPC) as part of its upgraded Single Market Strategy in 2015.

An SPC is an intellectual property right that serves as an extension of a patent right in the EU. With a manufacturing waiver, generic drugs makers can manufacture SPC-protected drugs in the EU to sell in other markets, and to prepare stocks

for when the SPC expires.

The Commission document continues, saying that an SPC manufacturing waiver for exports to countries outside the EU could allow the EU generics and biosimilars industries both to create thousands of high-tech jobs in the EU and start many new companies. The industry is currently import-dominated.

"Between 54% and 70% of the active pharmaceutical ingredients market in Europe (depending on the member states) is supplied

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by India, China and Israel. Active pharmaceutical ingredients manufactured in Poland, for example, have significant penetration in some of its neighbouring markets, but a negligible one in the EU-15 market.”

The regular patent for a pharmaceutical product in the EU is 20 years but an SPC can extend this patent right for a maximum of five years. Specifically, SPCs aim to offset the loss of patent protection for pharmaceutical products that occurs due to the compulsory lengthy testing and clinical trials these products require prior to obtaining regulatory marketing approval. This period can last 12 years.

The generic industry is keen to obtain this SPC manufacturing waiver so it can start manufacturing drugs even while an SPC is in place.

Its main argument is that this will ensure better access to generics, as the drugs will be available from day one of the SPC expiry in the EU.

In addition, EU-based generics and biosimilars manufacturers claim that this waiver will boost their competitiveness on a global scale.

### BOOSTING EMPLOYMENT

The study on “Assessing the economic impacts of changing exemption provisions during patent and SPC protection in Europe”, which was commissioned by the EU executive, was completed in late 2016 and published late last week.

This study, together with another titled “Economic Analysis of Supplementary Protection Certificates”, will be the main basis for a public consultation on SPCs.

The study claims that an SPC export waiver to third countries could result in net additional sales to European generic producers of up to €7.4bn by 2025, taking into account the potential negative impact on the

EU-based branded export sales.

Referring to data from Medicines for Europe, which represents the European generic, biosimilar and valued added pharmaceutical industries, the study noted that the EU generic and biosimilar industry directly employs 160,000 people.

Such an export waiver could bring an additional 20,000-25,000 jobs, representing a 13-16% increase in employment.

“We estimate the net additional sales to EU-based generic producers that could result from an SPC export waiver within Europe to range between €207.9m and €416m by 2025, depending on assumptions regarding the diversion from other European generic and branded producers,” the study emphasises.

Adrian van den Hoven, Director-General at Medicines for Europe, told EURACTIV.com that the public consultation on the SPC manufacturing waiver is perfectly in line with the renewed EU Industrial Policy Strategy recently launched by the executive.

“The SPC manufacturing waiver is the engine for a smart and sustainable European industry,” he said, adding that this is the “perfect mix” to guarantee patients’ access to medicines by increasing jobs and growth while boosting the competitiveness of European SMEs across and outside the EU.

### IT WILL ‘KILL’ INNOVATION AND INVESTMENTS

On the other hand, the pharma industry does not share this view and warns of possible severe implications on innovation and investment in the EU.

“An SPC manufacturing waiver would be detrimental to innovation, to research and development in Europe and to the economy as a whole,” Nathalie Moll, the Director

General of the European Federation of Pharmaceutical Industries and Associations (EFPIA), told EURACTIV.

The pharma boss claimed that for European SMEs in the life sciences sector, which are considered critical for innovation and growth, such a waiver would make attracting investment more difficult as investors look for the most favourable intellectual property (IP) environment to decide on their investments and can find such environments elsewhere.

“Europe is no longer alone in terms of attracting investment in R&D for innovative start-up to SMEs and larger innovative industries. Many regions of the world are equipping themselves with extremely attractive incentives which compete against European investment attractiveness.”

### MINIMAL BENEFITS

For the pharmaceutical industry, such a waiver would send a worrying signal about the EU’s respect for, and seriousness about, building a knowledge-based economy.

“This would also be at odds with the block’s trade policy, in which the EU has consistently argued against localisation policies and in particular against using IP tools to favour domestic production. There are also potential export losses to European originator companies resulting in a drop in export value for the EU,” Moll emphasised.

As far as long-term benefits for EU-based generic manufacturers go, EFPIA pointed out they would be “minimal”.

“The window of opportunity for exporting European generics to non-European markets prior to European SPC/patent expiry is often quite limited, as loss of exclusivity would either be earlier or not significantly later than SPC expiry in European markets.”

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Moll went further, claiming that any potential benefits are also likely to be short-lived, as an SPC waiver would certainly encourage other third potentially importing countries, which are more competitive from a manufacturing perspective, to take similar measures, negating any benefit for generic manufacturers and the economy in Europe.

Some suggest that the generics companies will stockpile in Europe and flood the market with generic drugs when the SPC expires. Asked whether this was already happening with generics manufactured outside of the EU, Moll replied, "Currently generic medicines are often launched in Europe immediately upon SPC expiry, especially in the case of products with large market shares."

"In fact, in some cases products are launched 'at risk' by generic companies, before the SPC expiry. This practice would be facilitated by such an exemption and one could assume that stockpiling for launch in Europe when the SPC expires, rather than for export, could also occur as a consequence of introducing an SPC manufacturing waiver."

## A NEW STUDY

In addition, a new study, which was commissioned by the pharma industry and the US Chamber of Commerce, was released on Thursday (12 October) and is in direct opposition to the Commission's findings.

It says the implementation of an EU-wide SPC manufacturing and export exemption would potentially result in annual losses ranging from €2.26bn up to €4.52bn to the global innovative biopharmaceutical industry.

Of these losses, up to €1.92bn concern the European innovative biopharmaceutical industry.

As far as the impact on employment and R&D investment in the biopharmaceutical sector is concerned, the study claims that a manufacturing waiver would cause between 4,500 and 7,700 direct job losses (with an additional 19,000-32,000 indirect job losses) and a decrease in R&D investment of between €215m and €364m.



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