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## ELECTRONIC IMMUNISATION RECORD

SPECIAL REPORT | 6 - 12 OCTOBER 2017  
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# Commission backs electronic immunisation record to manage vaccination

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By Sarantis Michalopoulos



Andriukaitis: "This is necessary, absolutely. It's a big step for coordinating member states needs." [Tasos Fokas]

Updated with EU Health Commissioner Vytenis Andriukaitis comment.

The European Commission supports the creation of an electronic immunisation record system that will help EU member states enhance their cross-border cooperation and simultaneously enhance prevention of infectious diseases.

An increase in vaccine hesitancy combined with the insufficient preparedness of the EU member states' healthcare systems against infectious diseases, has raised eyebrows in Brussels and the EU capitals, which now seek ways to minimise the outbreaks risk.

A recent example was the measles outbreak, which has so far caused 42 deaths in EU countries in 2016 and 2017. According to the European

Centre for Disease Prevention and Control, the measles outbreaks in the EU are still on the rise, posing severe threats for the public health.

E-Health solutions are emerging as a crucial means to strengthen national healthcare systems and provide them with tools that will help policymakers encourage vaccination as well as monitor its proper implementation.

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EU Health Commissioner Vytenis Andriukaitis told EURACTIV that “this is necessary, absolutely. It’s a big step for coordinating member states needs”, showing how seriously the EU executive is taking this measure.

“The digital revolution is here and in many cases it’s moving faster than it was previously expected. So, we have to benefit from it, not just live with it,” told EURACTIV Martin Seychell, Deputy Director General of the European Commission’s DG Sante.

### COMMISSION AMBITION

Speaking at the “Exploring the needs and future developments of immunisation records in the EU” session at the European Health Forum Gastein in Austria, Seychell highlighted the importance of an immunisation record system (electronic version of vaccine registries) to enhance prevention in the EU.

An immunisation record system provides a history of all the vaccines adults or children have received. Through this data gathering, EU countries will be able to properly monitor the vaccination of the population and upgrade cross-border cooperation in the event of diseases’ outbreaks.

Such a system will also help EU citizens, who need treatment or move to another country, be able to present their whole health record.

“If you have commonly agreed rules it’s easier to work together [...] as for infectious diseases, member states need to be jointly prepared, not just individually.”

Seychell said the executive was supportive of the idea. “We are working on the digital agenda and health is an important part of that,” he noted.

According to the EU official, immunisation records will enhance

the prevention of diseases across Europe, considering that a potential threat is by its nature cross-border.

“The countries have realised that they need information not only about their own situation but also about other countries as well,” he explained, adding that there is a wider view that things need to be accelerated.

Some EU countries have taken technological steps in this direction but there are others, which start just now. The Commission claims that for those who have already invested in specific technologies, past investors should be protected.

Another key issue is the funding. Some EU money is already being used from the Connecting Europe Facility, but looking at the next financial framework “this is something we need to keep firmly in mind,” Seychell said.

There are also several technical and legal issues along the way and the executive warns that they should not be underestimated.

### DATA OWNERSHIP

The collection of data has taken center stage in the discussion. For Seychell, the reason why ethical issues are so strong in the ownership issue is that people do not owe their health data.

“Part of it is in a hospital, in GP’s clinic or to employers,” he noted, adding that patients should be in the core of the talks.

“If we establish the ownership rights then most of the problems will disappear because it’s now my data and then we are talking about delegation,” he explained, citing as example the data donation or sharing it with GPs.

The Commission official continued, saying that citizens are not really worried about data being used in advanced public health or advanced new treatments. “What they want to ensure is that the data will not be misused by those who should not use them or use them for the bad purpose,”

he stated.

“That means we need to have a strong and good governance. Like we do in many other aspects where data is also sensitive,” he concluded.

### WIDENING VACCINATION COVERAGE

During the event, a French website was also presented, which manages immunisation records and hopes to increase vaccination coverage rates.

Through this tool, which is called MesVaccins.net, one can get personalised information on vaccinations and share data with healthcare professionals.

“Vaccine hesitancy is growing while vaccine recommendation is evolved rapidly and getting increasingly complex [...] thus it’s difficult for the general public to understand and apply the vaccine recommendations,” project founder Jean-Louis Koeck said.

Koeck insisted that the complexity around vaccination is offered as an opportunity for anti-vaccines movements, which are pretty well interconnected and “can spread simple but false messages through the Internet without any control”.

“We are trying to simplify through personalisation [...] that’s a new way to prevent vaccine hesitancy at a large scale,” he noted.

In a recent interview, Commission Vice President Andrus Ansip said digital identity could be extremely helpful for the vaccination of children in Africa, to keep track of vaccinations made and avoiding repeated vaccinations, which can be dangerous.

## INTERVIEW

# Vaccines boss: Clear privacy rules are needed for electronic immunisation record system

By Sarantis Michalopoulos



Patricia Massetti: "Harmonisation is important for an electronic immunisation record system to work. Only in this way can proper data flows and usage be ensured." [Tasos Fokas]

**A**n electronic immunisation record system, which aims to better monitor vaccination among populations, will need clear privacy rules and individuals should be the owners of their own data, Patricia Massetti told EURACTIV.com in an interview.

Patricia Massetti is an associate vice-president and European Vaccines Lead at MSD. She is also a Board member at Vaccines Europe, which represents the major European vaccine companies.

She spoke to EURACTIV.com's Sarantis Michalopoulos on the sidelines

of the European Health Forum in Gastein (4-6 October).

**A number of EU countries have been experiencing large outbreaks of measles in 2017. Many see the**

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***movement against vaccines behind the case. What went wrong? Is it down to a lack of communication? Is it a policy problem?***

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I would argue that it is due to a number of reasons, which are all interconnected. Yes, vaccine hesitancy is definitely a factor, but it's not the only one. Infectious diseases do not respect national borders.

In Europe, we need to set a common roadmap involving governments, health authorities, scientific societies, healthcare professionals, civil society and industry. This is the objective of the Joint Action on Vaccination launched by the Commission earlier this year. The Joint Action aims to provide the much-needed political leadership to move forward and ensure public health crises, such as the measles outbreak, do not re-occur.

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***How can EU policymakers put an end to the growing scepticism towards immunisation?***

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Addressing vaccine hesitancy is not an easy task. Different factors such as confidence, convenience or complacency must be taken into consideration. Vaccination hesitancy may lead to decreased vaccination coverage. Therefore, maintaining confidence in it is critical for sustainable immunisation programmes to ensure good public health.

There is no single solution to all these issues, but there are a number of relevant stakeholders who can help in addition to policymakers. For example, healthcare professionals have proven to be an important determinant in vaccine uptake. This is relevant for them but also in recommending vaccines to the general public as well as to at-risk populations. Additionally, access can be a barrier. As a result, some countries have extended their

access points for vaccination by considering alternative channels. An option includes vaccination by pharmacists and onsite vaccination in hospital wards.

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***What are the main challenges vaccines are currently facing within the EU?***

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As mentioned by the European Commission at the European Health Forum Gastein, fragmentation is one of the major issues Europe is facing. This pertains to healthcare systems and directly affects successful implementation of existing immunisation programmes.

The absence of common tools to monitor vaccine coverage rates, and predict potential outbreaks, is an important issue and can be the cause of supply and demand challenges within countries.

This is frustrating as vaccination is one of the greatest public health success stories of the last two centuries. Disease prevention enables better health outcomes, while also reducing unsustainable expansion in health spending. Of course, this is a debate that needs to take place under the umbrella of a more general discussion on health systems and their focus. Prevention should be a key priority.

Vaccines Europe has identified a number of areas, which could significantly strengthen vaccination in Europe such as reinforcing European surveillance capabilities to support National Immunisation Strategies and Programmes, engaging healthcare professionals in actively increasing vaccination coverage, addressing the root causes of vaccine shortages, and ensuring an open and continuous multi-stakeholder collaboration to overcome barriers/blocking factors to the discovery and development of the next generation of vaccines.

The upcoming Joint Action on Vaccination will have a major role in the development of effective guidance

to support the establishment and implementation of well-functioning national immunisation programmes in member states.

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***In what way could the EU member states better monitor the vaccination of the population? Do you support an EU-wide approach?***

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Monitoring population vaccination is a very difficult endeavour given the current context. The systematic collection, analysis and dissemination of health-related data are essential for decision-making and public health at all levels. We need data for evidence-based programmes and assessing the effectiveness of what is being done.

Furthermore, as we heard at the 'Exploring the needs and the future developments of immunisation records in the EU' EHFG event, an electronic immunisation record system (also called Informed Immunisation System or IIS) would represent an important part of the solution. Through this data gathering, EU countries would be able to monitor properly the vaccination rates of the population and enhance cross-border cooperation in the event of disease outbreaks.

Ideally, we are hoping for a European Immunisation Registry fed by national systems. However, major obstacles, such as data ownership and protection, interoperability within the healthcare systems, uniformity of data coding, IT performance and funding have to be overcome.

The current focus on eHealth and the EU's Digital Single Market provides an opportunity for immunisation information systems to become an integral part of electronic health systems and benefit from a structured framework.

During that workshop, it was also said that the European Centre for Disease Prevention and Control

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(ECDC) is working on guidelines for immunisation registries to be used by all member states, expected early 2018. Of course, it's too early to tell how this could work, as there is a series of challenges that need to be addressed such as interoperability of these systems and compliance with already existing ones. However, we could see that a concrete action plan is now underway.

**How do we deal with the data collection issue? Will the member states take over that responsibility?**

We would need a clear EU-wide mandate and approach. I mentioned the challenge of interoperability. This cannot be solved without an EU-wide approach. We could go into many more details here and discuss all kinds of legal, operational, semantic and technical obstacles, but I am afraid I would have to keep you here for hours!

All these obstacles can be overcome through cooperation between the member states with the guidance of the European Commission. Harmonisation is important for an electronic immunisation record system to work. Only in this way can proper data flows and usage be ensured.

Such a system also needs to be transparent and accessible to the public. Data ownership is key, and the individual should be the clear owner of his or her own data. We need clear privacy rules that will help build up trust in the system. A system that is not trusted will not work.

We need strong support for electronic immunisation record systems, allowing each citizen to manage his or her vaccination status and remain up-to-date with his or her immunisation throughout the lifespan. These systems can help increase vaccination coverage rates, prevent future outbreaks and monitor public health performance. They can also potentially allow for personalised recommendations on vaccination according to the individual's characteristics, such as health, age and gender, lifestyle and occupation. It's encouraging that the European Commission shares the same view.



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