Up to 3 million people die every year from vaccine-preventable diseases.

The rise of anti-vaccination campaigns has in recent years had a detrimental effect on EU public health as “forgotten” diseases such as measles re-appeared in Europe, raising eyebrows among policymakers.

What’s the role of patient groups in providing the right information on vaccination? What is the role of the European Commission in harmonising vaccines supply?
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Parents have a particular responsibility to protect their children, as they are more vulnerable to infections, but vaccination should be seen as a lifelong approach that applies to adults too, centre-right MEP Renate Sommer told EURACTIV.com.

"Children are the most vulnerable group and have an increased risk for infections because their immune systems are not yet strong enough. Those who refuse important vaccinations for their child are not just risking the lives of their own child; they are also risking the lives of others," the European People’s Party politician emphasised.

Adult vaccination has been given less emphasis than other health priorities. But with an aging population, the burden of vaccine-preventable diseases and their complications in adults and elderly are likely to grow.

Vaccinating these groups would allow them to stay healthy and active for longer, with fewer and shorter hospital stays, less time off work, less dependency, and a lower burden of chronic illness. In addition, increased adult vaccination coverage rates could contribute to the fight against antimicrobial resistance.

Sommer argues that an adult should get tetanus shot every ten years, for example, and that certain childhood vaccines wear off over time so an additional dose of certain vaccines is necessary to remain protected.

"Some vaccines are actually only recommended for adults, who are more at risk for certain diseases like e.g. shingles. Others have an increased risk for diseases because of travel, their job, or individual health conditions. Therefore, it is important to check Continued on Page 5
the personal vaccination record once every now and then to see whether the vaccination status is up to date,” she said.

In 2014, the Council conclusions on vaccinations as an effective tool in public health invited member states to “actively offer appropriate vaccination to population groups considered to be at risk in terms of specific diseases and to consider immunization beyond infancy and early childhood by creating vaccination programmes with the life-long approach”.

Europe is currently faced with measles outbreaks in a number of countries due to vaccine hesitancy, lack of information and the intense lobbying of anti-vaccination movements across the bloc.

According to the European Centre for Disease Prevention and Control (ECDC), measles outbreaks are still occurring in 2018 while four countries have also reported fatalities.

“There is a risk of spread and a sustained transmission in areas with susceptible populations,” ECDC said in a statement last week.

Most cases were reported by Romania (5,224), Italy (4,978), Greece (1,398) and Germany (906), accounting for 35%, 34%, 9% and 6%, respectively, of all cases reported by EU/EEA countries.

The European Commission and 20 European countries are currently finalising proposals for a joint action plan aimed at strengthening cooperation against vaccine-preventable diseases.

A Commission spokesperson told EURACTIV that the proposals, which will probably take the form of a Council recommendation, are due to be presented at the end of April.

Vaccination policy is a national competence and the proposal will aim to boost member states’ coordination and cooperation with industry and other stakeholders at EU level, in order to reinforce and consolidate vaccination programmes all over Europe, increase vaccination coverage and enhance preparedness at the EU level.

**ONLINE FAKE NEWS BOMBARDMENT**

Commenting on vaccine hesitancy, French Socialist MEP Gilles Pargneaux told EURACTIV.com that it has become a worrying phenomenon.

“Untrustworthy online sources are bombarding our citizens with unreliable, misleading and unscientific information, triggering delays or complete refusal in taking necessary vaccines,” he said.

Along the same lines, Sommer explained that there was simply no scientifically-based justification to forego vaccination or even to consciously refuse it.

“We have to explain this to the people. We need to remind our citizens of how important vaccinations are and of how serious are the consequences of failing to get vaccinated. Just because infections like polio and diphtheria no longer occur in the EU does not mean they have been eradicated around the world. The absence of these serious diseases in the EU is rather the result of a comprehensive vaccination programme lasting decades,” she noted.

Sommer also pointed to the high speed at which targeted misinformation spreads today as a reason for the drop in vaccination rates.

“The worst success of these people is when parents become uncertain as a result of the misinformation and do not have their children vaccinated in order to protect them from the allegedly bad side effects.”

“I feel that this is grievous bodily harm, as these children are rendered entirely defenseless against the most serious infections which can leave them disabled for the rest of their lives or even lead to death,” Sommer warned.
How patient groups could help tackle ‘fake news’ on vaccination

By Claire Stam | EURACTIV.com

Patient groups play a crucial role in providing the right information and thus tackling fake news on vaccination, according to experts, who say this is increasingly necessary to restore confidence in this field.

The rise of anti-vaccination campaigns has in recent years had a detrimental effect on EU public health as “forgotten” diseases such as measles re-appeared in Europe, raising eyebrows among policymakers.

Organisations representing patients insist that getting the right information on vaccination is key to providing patients in Europe with access to high-quality, patient-centred health and related care as well as to further improve safe and timely access and availability of medicines.

Patient groups are vital in providing the right information on vaccination, Sam Nye, executive director of the Confederation of Meningitis Organisations (CoMO), told EURACTIV.com.

“Up to three million people die every year from vaccine-preventable diseases, and patient groups have a vital role to play in lowering this number”, she said.

The expert added that these patient groups “lobby governments for better access to vaccines, coordinate awareness campaigns that promote the effectiveness and safety of vaccines, and also work on the ground to dispel anti-vaccine myths through sharing both scientific facts and their own experiences.”

The Confederation of Meningitis Organisations (CoMO) is an international member organisation working to reduce the incidence and

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impact of meningitis worldwide. CoMO brings together 75 patient groups, health professionals, and meningitis survivors and their families from more than 30 countries around the world.

Nye explained that many of the patient groups his organisation works with are set up by families who have been directly affected by meningitis. “The main reason they do what they do is to prevent other families from facing the pain and loss that theirs did. By sharing their stories in their local communities, they are able to highlight the importance of vaccination and the tragic consequences of vaccine-preventable diseases”, she noted.

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She warned that vaccine-preventable diseases, including the most common strains of bacterial meningitis, measles, and influenza, can strike anyone of any age.

“Patient groups raise awareness of this and provide members of the public with the information they need about how to protect themselves and those around them from these diseases. Strategies such as encouraging grandparents to protect themselves in order to protect their grandchildren are an example of methods being employed”, he emphasised.

TRUSTED AND TRAINED HEALTH MEDIATOR

For Nina Renshaw, Secretary General at the European Public Health Alliance (EPHA), the focus should be on listening to concerns and on restoring confidence by presenting complete, unbiased, transparent information from neutral sources. She cited the Cochrane Collaboration, WHO, Lancet, BMJ or ECDC as examples of reliable information.

“This information could be presented in a repository”, Renshaw told EURACTIV. “Many citizens are looking for this information but if they simply google vaccines, they will not be directed primarily to credible independent information”. She recommended not to shy away from discussing risks but to put them into context, a move which, in her view, should include an overview with links to EU-funded relevant research to date.

Furthermore, she added that the European Commission should publish conclusions of the success – or not – of their Joint Vaccine Procurement initiative. “Why hasn’t there been better uptake by member states? What are plans to extend JP? What’s the evidence base?” she wondered. “We need to better understand the reasons for those shortages”.

“A communications exercise from the EU institutions risks backfiring by doubling up on pre-existing scepticism”, she also warned. “The EU should rather support the most trusted institutions in respective countries or regions in communicating. That might be health services, health professionals, or academia, based on evidence and trust monitor”.

Renshaw gave a practical example of the positive impact targeted information had in Romania: The organisation conducted a large survey of Roma communities, which showed that of the circa 2,000 children reached by the survey, 882 were unvaccinated.

“But, good news, in around 300 communities reached by trained Roma health mediators from the local communities, they have achieved vaccination coverage of close to 100%,” Nina Renshaw said.

“So we know what works: allowing people to discuss their concerns with trusted and trained people. Could the Health mediator system be extended to other groups (including, for example, religious communities with concerns or schools in certain areas)? This approach has also proved to be very resource-efficient, but the main challenge is to make sure the EU can provide resources to ensure these jobs are long-lasting and expertise is not lost”.

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Lifecourse vaccination in Europe: Influenza prevention

**EUROPEAN POPULATION FOR WHOM FLU VACCINATION IS RECOMMENDED**

- 5% Children younger than 2 years
- 41% Persons with underlying chronic health conditions (such as cardiac, lung, kidney, liver, blood or metabolic diseases or g. diabetes, or weakened immune systems)
- 2% Pregnant women
- 48% Adults aged 65 years and over

**INFLUENZA VACCINATION COVERAGE RATE IN ADULTS AGED OVER 65**

- 44% in EU
- 75% International & European recommendations (WHO/EU Council). Target vaccination coverage rate (VCR) of 75% for the elderly should have been reached since 2014-15.

**INFLUENZA VACCINATION HELPS REDUCE COMPLICATIONS FROM CHRONIC DISEASES**

- Potential to save up to 40,000 who prematurely die every year in EU due to causes associated with influenza.

**BENEFITS OF LIFELONG FLU VACCINATION**

- Rise Influenza Awareness and Public Trust through effective communication and training.
- Promote influenza vaccination uptake among all healthcare professionals to protect themselves and their patients.
- Recognise importance of influenza burden & prevention in all recommended groups by establishing vaccination coverage rate targets in national policies in line with WHO and EU recommendations.
- Strengthen exchange of good practices at EU level and development of Healthcare Professionals' collaboration.
- Implement appropriate monitoring of influenza epidemiology and vaccination rates for effective and timely vaccination programme management and communication.

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Adult vaccination has been given less prominence than other health priorities. But given our ageing population, the problem of vaccine-preventable diseases and related complications in adults and elderly is likely to grow.

Vaccinating these groups would allow them to stay healthy and active longer, with fewer and shorter hospital stays, less time off work, less dependency and a lower burden of chronic illness.

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Commission could play greater role in harmonising vaccines supply, industry says

By Sarantis Michalopoulos | EURACTIV.com

The European Commission could play a decisive role in further harmonising the regulatory framework of vaccines and therefore avoid delays in the supply of vaccines in case of shortages or emergencies, Vaccines Europe told EURACTIV.com.

Vaccines Europe, which represents the major European vaccine companies, believes that a greater involvement by the Commission could facilitate the availability of vaccines in the EU.

Europe is a leader in vaccines with 80% of vaccines from the major research manufacturers being produced in Europe and of this, 86% exported for worldwide use.

The vaccines sector currently faces a number of challenges ranging from anti-vaccination campaigns and new cross-border infectious diseases to complex and lengthy authorisation processes.

The recent measles outbreak in Europe sparked a debate about vaccination and public awareness of the issue. According to the European Centre for Disease Prevention and Control, the highest number of measles cases since 1 January 2017 were reported in Romania (8,274), Italy (4,885) and Germany (919).

In light of these developments, and following the launch of a Joint Action on Vaccination in Europe, the European Commission is due to publish tomorrow (26 April) an EU Council recommendation aiming to

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boost cooperation among member states, reinforce immunisation programmes in a sustainable way and, above all, ensure that EU population is sufficiently vaccinated.

But the lack of harmonised regulatory framework in Europe and worldwide, the industry says, can limit the flexibility in terms of innovation and curb its ability to supply vaccines to specific countries or when facing an infectious disease epidemic.

“In example, further to initial approval, each change performed during the life of the vaccine, either in manufacturing process or composition, requires authorizations to be implemented, which, for a global company, could mean more than 100 pre-approvals, taking up to four to five years for one change worldwide,” Laura Gutiérrez, vice-president, head of public affairs Europe for Sanofi, told EURACTIV.

The vaccination policy remains a national competence and the lack of harmonisation usually comes from differences in the implementation of EU directives at the national level.

Magdalena Rodriguez de Azero, executive director of Vaccines Europe, said that over the last decades, the EU institutions had played an important role in the establishment of a harmonised regulatory framework across member states.

“The implementation of the mutual recognition decentralised and centralised procedures, as well as the mutual recognition of testing performed by the Official Medicines Control Laboratories (OMCLs), are good examples of regulatory harmonisation in the EU.”

According to the vaccines industry, there is still room for improvement and the EU executive can take steps in this direction.

“A major improvement would be the implementation of common labels and packs across the EU combined with the replacement of the paper patient leaflet by an electronic leaflet. These changes would streamline vaccine manufacturing, optimise the use of existing capacity and thereby increase supply and improve public health. These changes would also facilitate the transfer of vaccines between EU countries in case of shortages,” de Azero said.

She went further, saying the EU has a major role to play in the global harmonisation of regulatory requirements.

“We strongly encourage the European Commission to play a leading role in the reflection on harmonisation of regulatory requirements at the level of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and in the implementation of ICH guidelines in the EU,” she concluded.

VACCINES ARE NOT LIKE DRUGS

The vaccine manufacturers point out that vaccines’ manufacturing is a completely different reality compared to drugs, resulting in lengthy and complex processes.

“Compared to medicines, vaccines are highly technical biological products with complex and lengthy manufacturing, control and release processes, starting from live micro-organisms to end with safe and sterile products. Cycle times can average up to two years or more, with quality control tests representing 70% of that time,” Gutiérrez explained to EURACTIV.

Another crucial difference compared to drugs is the clinical trials.

“The biggest difference between vaccines and drugs is the larger number of individuals included in vaccine clinical trials (eg. 70,000 enrollees for rotavirus vaccine Phase 3 trial), which ensures collection of a significant amount of evidence of the safety and efficacy of a vaccine before it receives marketing authorisation,” Gutiérrez explained.

“As for any drug, vaccines are held to the highest standards of safety and quality before approval. And after approval, post-marketing surveillance continues during the vaccination programmes implementation in the specific local epidemiology context and according to the country-specific recommendation of implementation.”

The expert explained further that vaccines must also be endorsed by competent local authorities, which provide a country recommendation for use as part of the local immunisation programmes.

In total, the development of a new vaccine can take 14 to 25 years from early research to market authorisation. In addition, at EU level, the average access time to new vaccines is estimated at 6.4 years, from registration to effective population access.

“With these differences in mind, we believe that an open and constructive dialogue enables health authorities, member states, regulatory authorities, scientific experts, and manufacturers to collectively develop solutions is essential to reach a sustainable supply of quality and a healthy vaccines ecosystem,” Sanofi’s Gutiérrez emphasised.
How Italy’s scientific community joined forces and shaped national vaccination plan

By Sarantis Michalopoulos | EURACTIV.com

If the scientific community sticks together and makes a coordinated effort, it can be very influential in shaping national vaccination plans, Italian professor Paolo Bonanni told EURACTIV.com, citing Italy as a prime example.

Dr Bonanni stressed that the voice of the scientific world is sometimes not heard or taken into consideration, but with a concerted campaign, they can be really influential on vaccination policy.

The Italian professor was one of the scientists behind the “Calendar for Life” initiative, which resulted in a national vaccination plan for Italy including a life-course approach to immunisation to maximise protection against deadly diseases at all ages.

The “Calendar for Life” was launched in 2012 by four scientific societies and professional associations in Italy: The Italian Society of Hygiene and Public Health, the Italian Society for Paediatrics, the Italian Federation of Family Paediatricians and the Italian Federation of General Practitioners.

“At the time, the concept of vaccination was still not quite well understood at the public level, so we decided to propose the best possible calendar for vaccination based on

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scientific evidence. We thought this should be proposed to the population as the best practice for them in order to be protected from diseases,” Bonanni told EURACTIV.com.

In the beginning, the initiative intended to help the regional authorities increase the vaccination rates. But then it became really successful and the organisations decided to publish the second edition of the Calendar of Life in 2014.

“The initiative was taken as a role model for the national vaccination plan, which was adopted in 2017. Our calendar was the basic inspiration for the ministry of health to propose a new vaccination plan, which is now law in Italy,” Dr Bonanni noted.

Asked how the Italian scientific community managed to make its voice heard, considering that in many member states this is not the case, he replied it was a combination of several factors.

“There were the right people at the right place and we were convinced that what the scientific community proposed was the best possible evolution of our national vaccination plan.”

The Italian government approved the new plan for vaccination in February 2017 and five months later adopted a new mandatory vaccination law for schools, which was another aspect that had an impact on the coverage.

“Altogether, the vaccination plan and the mandatory law had had a very positive impact,” he said, pointing to increased vaccination rates as a tangible result.

‘OCCUPYING’ THE SOCIAL MEDIA

The European Centre for Disease Prevention and Control (ECDC) published on 23 April fresh data about the measles outbreak in Europe, pointing out measles vaccination gaps in teenagers and young adults.

The data showed that up to 80% of teenagers and young adults who contracted measles in 2017 had not been vaccinated.

“ECDC analysis of sub-national data indicates that even countries with high overall levels of vaccine coverage may have groups that are unvaccinated. In recent and ongoing measles outbreaks, ECDC’s recent rapid risk assessment identifies healthcare workers as among those affected,” the report noted.

Commenting on the report, EU Commissioner for Health and Food Safety Vytenis Andriukaitis said all stakeholders should take the new data seriously.

“Measles is gaining pace in an increasing number of EU countries. This demonstrates that vaccine-preventable infectious diseases do not respect borders and one country’s immunisation weakness puts the whole Union at risk.”

The European Commission will propose on Thursday (26 April) a much-awaited initiative for strengthened cooperation against vaccine preventable diseases, calling for joint action to increase vaccination coverage and “ensure that everyone in the EU has access to vaccination, thus bridging inequalities and gaps in immunisation”.

In an interview with EURACTIV earlier this week, ECDC’s Director Andrea Ammon noted that there is a general skepticism against science and opinions of experts and mistrust in many countries when it comes to public authorities.

She also emphasised the negative role of anti-vaccination campaigns, stressing that more efforts should be made in the social media sector.

“We, in the public health authorities at EU and national level, are working to occupy more of the space on social media, as it is currently almost entirely occupied by people who are against vaccination,” she explained.
With the European Commission’s new vaccination proposals, scientists have a good opportunity to join forces and use IT tools to explain their scientific opinions to people, EU Health Commissioner Vytenis Andriukaitis told EURACTIV.com in an interview.

The Commission issued a series of recommendations on 26 April aiming to boost cooperation among member states in the vaccines field.

The objective is to combat vaccine-preventable diseases, which claim the lives of up to 3 million people every year.

The EU executive wants national governments to come up with national and/or regional vaccination plans by 2020, including a target of at least 95% vaccination coverage for measles.

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The data showed that up to 80% of teenagers and young adults who contracted measles in 2017 had not been vaccinated.

Speaking on the sidelines of

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the presentation, Andriukaitis told EURACTIV he was optimistic that member states can make this happen, considering that in every country the situation is “really challenging”.

“Evidence shows that we need to react immediately. All countries now understand that they don’t have any chance to act alone or isolate themselves because the cross-border movement of people is absolutely different compared to 20 years ago. The Schengen concept is a crystal clear example,” the EU health chief said.

He also stressed the need to move toward digitised healthcare systems, as this will help countries meet the Commission’s recommendations on vaccination and improve IT infrastructure.

He explained that through IT tools, member states will be able to communicate better, and provide clear information to monitor the epidemiological situation and react immediately.

**AN OPEN PLATFORM AGAINST FAKE NEWS**

The EU executive also proposed the creation of a European vaccination information portal by 2019 to provide “online objective, transparent and updated evidence on the benefits and safety of vaccines”.

The rise of anti-vaccination campaigns, especially via social media, has raised eyebrows among policymakers in Brussels and EU countries, and they are trying to find ways to tackle rising vaccines hesitancy.

The Commission believes that by establishing such a platform, EU citizens will be able to have access to publicly available information and tackle fake news against vaccination.

But for Andriukaitis, this is also a big opportunity for the scientific community to join forces.

“We proposed specific and clear tools to strengthen and establish our platform, which can be open to scientific opinions. Scientists now have a good opportunity to join their forces using IT tools to express and explain their scientific opinions to people publicly, discuss risk topics and exchange views.”

“Our proposal allows the big scientific community to join forces and not to be in isolation because such a mentality is dangerous,” EU Health Commissioner emphasised.

Andriukaitis also pointed out the role of social media in providing the right information, encouraging “social media players also to join their forces”.

“It’s the responsibility of all of us to have access to reliable and scientifically verified data.”

The executive also proposed a common vaccination card that can be shared electronically across borders. This is an area the Commission will address next year.

Referring to the proposal the executive made on 25 April to increase availability and boost healthcare data sharing, Andriukaitis said: “It can help us align our possibilities to use the same IT readable format and add electronic vaccination cards, which can help us unite patients’ records”.

“I count on our teams, which can present all solutions until 2019.”
We all take small steps every day to protect ourselves and our loved ones.

But have we thought about all of the valuable steps we can take?

Life is a health journey which can be protected against life-threatening infectious diseases.

Read more about the protective power of vaccination. http://eurac.tv/9Pv8
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