

7th December 2018

Statement

Vaccines Europe welcomes the EU Council Recommendation on strengthened cooperation against vaccine-preventable diseases. The Recommendation represents a major step towards addressing the different vaccines and vaccination-related challenges faced by the EU Member States such as increasing vaccination hesitancy, low vaccine uptake and supply issues. Implementing the Recommendation will require stronger collaboration between stakeholders, in particular national public health authorities and the European Commission. Vaccines Europe is committed to engage with authorities and other stakeholders on the issues listed in the Recommendation where industry can contribute, such as research, development and improving sustainable supply of vaccines in Europe and globally.

Vaccination is one of the most powerful and cost-effective public health measures developed in the 20th century and remains the main tool for primary prevention of communicable diseases. Vaccination programs should go beyond childhood, taking a life-course approach to address epidemiological shifts in the burden of vaccine-preventable diseases. Moreover, vaccination can be an important instrument in addressing antimicrobial resistance.

The actions agreed by the EU Council to address **vaccine hesitancy**, including stronger engagement and education of all healthcare professionals in actively increasing vaccination uptake (e.g. through a Coalition for Vaccination), are crucial in view of improving the suboptimal uptake of vaccines. As the recently published Commission expert report¹ states, EU citizens' confidence in vaccination is decreasing. It is thus timely to establish a **European vaccination information portal** in 2019, as a platform to share with all EU citizens information on the benefits and safety of vaccination. Initiatives such as www.VaccinesToday.eu have already demonstrated the value of highlighting scientific information on vaccines and vaccination on social media.

The recommendation to the Member States to **leverage community-based providers in order to broaden opportunities to offer vaccination** can support optimal vaccination coverage in the EU and also reach out to the most **vulnerable groups** in society to reduce health inequalities and gaps in vaccination coverage. Pan-EU vaccination campaigns focused on different vaccine-preventable diseases (e.g. a European Influenza Day to launch seasonal influenza vaccination every year) could also contribute to increasing protection through vaccination.

Furthermore, Vaccines Europe welcomes the Commission intention to establish a **European Vaccination Information Sharing (EVIS) system**, coordinated by the ECDC. Vaccines Europe believes that immunisation information systems are the cornerstone of improved vaccination policies in a digital Europe, primarily by facilitating patient engagement, citizen empowerment and increased immunisation coverage. The recommendation to develop a common **EU citizen digital vaccination card**, or similar interconnected systems to capture the immunisation status of EU citizens, will help to facilitate the interpretation of vaccination records and ensure the continuity of immunisation across borders.

In the fragmented landscape of monitoring **the benefits and risks of vaccines** (regional, national and EU levels), there are recurrent challenges in **generating real-life effectiveness** and safety data, combining information from different stakeholders. Vaccines Europe believes that there is still a need for standardisation and common approaches in vaccine outcome data collection, improved and harmonised communication and collaboration at EU level across all Member States. The work already undertaken in the IMI Advance project² that established common grounds and rules for collaboration between public and private stakeholders should be taken into consideration.

¹ State of Vaccine Confidence in the EU 2018: https://ec.europa.eu/health/sites/health/files/vaccination/docs/2018_vaccine_confidence_en.pdf

² Accelerated Development of Vaccine benefit-risk Collaboration in Europe (ADVANCE): https://cordis.europa.eu/project/rcn/203713_en.html

Vaccines Europe believes that the recommendation to develop a concept for a mechanism for exchanging vaccine supplies from one Member State to another in case of outbreaks could help to mitigate the impact of shortages. The recommendation to create **a virtual data warehouse** of vaccine needs and stocks, if established, should ensure that it complies with EU competition law and would need to be carefully thought through, so all stakeholders comply with their respective obligations and commitments.

Although stockpiling can absorb short-term fluctuations, caution should be applied in making stockpiles the sole solution, for example as response to outbreaks, which requires more complex planning. What is needed are principles on how stockpiling is managed, covering many aspects from logistics involved to the costs. Specifically, such principles should address the ability to move products across countries (common label on the primary container; e-leaflets, common/single packs across Europe; no divergence on the presentations, etc.). Vaccines Europe members are open to discuss the framework of a stockpiling model in the EU in the interest of public health, for example to prevent shortages in a country, to fight outbreaks, to manage manufacturing problems, etc., and the model should complement Member States' existing vaccine purchasing systems.

Vaccines Europe underlines the importance of an **early dialogue** with researchers, developers, national policy makers, regulators and public institutions, such as: ECDC, HTA agencies/NITAGs and WHO in order to support new vaccines development, marketing authorisation and early access for citizens to innovative vaccines, including for emerging health threats. This will help to define vaccine research priorities of the future and will allow all stakeholders to have a common understanding of the blocking factors concerning the development of innovative vaccines to address unmet medical needs. We would like to emphasise that earlier and continuous dialogue on future vaccine demand in EU Member States as well as better procurement practices that allow for timely planning of manufacturing, are critical to improve vaccine supply both short and long-term.

Finally, the most important role the vaccine industry can play is to continue to **develop and manufacture safe, effective and high-quality vaccines** and support initiatives that enhance fact-based information about vaccines and vaccination. Vaccines Europe is looking forward to collaborate and support the implementation of the EU Council Recommendation in order to secure full protection of all EU citizens against vaccine-preventable diseases.