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CHOISEUL**

CONFERENCE REPORT



European Vaccination Conference

Institut Pasteur, Paris (France)

November 20th, 2018

With the institutional support of



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Introduction



On November 20th Institut Choiseul organised the European Vaccination Conference at the Institut Pasteur in Paris which brought together all the vaccination stakeholders, in a national and European context of debates to talk about the reinforcement of the efficiency of vaccination policies. This event gave the opportunity to address two major French and European issues :

- The need for an innovative and flexible vaccination ecosystem in order to **achieve a better match between supply and demand of vaccines over the long run.**
- The need for **robust electronic immunisation information systems, which are at the very heart of vaccination programmes' effectiveness.**



Built as a dialogue platform on vaccination strategic issues, this Conference was opened by the **European Commissioner for Health and Food Safety, Vytenis Andriukaitis**. Although vaccination saves between 1 and 3 million lives each year, the Commissioner highlighted that numerous cases of vaccine-preventable diseases, which are sometimes lethal, especially measles cases, had been observed these past few years in Europe. Speaking in front of health and industry professionals, scientists, public decisionmakers and civil society stakeholders, Commissioner Andriukaitis said he was *“afraid that too many people had forgotten the terrible consequences”* of these diseases. He recalled that the European Commission suggested solutions regarding

vaccination. The creation of an electronic European vaccination passport or the creation of a virtual data warehouse on vaccines needs and stocks, in order to facilitate rapid information exchanges of information and vaccines supply in case of epidemics, are among those solutions.

Given that patients' trust in vaccination is strongly linked to their trust in healthcare providers, the European Commissioner also announced a coalition of healthcare workers associations to address this issue at the beginning of 2019. The Commissioner hopes that these initiatives will encourage European member states to *“increase vaccine acceptance and coverage, strengthen national vaccination systems and improve health security and preparedness in Europe”*, thanks to a *“coalition of the willing”* among all European stakeholders.



Pascal Lorot, President of Institut Choiseul, also stressed the need for a *“reinforcement of the cooperation at the EU-level in order to fight against vaccine-preventable diseases which do not know borders”*.

Roundtable 1

Improving vaccines supply thanks to an innovative and flexible vaccination ecosystem



Speakers :

- **Geneviève Chêne**, Coordinator of the European Joint Action on Vaccination, Inserm (France)
- **Agnès Firmin Le Bodo**, Member of the French Parliament, Pharmacist (France)
- **Géraldine Ménin**, Head Pharmacist, Sanofi Pasteur Europe (France)
- **Michael Pfleiderer**, Principal Consultant, Biopharma Excellence (Germany)
- **Giovanni Rezza**, Research Director, Istituto Superiore di Sanità (Italy)
- **Michel Stoffel**, Head of Europe Region of Global Regulatory Affairs, GSK, and Chair of the Working Group on Regulatory Affairs, Vaccines Europe (Belgium)

Vaccine stocks management and vaccines shortages are major challenges for the vaccine ecosystem. We have seen over the past few years in Europe an increase in shortages and vaccines supply tensions: shortages have been observed in 21 European countries, according to the French Senate report on drugs and vaccines shortages¹. A few weeks after the release of this report, Agnès Firmin Le Bodo, French Member of Parliament, a member of the Social Affairs Commission and a Pharmacist (France) considers that “*2017 has been a terrible year in terms of vaccines shortages*”, highlighting the urgent need for a common and appropriate answer at the European scale.

Speakers from all over Europe took turns pointing out that vaccines supply problems only increase vaccine hesitation. With the rise of misinformation and while some Governments have made some pediatric vaccinations mandatory - such as France where the authorities extended mandatory pediatric vaccination to eight additional diseases - MP Agnès Firmin Le Bodo considers that “*it is the role of public authorities to certify that vaccines are efficient*”. She thinks that supply and availability issues weaken the credibility of vaccination programmes and policies.

For Giovanni Rezza, Research Director at the Istituto Superiore di Sanità (Italy), “*we must understand that people are anxious about vaccination. We have to share the information to bring back confidence*”. On this matter, Professor Geneviève Chêne, Coordinator of the European Joint Action on Vaccination (JAV², Inserm France), underlines that mistrust of vaccines is greater amongst the younger than the older populations, as Agnès Firmin Le Bodo confirmed. The French MP reaffirms the urging need to explain that vaccination not only protects oneself but also others. Indeed, by protecting himself, one prevents the spread of diseases and contributes to the protection of those who cannot be vaccinated, especially immunocompromised individuals and the most fragile ones (pregnant women, newborn babies, etc.). The World Health Organisation (WHO) therefore recommends a 95% coverage rate for most paediatric vaccines.

¹ French Senate, *Report of the Informative Mission on drugs and vaccines shortages*, October 2nd, 2018

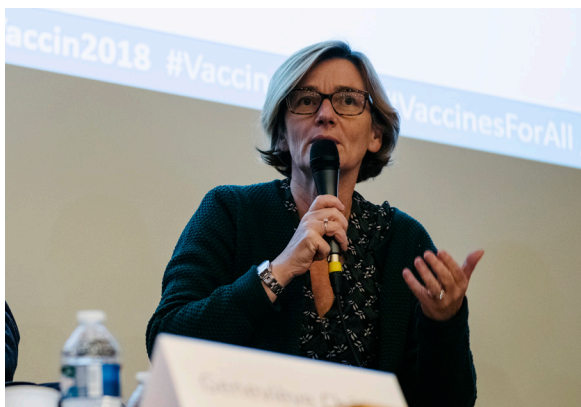
² Co-financed by the EU health programme and the Member States, the Joint Action on Vaccination (JAV) has been officially launched on September 4th, 2018 by the European Commission for three years. The JAV has for ambition to reinforce the cooperation between Member States in order to settle long-lasting vaccination policies and to reinforce vaccination coverage in Europe. France occupies a special place in the JAV, as this initiative is coordinated by the National Institute for Health and Medical Research (Inserm) and gathers 20 partner countries.

Furthermore, Geneviève Chêne adds that “*mistrust in vaccination is also shared by some healthcare providers*”, a challenge and key area of work for the Joint Action on Vaccination. She thus calls for a better **training of healthcare professionals on communication with patients on epidemiology and vaccination issues**. “*The role of healthcare professionals and the argument on product quality are crucial*” to fight this growing mistrust, she says.

When it comes to vaccines supply issues, all speakers agree to say there are several causes. Amongst them: long-term production and quality controls challenges, regulatory complexity and procurement practices, along with diverging vaccination calendars across Europe.

Supply issues are in particular due to the **specific features of vaccines**. As Géraldine Ménin, Head Pharmacist of Sanofi Pasteur Europe, explains, a vaccine is a product with a very long lifecycle (between 6 and 36 months on average) which makes the upcoming demand anticipation even harder; 70% of manufacturing time is dedicated to quality control. The lack of flexibility in the production process reduces the possibilities of quickly adapting the production to the demand as for other pharmaceutical goods. Solutions are however being considered and implemented by the industry: for Géraldine Ménin, “*the continuous improvement of manufacturing processes, production capabilities and controls will help securing supply*”.

The cooperation between industrials and public authorities is also at the heart of the debates. Michel Stoffel, Vice President and Head of Europe Region for Global Regulatory Affairs at GSK (Belgium) recalls that opening a new production site requires between 5 and 10 years (8 to 9 years on average). Investment made by the industry are even riskier as the demand for vaccines cannot be anticipated in the long term and with regard to the investment needed (“£4.5 billion in 10 years for GSK’s productive apparatus”). For Géraldine Ménin (Sanofi Pasteur Europe), changes in vaccination calendars impacts the industry’s capacity to anticipate. It is therefore of paramount importance that authorities take into account vaccines manufacturing length when shaping vaccination policies, and that a dialogue is established at an early stage between authorities and the industry to better anticipate the demand.



Michel Stoffel (GSK) and Geneviève Chêne (Inserm) both acknowledge that some simplification and cooperation efforts have been made by public authorities in Europe. If Michael Pfeleiderer, Principal Consultant at Biopharma Excellence (Germany) argues that there is a certain harmony at the European level on this point, he insists on the need for a better “**private-public**” cooperation. Indeed, the **persisting complexity** is partly due to the numerous and dispersed regulatory bodies in Europe. This analysis is shared by Michel Stoffel, also Head of the Working Group on Regulatory Affairs of Vaccines Europe, for whom “*the problem has to be treated on a global level, where we face different regulations*”.

Procurement practices and tenders were also discussed, insofar that their efficiency is a key element for the effectiveness of the vaccination programmes and improvement of vaccines supply. For Géraldine Ménin (Sanofi Pasteur Europe), some of the current procurement practices are not adapted to the specific features of vaccines and a better dialogue between the industry and authorities is needed. Michel Stoffel (GSK) highlights that in some countries, “*tenders are often under the production costs of vaccines*”, a problematic issue while it is critical to reinvest the investments benefits in the research for new vaccines and the construction of new production plants. Géraldine Ménin adds that tenders are too often based on prices only. A direct consequence is that the number of companies able to provide the necessary investments to stay on the market is declining. Moreover, tenders are often issued only few weeks or months ahead of the expected delivery therefore mismatching with the much longer delays of vaccines production. These short delays are significantly increasing the risks of shortages. This assessment is also shared by Agnès Firmin Le Bodo: for the French Member of Parliament who is also a pharmacist and a member of the French National Assembly’s Social Affairs Commission, these tenders are not adapted to the specific features of vaccines. For Michael Pfeleiderer, a coordination and a harmonisation of procurement practices is possible: a joint procurement system amongst European member states could be considered but its implementation would be extremely difficult. Giovanni Rezza, also a Member of the Joint Action on Vaccination in the working group dedicated to the issues of vaccines availability animated by the Istituto Superiore di Sanità, stresses out the difficulties to harmonise these practices even at the national level in Italy.

It should be recalled that the improvement of vaccines availability cannot be done at the expense of their **quality**, which would only but increase vaccine hesitancy. Michael Pfeleiderer (Biopharma Excellence) touches upon the challenges brought by the emergence of foreign markets such as India or China. For Michel Stoffel (GSK), it is essential to produce vaccines of the highest quality possible that have demonstrated their safety and efficiency. Up to now, no vaccine produced in China or India has passed the required standards of the European Medicine Agency.

Although operating in a globalized market, vaccines producers must **adapt their production to the different national vaccination calendars**. Harmonising these national calendars in Europe would ease vaccines supply for several countries, along with the possible mutualisation of stocks in case of health issues or epidemic outbreaks in a given country. As Coordinator of the European Joint Action on Vaccination, Geneviève Chêne mentions the necessity to work on vaccination calendars “convergence” rather than to harmonisation, an opinion shared by Giovanni Rezza (Italy) and Agnès Firmin Le Bodo (France). European countries face different epidemiological situations and heterogenous demographics: a pure and perfect harmonisation remains complex and could therefore be counterproductive. Agnès Firmin Le Bodo judges that “*harmonization is perhaps too strong a word: a convergence would already be a considerable progress*”. For Michael Pfeleiderer (Biopharma Excellence), this harmonisation or convergence of vaccination calendars “*is nothing unrealistic*” but has remained without any practical application for decades because of the national specificities regarding public health.

Geneviève Chêne (JAV) then points out that efforts and steps have been made at the European level to foster this convergence: “*a European network of technical committees on vaccination is being formed under the initiative of the ECDC³ and the Joint Action on Vaccination, to work on the mechanisms which could lead to the convergence of vaccination calendars*”. More globally, the goal of the JAV is to “*build a cooperation platform between European Health Ministries and European agencies such as the ECDC or the WHO Europe, the industry, civil society and healthcare professionals*”. For Geneviève Chêne, it is important that data is available in real time to estimate with precision the European needs in vaccines, and to target efficiently the least vaccinated populations.

IN BRIEF – Several solutions can be considered in order to strengthen vaccines availability in Europe:

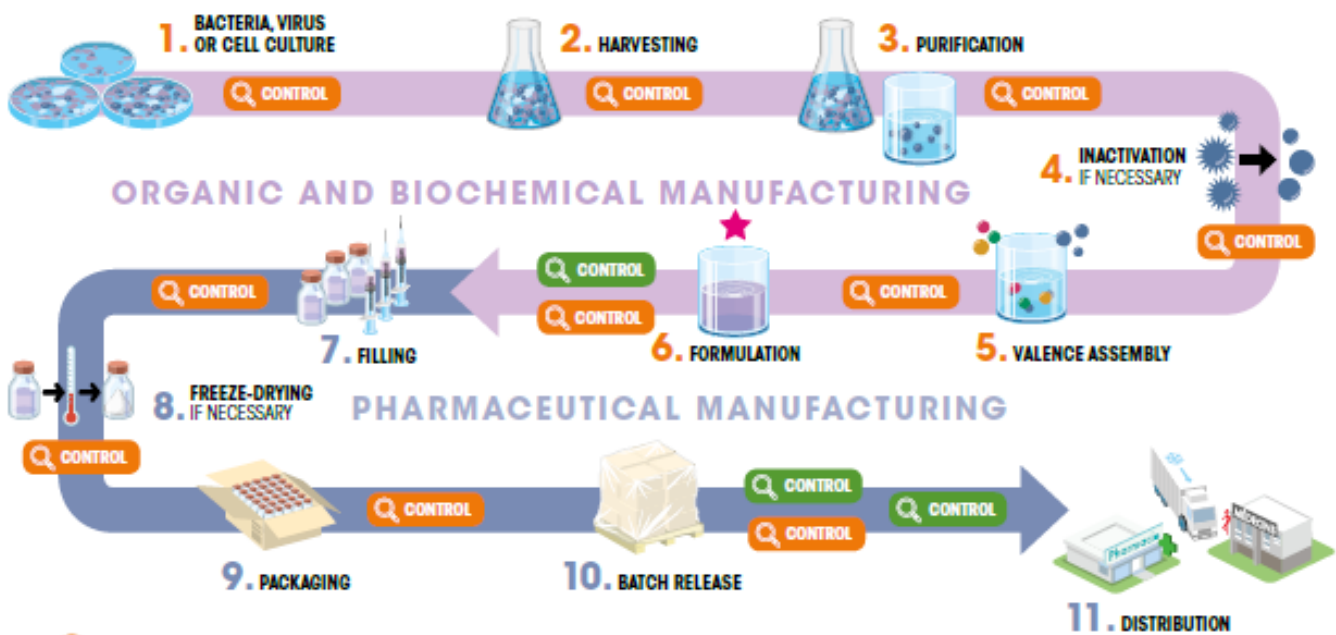
- Reinforce the **coordination between member states of the European Union** to anticipate and quantify the needs of vaccines
- Establish a **close and continuous dialogue between industrial actors and public health authorities**
- Take in account **the complexity and length of vaccines manufacturing** when shaping public policies
- Foster the **convergence of vaccination calendars** in Europe in order to ease vaccines supply for several countries and the mutualisation in case of health crisis in a given country
- Adapt **procurement practices in order to enable continuous investments in industrial production and research tools as well as a better volume planning** to secure supply levels adapted to the demand

³ European Center for Disease Prevention and Control

VACCINES:

Internal data Sanofi Pasteur 2017

A COMPLEX MANUFACTURING PROCESS



<p>INTERNAL CONTROL</p> <p>70% of manufacturing time is dedicated to quality control</p> <p>from 100 to >1000 quality control for each batch</p>	<p>HEALTH AUTHORITIES CONTROL</p> <p>★ BEGINNING OF THE SHELF-LIFE</p>	<p>Each vaccine contains from 1 up to 9 ANTIGENS</p>	<p>Production takes between 6 and 36 MONTHS</p>
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Source: Sanofi Pasteur, 2018

Roundtable 2

Immunisation information systems, key ingredients for efficient vaccination programmes



Speakers :

- **Radu Costin Ganescu**, Board Member, European Patients' Forum (Romania)
- **Boris Danilovic**, Executive Director, MSD Vaccins (France)
- **Jean-Louis Koeck**, Head of the immunisation information system MesVaccins.net (France)
- **Francis Mambrini**, President of the Federation of Ambulatory Medical and Paramedical Software Houses (France)
- **Yvon Merlière**, Electronic Medical Records Project Director, French National Health Insurance Fund (France)
- **Kåre Mølbak**, Executive Vice President, Statens Serum Institut (Denmark)

As European health systems slowly move towards e-health, electronic monitoring tools provide a real time picture of the vaccination coverage rate. They are essential to enable continuous and reliable assessments to effectively implement and/or adapt vaccination strategies and programmes according to the reality on the ground and to better protect all citizens.

In the context of the national launch of the “Shared Medical Record” in France, this second roundtable brings together key actors of the European vaccine ecosystem and immunisation information systems experts. The “Shared Medical Record” aims at centralising all the patients’ medical and healthcare information. By 2019, it should also contain a section devoted to vaccination records, which will help better inform patients and monitor their vaccination status.

Opening the discussions, Yvon Merlière, Director of the “Shared Medical Record” at the French National Health Insurance Fund (France) declared that *“if we manage to simplify and to give a high level of confidence to the Shared Medical Record, and later an access to the vaccination record directly in this tool, we will be able to improve the vaccination coverage in France”*. The French National Health Insurance Fund hopes that 10 million electronic records will be created each year to reach 40 million files in 2022. A few days after the national launch of the project, Yvon Merlière claims to be optimistic on the development of this tool which has received a strong support from public authorities.

For Francis Mambrini, President of the Federation of Ambulatory Medical and Paramedical Softwares Houses (France), *“the tools at the disposal of healthcare professionals must help reinforce and facilitate their implication in the management of vaccination recommendations and in the individual monitoring of their patients’ vaccination history”*.

Boris Danilovic, Executive Director of MSD Vaccins (France) is convinced that *“digital tools must help us **create a dialogue with the population in order to reinforce trust in vaccination**”* especially considering that *“the internet is a source of information... and misinformation!”*. Digital tools allow a more precise monitoring of patients and vaccination coverage rates. They can also help to **fight more efficiently against vaccine hesitancy** by spreading qualified information to patients and healthcare professionals. The use of digital tools enables the customization of contents for users and healthcare workers and therefore helps fighting against misinformation.

A Board member of the European Patients’ Forum (Romania), Radu Costin Ganescu is also convinced that spreading high-quality information is key in the fight against rising mistrust in vaccination. On this matter, Jean-Louis Koeck, Head of the immunisation information system MesVaccins.net (France), underlines that *“traditional campaigns on vaccination do not often work”*. This explains the importance of informing the public about the benefits of vaccination through digital means and personalised messages, as Boris Danilovic (MSD Vaccins) also puts it.

Even though the development of immunisation information systems represents many opportunities for both users and healthcare providers, it remains uneven in Europe. Several European countries already have well-functioning national systems, whereas France for instance is still testing them regionally. Other countries do not have immunisation information systems at all. In Denmark, as Kåre Mølbak, Executive Vice President of the Statens Serum Institut (Denmark), highlights, a health information system created in 2009 enables patients to gather their health and vaccination history. This tool helps doctors monitoring the medical situations of their patients and contributes to research thanks to data compilation and analysis.

However, the development of these digital tools in France and in Europe encompasses several challenges. For Francis Mambrini (France), it is crucial to have a **“user-centric” approach and to include the collection of vaccination data into the daily tools of healthcare professionals.** The goal is to avoid the split of data entries and to prevent data gathering on vaccination from becoming time-consuming. Francis Mambrini claims that healthcare professionals expect that *“we facilitate uses through a seamless integration of the creation, supply and consultation services to their softwares”*.



The issue of the **data security** is also at stake. As Francis Mambrini (France) stresses out, the efficiency of these systems depends on the confidence of patients and healthcare professionals in these tools. On this matter, France and Europe offer serious guarantees (certification of software hosts, general data protection regulation at the European level, etc.). For Francis Mambrini, it is extremely important to facilitate an optimal use of data. By doing so, aggregating the different data bases, both local and national, would be made possible to ensure a better targeting of the least covered populations and to increase vaccination coverage. He adds that *“the elaboration of European vaccination systems and the crossing of national systems and data bases would improve the precision and the distribution of the production of vaccines”*.

The goal is to implement a national system gathering and compiling information coming from local systems, and making these data available in the vaccination section of the “Shared Medical Record”. Francis Mambrini stresses that the French “Shared Medical Record” is a tool meant to gather this information at the national level, but that it must also be part of a comprehensive cross-border European information system.

For Yvon Merlière (France), the importance of the “Shared Medical Record” ultimately lies in the sharing of medical information between health professionals who follow the same patient, particularly in the event of emergency care.

In the long run, the challenge is to make **the use of digitalisation of individual vaccination data as automatic as that of the health insurance card in France. Digital tools, which are available to patients and professionals, can thus enhance the effectiveness of vaccination programs.** Radu Costin Ganescu (COPAC and EPF) is therefore in favour of developing a European Vaccination Record, a tool that he considers essential for people with serious illnesses who have to undergo treatment abroad. For patients, electronic vaccination records allow the compilation of the vaccines already done, and foreseeing those they will have to receive (text reminders, etc.). They also allow, to share their record with their healthcare providers or even to get information on the recommended vaccines.

IN BRIEF – Several actions and guidelines are possible to make immunisation information systems key ingredients for efficient vaccination programmes:

- **Foster the crossing and aggregation of data from different immunisation information systems** in order to enable a more precise monitoring of epidemiological trends and efficiently adapt health responses
- **In France, make the electronic “Shared Medical Record” a tool to increase vaccination coverage**, thanks to a dedicated section (foreseen for 2019), to ease the information of patients as well as the monitoring of their vaccination status
- **Place users at the heart of the development of immunisation information systems and digital tools**, by seamlessly integrating data collection into healthcare practitioners’ daily tools
- Use digital tools to **customise the information and contents on vaccination for patients and professionals** and enhance information sharing across healthcare providers
- Create by 2019 a **European portal of information on vaccination** which would provide patients with the detailed vaccination objectives and with transparent information on the benefits and the safety of vaccination, as recommended by the European Commission⁴
- **Strengthen EU cooperation efforts to create a European Vaccination Card** which would help monitor patients in Europe in a context of increased mobility, and which would provide authorities with precise information on the state of the vaccination coverage of populations



⁴ European Commission, *Proposal for a Council Recommendation on strengthened cooperation against vaccine-preventable diseases*, April 26th, 2018

Conclusion of the Conference



As a conclusion, **David Loew, Executive Vice President and Head of Sanofi Pasteur**, recalled how important it is that all stakeholders are committed and cooperate together in order to reinforce the efficiency of vaccination policies in Europe.

For David Loew, **Europe has been a long-standing leader in vaccines. Maintaining this position can only be achieved through a strong industry operating in a stable environment**, able to produce safe and effective vaccines of the highest quality and to innovate to meet future vaccine needs. In that sense, the industry has implemented a massive investment programme aiming at keeping the current industrial assets at the highest level of quality and increasing industrial capacities.

In this context, it is critical for David Loew to foster a **well-balanced vaccine ecosystem which recognizes the strategic value of the EU vaccine industry and rewards innovation**. As such, vaccines value should be adequately rewarded in Europe and public procurement models should account for their specificities to maintain market attractiveness and foster continuous investments in innovation. Indeed, cost-containment policies and tender processes -based solely on the criteria of the lowest price- appear as a threat, not only to the long-term durability of vaccine manufacturing, but also to the European vaccines industry's innovation capacity, and the vaccines ecosystem in Europe as a whole. Speaking about **the vaccine markets' high degree of concentration**, David Loew said this signal should be taken seriously to ensure that future generation will continue to be vaccinated against essential infectious diseases.

More generally, **strengthening cooperation between public and private actors should ensure an increase in vaccination coverage and a greater efficiency of vaccination programme**. This will especially be made possible through a reinforced use and access for various actors to electronic and digital data from large data bases. In the era of "big data", being able to work on study protocols pre and post-commercialisation of products, based on healthcare resources use and hospitalisations, available from national health insurances, appears essential. In the United-States for instance, the "Kaiser Permanente" data-base contains integrated anonymised medical information from millions of patients, allowing very powerful real-life study results to inform public decision-makers. This kind of tool is of paramount importance to evaluate and effectively adapt national vaccination strategies and programmes. Protecting all European citizens against vaccine-preventable diseases is a shared commitment and joint responsibility of the entire public health community.

About us

The Institut Choiseul is an independent think tank amongst the most influential ones, dedicated to the analysis of economic issues and challenges facing society. Through the organisation of the European Vaccination Conference, the Institut Choiseul aims at deepening the strategic issues of vaccines and helps the health sector keep pace with contemporary changes.



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