Vaccination challenges and EU cooperation: what is the way forward?

Summary report of a workshop discussion held on 19 November 2018, Palais des Academies, Brussels
About FEAM, The Federation of European Academies of Medicine (www.feam.eu)

FEAM is the European Federation of National Academies of Medicine and Medical Sections of Academies of Sciences. It brings together under one umbrella 19 National Academies representing thousands among the best scientists in Europe.

FEAM’s mission is to promote cooperation between National Academies of Medicine and Medical Sections of Academies of Sciences in Europe; to provide a platform to formulate their collective voice on matters concerning human and animal medicine, biomedical research, education, and health with a European dimension; and to extend to the European authorities the advisory role that they exercise in their own countries on these matters.

About the FEAM European Biomedical Policy Forum

The FEAM European Biomedical Policy Forum provides a platform for discussion on key policy issues for the biomedical community.

The Forum is an initiative from the Federation of European Academies of Medicine (FEAM). It aims to bring together representatives from academia, research charities, industry, European and national trade associations and professional bodies, regulators, public health bodies, and patient and consumers groups. If you would like further information on the FEAM European Biomedical Policy Forum or becoming a partner, please contact info@feam.eu

Disclaimer

Opinions expressed in this report do not necessarily represent the views of all participants at the event, the Federation of European Academies of Medicine (FEAM) and its Member Academies, or the FEAM European Biomedical Policy Forum partners.

All web references were accessed in October 2018.

Acknowledgments

FEAM warmly thanks Gary Finnegan for moderating the workshop, the speakers for their contribution and Dr. Robin Fears for writing this report. FEAM is very grateful to the Belgian Royal Academy of Medicine (ARMB) for hosting the workshop. The date of this workshop also coincided with Silvia Bottaro, FEAM Forum Policy Officer, moving on from FEAM to take up new challenges. All present warmly thanked and congratulated Silvia for her commitment and very impressive efforts in establishing the Forum for FEAM.
# TABLE OF CONTENTS

- Introduction ........................................................................................................... 4
- Summary .................................................................................................................. 4
- Report of the event .................................................................................................. 6
  - Welcome and introduction ..................................................................................... 6
  - How can European countries improve vaccination in the wake of the measles outbreak? Views from academia .............................................................................. 6
  - Panel session 1. How can vaccination levels be improved through better public dialogue? ............................................................................................................... 9
  - Panel Session 2. Vaccination and EU policies: How to strengthen cooperation at the EU level? ................................................................................................. 13
  - Concluding remarks .............................................................................................. 16
- Annex I - Agenda .................................................................................................... 17
- Annex II - Speakers’ biographies .............................................................................. 18
Introduction

This report summarises the key points of the Federation of European Academies of Medicine (FEAM) European Biomedical Policy Forum workshop discussion on “Vaccination challenges and EU cooperation: what is the way forward?”, which was held in Brussels (Belgium) on 19 November 2018.

Background

Vaccination is one of the most important medical measures developed in the 20th Century and the main tool initially for the primary prevention of communicable diseases. Despite the contribution made by vaccines to people’s health and well-being, vaccination programmes today face major challenges in the EU: declining coverage, supply shortages and vaccine hesitancy leading to refusal.

In April, the European Commission adopted a proposal for a Council Recommendation and a Communication on Strengthened Cooperation against Vaccine Preventable Diseases, with a focus on three pillars of action: 1) tackling vaccine hesitancy and improving vaccination coverage; 2) sustainable vaccination policies in the EU; 3) EU coordination and contribution to global health. This creates the momentum to stimulate debate and share ideas which can inform the work of policy-makers and the biomedical community in these areas.

The aims of the workshop were:

How can vaccination levels be improved through better public dialogue? Which concrete actions can be taken by European and national health authorities and other biomedical stakeholders to engage with the public and address concerns about vaccination?

Which policy interventions could be taken by the European Commission and Member States to ensure that vaccination programmes function well? Which areas would benefit from increased cooperation at EU level?

Summary

Vaccination has long been regarded as one of the greatest advances in medicine and public health, yet it has again now become a subject of controversy. Scepticism and misinformation is leading to declining EU rates of uptake of some vaccines, particularly measles.

Previous work by FEAM and EASAC has made recommendations on a wide range of issues for vaccine coverage, quality, availability, innovation and uptake. This FEAM European Biomedical Policy Forum event was designed to continue catalysing discussion on scientific and social aspects, and action at the science-policy interface. The workshop brought together contributors from the academies, other
leading academics, WHO, NGOs, industry, the European Commission and its key agency, the European Centre for Disease Prevention and Control.

Major conclusions from the workshop were:

The determinants of low vaccine uptake are complex: including public hesitancy, health care professional uncertainty, and logistic obstacles to access to health and vaccination services.

There are significant opportunities to improve vaccine uptake but there is need for better community-level research to identify specific problems and determine the options for education, information and engagement. Lessons learnt from community and country case studies, including WHO TIPs and the introduction of mandatory vaccination, can help to promote evidence-based interventions over the life course but must recognise the dynamic nature of vaccine confidence and the potential for political and other polarisation.

Lay group hesitancy is context-specific: to address demand challenges and system weaknesses, there must be improvements in training for health care professionals alongside the articulation of vaccine value and robust countering of misinformation in public engagement.

Advances to fill knowledge gaps and tools to improve dialogue will come from current EU projects, e.g. the Innovative Medicines Initiative Advance work and the practical objectives for new collaborative work, e.g. Joint Action on Vaccination.

Citizens, patients and their NGOs can play important roles as an antidote to misleading representations on vaccine risk found in the media and elsewhere, and must be involved, with other stakeholders, in deliberations on national and EU policy and strategy development.

Opportunities for building coordination between public and private sectors can capitalise on industry commitments to improve vaccine uptake, ensure security of vaccine supply, identify and pursue research and innovation priorities for vaccine quality and for addressing hitherto unmet medical needs.

The EU academies of science and medicines and their networks also have vitally important continuing roles: in bringing together all required disciplines and expertises to share data and perspectives and to clarify issues; to raise public, professional and policy-maker awareness; and to support and inform European Commission initiatives in sustainably tackling vaccine hesitancy, strengthening national programmes and supporting collaboration.
Welcome and introduction

The meeting was opened by Pr. Jean-Michel Froidart (Perpetual Secretary, Belgian Royal Academy of Medicine) who welcomed the participants and noted that the origin of the Palais des Academies, in 1828 came during a very significant Century for the history of Belgium – and also for the development of vaccines, with the pivotal achievements of Pasteur. In the 21st Century, some deny the value of vaccines: academies have a very important role in promoting research and also in the dissemination of robust knowledge about vaccines to the public and policy-makers. FEAM is a key partner in helping the European Commission to support informed debate and action on vaccination.

How can European countries improve vaccination in the wake of the measles outbreak? Views from academia

In introducing the Workshop, Pr. George Griffin (President of FEAM) described the roles of FEAM to promote collaboration and capacity building between academies of medicine and, based on their expertise in research and clinical medicine, give the best advice for public health. Vaccination is one of the greatest advances in public health yet there is scepticism and its value is challenged by some, with deleterious consequences, notably for the recent incidence of measles in parts of Europe.

This FEAM European Biomedical Forum event is part of a series examining particular issues for health care in Europe (most recently on Personalised Medicine). FEAM is committed to working on mutual interests with other academy networks in Europe and earlier in 2018, together with EASAC, published a commentary on “Vaccination in Europe”. The joint statement served as a basis for a subsequent discussion on scientific and social aspects (Amsterdam, October), to be described in the next presentation, and by this Forum event addressing the science-policy interface.

Pr. Jos van der Meer (Past-President of EASAC) presented the recommendations from EASAC and FEAM and summarised the subsequent discussion on those recommendations in Amsterdam. The origin of this FEAM work with EASAC derives from the European Commission’s consultation on the Roadmap “Strengthened cooperation against vaccine preventable diseases” when the academy networks decided that a more detailed commentary on scoping the EU strategy was warranted than was possible in the consultation format. The academies’ commentary (Box 1) made recommendations on a wide range of issues for vaccine coverage, quality, availability, innovation and uptake. Since then: (i) the European Commission adopted its proposal for a Council Recommendation and

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Communication; and (ii) “The State of Vaccine Confidence in the EU, 2018” has been published, to be discussed subsequently.

**Box 1: Summary of recommendations from the commentary by FEAM and EASAC on vaccination**

1. Investigate the reasons for low and decreasing vaccine uptake at the level of EU Member States in order to develop tailor-made interventions. Make use of the WHO TIPs initiative.

2. Develop and implement a European vaccination card and registry. Do not give normalisation of vaccine programmes among different countries a high priority.

3. Recognise that not all vaccines in the vaccination programme are of equal relevance for public health and for individual protection. Make priorities within these programmes.

4. Recognise that not all vaccines are of optimal general quality in terms of efficacy and side effects.

5. To deal with the problem of vaccine rejection and hesitancy, realise that the approach to vaccine hesitant, vaccine resistant and vaccine rejecting groups is different. With the help of social scientists, develop strategies to enhance vaccine uptake in vaccine hesitant and vaccine resistant individuals.

6. Develop a monitoring system for vaccine shortage and stimulate vaccine production by industry at the European level ensuring safety and quality of manufacturing.

7. Revisit the BCG vaccination programme in childhood: the vaccine does not induce long-lasting protection against tuberculosis and there is a serious worldwide shortage of the vaccine.

8. Investigate and optimise vaccination schedules for those vaccines for which there is a shortage.

9. Develop a priority list of those vaccines that need improvement.

10. Develop a priority list of vaccines for which there is high need.

Responses in the Amsterdam conference can be summarised as follows:

- **Vaccine uptake** (Recommendation 1): it is agreed to be a Member State problem. The TIPs approach is worthwhile but more is needed to clarify resources and costs of the WHO programme (see subsequent presentation by Siff Malue Nielsen). Explanations of the decline in vaccine uptake are multifactorial and maybe simple logistic problems in addition to refusal due to misconceptions play a role.

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3 See [https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5925775_en](https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5925775_en). This covers topics for: tackling vaccine hesitancy and improving coverage; sustainable vaccine production in the EU; and EU coordination and contribution to global health. This proposal has been approved by the Council of Ministers in December 2018.


• **Vaccine strategies** (Recommendation 2): a vaccination ‘card’ would be useful but attempts to normalise vaccination programmes (e.g. choice of dose and timing) among different countries would probably fail. The national advisory committees have key roles, supported by ECDC work to strengthen coordination and harmonisation. The Innovative Medicines Initiative ADVANCE project\(^6\) aims to contribute to the vaccine debate, e.g. by risk-benefit assessment based on real-world and real-time data (see subsequent discussion).

• **Quality** (Recommendation 4): current quality issues for the influenza vaccine need to be addressed in terms of improving the antibody response and the fit to prevalent strains. Potential measures to be taken include use of higher dose for poor responders, better adjuvants, better prediction of next year’s strains, and targeting other antigens.

• **Vaccine rejection and hesitancy** (Recommendation 5): it continues to be important to clarify differences between population groups and to convey positive messages. There is a disconnect between anti-vaccination lobby groups (e.g. in their activities on social media) and the messages produced by professional and governmental activities.

• **BCG** (Recommendation 7): differing national practices regarding BCG vaccination programmes require further examination of the issues for conferring specific protection versus trained immunity. The current evidence base is discussed in detail in the forthcoming report of the Amsterdam meeting.

• **Priorities** (Recommendations 9 and 10): improvements, where needed, should be considered in terms of antigenic quality and adjuvant quality. The societal priorities for vaccine innovation could provide the basis for European public-private partnership in vaccine discovery and development so that choices are not left only to the decisions of industry.

*George Griffin* supported these conclusions by emphasising that strong scientific underpinning is essential throughout vaccinology – for the design and manufacturing of vaccines and adjuvants through to devising vaccination schedules and promoting acceptance. There are opportunities for better coordination between industry and public health authorities to enhance security of supply.

Surveys of public concerns about the risks and benefits of vaccination in Europe revealed the major concern as safety (followed by concerns about effectiveness, lack of necessity, and insufficient evidence). France was the Member State whose population had the highest concern about safety; the lowest concern was expressed in Portugal and Finland. Vaccine hesitancy can be considered as a normal reaction to uncertainty whereas refusal is abnormal. Efforts to inform and educate the hesitant require greater participation by the social sciences.

This point was amplified in general discussion, moderated by *Gary Finnegan* (health journalist), in the context of what academies can offer in training on social media skills and involving the social sciences. The strengths of FEAM and EASAC include their access to social sciences and humanities and their wide geographical spread to underpin education initiatives. Unfortunately, many doctors are also poorly trained in how to communicate and, in some cases, poorly informed about vaccines (General Practitioners in France exhibit a similar degree of scepticism as the lay public); most medical students receive little instruction about vaccines. The IMI ADVANCE project\(^5\) is exploring options for training GPs in vaccination issues as well as developing other tools to tackle complacency and hesitancy.

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\(^{6}\) “Accelerated development of vaccine benefit-risk collaboration in Europe”, [www.imi.europa.eu](http://www.imi.europa.eu), with objectives to develop and test methods and guidelines for a framework for reliable data on benefits and risks, to help regulators, public health authorities and public confidence.
However, in a point developed subsequently, it was observed that vaccine uptake is also determined by practicality: facilitating access to health services improves coverage.

Panel session 1. How can vaccination levels be improved through better public dialogue?

**Pr. Mike Catchpole (Chief Scientist, European Centre for Disease Prevention and Control)** introduced the challenging epidemiological context for measles, comparing the EU map of measles vaccination coverage in 2017 with disease notification rates to conclude that even in countries with high coverage, there are problematic hotspots. Moreover, in 2017 only 4 Member States achieved the desired threshold (95%) for measles vaccination coverage.

Society can be characterised as in transition from the deferential (informed by experts) to referential (exposed to social media). ECDC Technical Reports on vaccination have reviewed the literature on motivating hesitant population groups, on hesitancy among health care workers, and have catalogued interventions addressing hesitancy. These ECDC resources have been used to engage with lay and professional groups, with the following conclusions:

- No group is entirely hesitant but there are pockets of hesitancy in all population groups.
- There are concerns about the possible formation of clusters of vaccine-hesitant groups, which might expand and affect the general public.
- With regard to health care professionals – there are inconsistencies in perceptions about vaccination which influence their personal and professional actions. Their most important concern is safety, they acknowledge the impact of anti-vaccination content in the media and accept their responsibility to respond to patient hesitancy.

From these analyses it was recommended for policy and practice, particularly with regard to marginalised groups: to invest in education for health care professionals; to facilitate reminders about scheduled vaccination (e.g. efficient public alert systems); to include measles in dealing with broader concerns and support for mothers about family health; to address stigma and discrimination in marginalised groups and to cooperate with outreach workers.

Country case studies exemplified use of ECDC communication tools on “let’s talk about hesitancy” and “let’s talk about protection”, demonstrating the importance of customising – as well as translating – material for specific communities. ECDC continues to collaborate with other key groups, such as WHO Europe, and has various projects under development, e.g. on HPV vaccine hesitancy; the role of social media in vaccination decision-making; and training for health care professionals on communication for increasing vaccination acceptance.

Mike Catchpole concluded that vaccine hesitancy is a global problem, but complex and context-specific. Primary health care professionals are key in motivating families; science, policy and practice need to work together; terminology should be positive and harmonised; and now is the time to act.

**Siff Malue Nielsen (Consultant, Vaccine-preventable Diseases and Immunization, WHO Regional Office for Europe)** contrasted the success of DTP and MCV vaccination in the WHO European region (1980-2017) with the problems of measles (2000-2018) where there has again been an increase and indeed deaths in cases in 2018. In reinforcing points made by the previous speakers, the nature of
vaccine hesitancy was again described as complex and context-specific. Some of the vaccination demand challenges are structural, e.g. reflecting complications of access to vaccine provision in some countries; confusion about vaccine significance in countries where some vaccines are mandatory but others are not; and equity challenges in reaching marginalised groups. Difficulties in clarifying and quantifying challenges are compounded by limitations: in data, evidence on different drivers and barriers to uptake, political prioritisation, and in the capacity of systems to respond.

The qualitative research for new vaccine introduction and the tailoring Immunization Programme (TIP) is a structured process, informed by behavioural science and theory, undertaken to understand enablers and obstacles, and utilising evidence-based interventions to increase vaccination coverage. Positive outcomes from TIP case studies and new vaccine introduction research were presented on:

- UK Charedi Orthodox Jewish community – that has experienced repeated measles outbreaks and where, it had been assumed previously that vaccine hesitancy was religious in origin. However, it was found that the main problem was a practical one – inconvenience in accessing health services.
- Moldova, focusing on HPV vaccine – where it had been previously assumed that the community was distrustful of the vaccine and doctors’ motives. However, it was found that doctors themselves were often hesitant.

Thus, preconceptions about vaccine hesitancy need to be analysed by community-level research; and evidence-informed interventions can increase vaccination coverage. There is continuing need to collect better data, to attract decision-maker attention, commitment and investment, and to strengthen inter-sectoral collaboration and community relations. In seeking to answer the question “how can vaccination levels be improved through better public dialogue?” it has to be appreciated that the question is too broad. To reiterate, low uptake/hesitancy is complex, context-specific and target group-specific. It should not be assumed that recipients are always the problem, it may be that there are system weaknesses.

Pr. Heidi Larson (Professor of Anthropology, Risk and Decision Science, London School of Hygiene and Tropical Medicine) agreed that the question was very broad and complex. Public dialogue involves diverse groups (including professionals, patients, citizens, media) and discussion between different groups may become polarised. Dialogue is required at multiple levels, recognising that perceptions of evidence are changing (as in the deferential to referential transition presented earlier). Dialogue often involves emotion and some in the public may not readily believe “positive” messages – so that professionals must be seen to be communicating openly and honestly. There has been a shift in debates in the past few years, where anti-vaccination groups have become bolder in assertions while public health professionals seek to avoid emotion.

Recent insight into what drives hesitancy is provided by the publication “State of vaccine confidence in the EU 2018”4 and other comparisons, confirming that some EU countries are more sceptical about vaccine safety than other countries around the world. Specific analysis of GP behaviour was made in regard to their recommendations on MMR, flu vaccine and flu vaccine for pregnant women. MMR is usually recommended (least so in Slovakia and the Czech Republic), but GPs are less positive about flu vaccines, especially for pregnant women.

Analysis of changes in EU vaccine confidence (with regard to vaccine importance, its safety and effectiveness) between 2016-2018 discloses a dynamic situation, indicating that there may be
opportunities to influence change in confidence, when that is still at an early stage. Confidence has been decreasing in Poland but increasing in Slovenia, Greece, Italy and the UK.

Figure 6: Change in vaccine confidence between 2015 and 2018 across 20 EU member states. The change in the percentage respondents agreeing with the four vaccination survey questions in the 2016 study (Larson, 2016) (and see Section 3). Positive values represent higher agreement in 2018 and significant results (at the multiple hypothesis-controlled 95% level) are denoted with an asterisk (*). Countries are sorted by the highest average change in agreement across all questions confidence in Slovenia is the most improved, confidence in Poland is the most deteriorated.

Source: The State of Vaccine Confidence in the EU: 2018 (Larson et al. 2018)

The main factor continuing to drive low confidence is concern on safety and, in general, younger people are less confident. Presentation of case studies from Denmark and the Netherlands reaffirmed the importance of understanding parental concerns (on HPV vaccination), of engaging with social media and of using language that younger people can relate to.

Pr. Paolo Villari (Professor, Department of Public Health and Infectious Diseases of Sapienza University of Rome – Representing the Institute Pasteur of Italy) presented on “Mandatory

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7 For example, see the evidence from part of the IMI ADVANCE project, a study on real-time global media monitoring on HPV explores the utility of such monitoring in support of communication proactivity and preparedness (P Bahri et al. on behalf of the Advance consortium 2017 BMC Medicine 15: 91).

8 See www.vaccinesconfidence.org for further examples and discussion of issues, including recent editorial in Lancet (“Looking beyond the decade of vaccines” November 17 2018) that highlights problems of vaccine hesitancy and the politisation of immunisation.
vaccination for measles: does it work?” Mandatory vaccination has been introduced recently in California, Australia, France and Italy, with discussions continuing in Romania and Germany.

What were the origins of mandatory vaccination in Italy? The Italian health care system has a history of performing well (according to WHO in 2000) but public satisfaction has been relatively low. According to ECDC data, in 2017 Italy contributed 35% of measles cases reported in the EU/EEA. Although vaccination rates in regions of Italy had increased during the early years of the 21st Century, concern has been expressed that the economic crisis might lead to a loss of commitment to planning disease prevention. Specifically, the adoption of austerity policies in the Italian health care system was found to be significantly associated with declining MMR vaccination rates. It was postulated that the introduction of mandatory vaccination for Italian children may help to counteract this trend. Although evidence for the impact of compulsory vaccination in Europe is still relatively weak, the introduction of mandatory vaccination in Italy is perceived to be an effective measure. However, there is still public scepticism about vaccination, now part of the broader mistrust of the State, established political parties and experts. The political rise of populist/anti-establishment groups may lead to a revision of mandatory vaccination although it might be retained for measles.

The National Verification Committee of Italy has made various recommendations for strengthening outbreak reporting and regional monitoring systems, maintaining the network of regional proficient laboratories, enhancing vaccination services, and designing effective communication strategies. The Institute Pasteur in Italy has also been active in devising various communication materials, including for children.

In Session 1 discussion among the Panel and with all participants, several themes were re-emphasised:

- It is important to take a life course perspective of vaccination – in addition to the critical phase of early childhood, vaccines are vital in adolescence (HPV), pregnancy (e.g. tetanus to prevent neonatal infections), travel medicine, in the elderly (e.g. for flu shingles and pneumococcal infection) and other at-risk groups (e.g. hepatitis A). Pregnancy can be considered as an important “teachable moment” to engage with women who are then focused on family health, and with other health care professionals (midwives). Vaccination is effective in pregnancy in protecting the neonate and is an area of active research.
- The challenges for engaging with different groups are often complex. In view of the evidence that younger people are more vaccine hesitant, it is necessary to educate early on vaccines during the biology and health curriculum and as part of learning to use social media. Lessons learnt using youth health ambassadors to communicate to their peers might be applied more widely.
- Are commercial interests in vaccination mistrusted? This is an issue for some groups but it may reflect more a mistrust of big business than of vaccines. Industry can help to build trust by publishing all data from clinical trials and health authorities can help by emphasising that medicines are part of the stringent medicines regulatory system governing quality, efficacy and safety.

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• What more should be done in the medical curriculum? ECDC and others are involved in training health professionals – the core competences must include how to communicate as well as knowledge of the science of vaccines.

• How should the concept of “herd immunity” be communicated? There is little strong evidence that using this term – appealing to altruism – helps to reduce vaccine hesitancy. The term “community immunity” is better and has gained acceptance.

Panel Session 2. Vaccination and EU policies: How to strengthen cooperation at the EU level?

Martin Seychell (Deputy Director General for Health, European Commission, DG Sante) agreed that vaccination represents a great public health achievement, which is not always recognised. Hence, the importance of the European Commission joining with other stakeholders to prioritise vaccination for the public health agenda. There are links to other major health issues e.g. vaccination is one of the approaches to reduce the incidence of antimicrobial resistance.

Immunisation cover can be regarded as one of the best proxy measures for health system general performance (e.g. in reaching out to marginalised groups). That is, if a health system cannot vaccinate effectively then it probably cannot also do other things. Hesitancy is an issue for vaccination rates but so too are unit costs, and shortages and mismatches between production and demand. Also, issues for vaccine uptake, particularly for measles, are part of the broader underestimation of the impact of infectious diseases. The problem of measles is growing – cases in 2017 were three-fold higher than in 2016 – and the problem cannot be left at the political level. Health professionals and civil society have a joint responsibility to speak out. The most worrying statistic is the prevalence of vaccination hesitancy among health professionals. Academies are well placed to communicate and advocate, to counter the spread of misinformation. And more must be done to collect data to monitor the impact of communication efforts.

Vaccination programmes are a Member State competence but there is a strong cross-border interest requiring collaboration in research, innovation and delivery in a concerted manner. The European Commission’s recent initiative includes:

• **Tackling vaccine hesitancy:** e.g. by supporting Member State communications on benefits of vaccines and the risks of infectious disease, establishing the European Vaccines Information portal to provide updated, accessible information and counter misinformation, and explaining why schedules may vary between countries. A newly-constituted Coalition for Vaccination will bring together stakeholders to deliver accurate information.

• **Strengthening national programmes:** e.g. by using the European Social Fund and Regional Development Fund to support infrastructure, training and evidence-sharing.

• **Supporting cooperation:** The EU may no longer be self-sufficient in vaccine production so there is need to strengthen supplies and mitigate shortages, together with developing the Roadmap of unmet population needs, identifying gaps and the research required to improve vaccine effectiveness.

Among particular points to be addressed will be the link with eHealth, e.g. sharing personal immunisation records between countries, and a focus on the importance of lifelong vaccination. A
Joint Action on Vaccination\textsuperscript{11} has started recently involving 20 partner countries and with agreed practical objectives, e.g. for digital data management principles and for supporting vaccine priorities (see presentation by Genevieve Chêne for further information).

\textbf{Andrija Visic (Policy and Government Affairs, Vaccines Europe)} introduced Vaccines Europe, representing 12 research-based companies, with 80\% of members’ production within Europe and 86\% exported outside of Europe (50\% to humanitarian groups).

The vaccines industry has considerable expertise and experience in development and manufacturing and shares common goals with academia and public health authorities in demonstrating and communicating the value of vaccines to society. Vaccines Europe supports the European Commission’s aims to increase the effectiveness and efficiency of EU and national vaccines R&D and has prioritised seven research areas in its strategy\textsuperscript{12}:

- Exploring emergent in vitro bioassay technologies and improving in vitro assays for antibody functional screening.
- Research for selection and analysis of immunological epitopes.
- Supporting research on structural vaccinology.
- Creating a toolbox of adjuvants with well-defined profile to shape the immune response.
- Improving approaches to a combined use of vectors, adjuvants, routes of immunisation.
- Identifying innovative design of clinical trials and methodologies to profile volunteers earlier in trials.
- Developing expertise and support infrastructure to perform controlled challenges in humans.

Recognising the concerns for reliable supply and preparedness (depending e.g. on manufacturing capacity, development time and human resources requirements), industry proposes implementing a mechanism to allow dialogue between industry and national competent health authorities so as to plan accordingly, alongside reducing the number of national/regional packaging and labelling requirements and streamlining regulatory requirements in Europe and worldwide.

Industry positions were also presented on other shared interests:

- Immunisation Information Systems, as the cornerstone of improved vaccination policies in a digital Europe, e.g. in facilitating clinical decision support, patient empowerment, vaccination coverage assessment, outbreak control, vaccine safety and effectiveness assessment and tracking of real-life impacts.
- Vaccine hesitancy and uptake\textsuperscript{13}, supporting the European Commission on stronger engagement of health professionals, supporting Member States in raising awareness, organising pan-European campaigns and facilitating patient access to vaccines by other channels, such as pharmacies.

\textbf{Pr. Genevieve Chene (Coordinator of the EU Joint Action on Vaccination, INSERM)} provided further information on the Joint Action\textsuperscript{10}, introduced in the presentation by Martin Seychell. The goal (by 2021)

\textsuperscript{11} Part-funded by the Health Programme, see https://ec.europa.eu/health/vaccination/overview_en.
\textsuperscript{13} See the online platform www.VaccinesToday.eu.
is to build tools to improve vaccination coverage in Europe and strengthen national immunisation plans. There are five major topics:

- Scientific evidence for national programmes
- Digital immunisation information systems
- Vaccine demand and supply
- Research and development
- Confidence: from research to intervention.

Each topic has core objectives, with specified work to identify tools, demonstrable in pilot actions. For example, for the R&D topic, priority-setting for vaccine research, and innovative mechanisms of funding are at the core; tools include concept and prototype for R&D priority-setting framework and mapping of possible funding mechanisms to decrease fragmentation; the pilot application is to a small number of vaccines on unmet needs for specific age categories. For the confidence topic, the core is dissemination of best practices and interventions to overcome hesitancy; tools include systemic overview of barriers and enablers, e-learning platform and monitoring tool for social media; the pilot applications include targeting communication to young people, and pre- and in-service educational activities in the medical and pre-medical curricula.

**Mariano Votta (Director, Active Citizenship Network)** presented a perspective from an Italian NGO representing more than 100 civic, patient and user organisations. At the national level, the Active Citizenship Network in providing information, advice and assistance, is part of the Tribunal of Patients’ Rights, and contributor to the work of the Citizen Advisory Centres and a member of the National Coalition of Associations for Patients suffering Chronic Diseases.

The work of well-informed citizens’ groups represents a good antidote to the misleading representations on vaccine risk found in the media. However, it is important that evidence-based efforts are made at the European as well as the national level. In order to involve citizens in discussions on policy and strategy at the EU level, the Active Citizenship Network is a member of consultative groups with DG Sante, DG Home and DG Justice and Consumers and also works to inform MEPs, and with the ECDC Technical Advisory Group.

One of the key messages from this citizens’ initiative is the importance of life course vaccination and one major commitment is to train citizens as advocates for vaccination. Citizens, in supporting the work of the Joint Action and the Coalition on Vaccination and other stakeholder groups, must ensure that vaccination is high on the political agenda. In discussion, the integration of information about vaccination with other health messages was also highlighted.

Other Session 2 Panel and general discussion extended many of the previous points:

- **Science advisory mechanisms and priorities for science-policy dialogue:** there is no single mechanism but it is very important to strengthen how science-based advice is generated, independently and impartially, so as to counter public mistrust about evidence. Among the key elements of the EU science advisory system are the European Medicines Agency, for example in providing vaccine pharmacovigilance data; ECDC, in communicating on multiple public health issues; and the Scientific Advice Mechanism, SAM, constituted by the European Commission to involve academy networks, including FEAM and EASAC, to ensure scientific excellence.
• **Coordination of priority setting in vaccine innovation:** it is important to build on what has already been done. Work by the Joint Action will set up an evidence-based framework and take account of the priorities developed elsewhere, e.g. by WHO.

• **Sustainability of project-based activities:** Commitment must be long-term, e.g. how will the data warehouse developed by the Joint Action be sustained when project funding finishes? This is a general challenge for projects – the first step is to ensure that project outputs are fit for purpose for its stakeholders; then there may be various options for continuing support, by Member States, other stakeholders or the European Commission.

• **Vaccine access:** who else should be involved? The community pharmacy is often closest to citizens in many countries and it is important to involve all health care professionals in outreach to promote vaccine uptake.

In concluding the discussion, Panellists were asked to reaffirm one particular priority for 2019. These included:

- Engage all stakeholders in the European Commission’s Roadmap (Seychell).
- Support collaboration between the public and private sectors (Visic).
- Build the contribution by the Joint Action (Chêne).
- Involve patients and citizens (Votta).

**Concluding Remarks**

In his closing remarks **Pr. Pierre Coulie (Member of the Belgian Royal Academy of Medicine)** congratulated all participants for a very stimulating meeting that had tackled complex issues in addressing needs for different groups and countries. Among the challenges to face is citizen’s scepticism about messages from “Brussels” as well as about vaccination. Academies are well-placed to provide the independent and accurate evidence needed to counter misinformation.

There is a lot of work to do. Vaccine issues are global and EU research can also help to tackle global priorities. The EU Roadmap is ambitious: FEAM with other leaders in the scientific and medical communities must continue to help to identify and deliver what is achievable.
Annex I - Agenda

19 November 2018 (13:30 - 18:30)
Palace of the Academies, rue Ducale 1, 1000 Brussels / Room Roi Baudouin

*Moderator: Gary Finnegan, Health journalist*

<table>
<thead>
<tr>
<th>Time</th>
<th>Session/Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>13:30-14:00</td>
<td>Registration</td>
</tr>
<tr>
<td>14:00-14:05</td>
<td>Welcome</td>
</tr>
<tr>
<td></td>
<td>• Jean-Michel Foidart, Perpetual secretary, Belgian Royal Academy of Medicine (ARMB)</td>
</tr>
<tr>
<td>14:05 -14:15</td>
<td>Introduction</td>
</tr>
<tr>
<td></td>
<td>• George Griffin, President, Federation of European Academies of Medicine (FEAM)</td>
</tr>
<tr>
<td>14:15-14:45</td>
<td>How can European countries improve vaccination in the wake of the measles outbreak?</td>
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<td>• George Griffin, President, Federation of European Academies of Medicine (FEAM)</td>
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<td>• Jos van der Meer, past President, European Academies’ Science Advisory Council (EASAC)</td>
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<tr>
<td>14:45-14:55</td>
<td>Session 1: How can vaccination levels be improved through better public dialogue?</td>
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<td></td>
<td>• Mike Catchpole, Chief Scientist, European Centre for Disease Prevention and Control (ECDC)</td>
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<tr>
<td>14:55-15:05</td>
<td>Impulse presentations:</td>
</tr>
<tr>
<td>15:05-15:15</td>
<td>• Siff Malue Nielsen, Consultant, Vaccine-preventable Diseases &amp; Immunization (VPI), WHO Regional Office for Europe</td>
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<tr>
<td>15:15-15:25</td>
<td>• Heidi Larson, Professor of Anthropology, Risk and Decision Science, London School of Hygiene and Tropical Medicine</td>
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<tr>
<td>15:25-15:55</td>
<td>• Paolo Villari, Professor, Department of Public Health and Infectious Diseases of Sapienza University of Rome – Representing the Institute Pasteur of Italy</td>
</tr>
<tr>
<td>15:55-16:15</td>
<td>Discussion with the audience</td>
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<tr>
<td>16:15-16:25</td>
<td>Session 2: Vaccination and EU policies: How to strengthen cooperation at EU level?</td>
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<tr>
<td>16:25-16:35</td>
<td>Impulse presentations:</td>
</tr>
<tr>
<td>16:35-16:45</td>
<td>• Martin Seychell, Deputy Director General for Health, European Commission, DG SANTE</td>
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<tr>
<td>16:45-16:55</td>
<td>• Andrija Visic, Manager, Policy and Government Affairs, Vaccines Europe</td>
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<tr>
<td>16:55-17:25</td>
<td>• Geneviève Chêne, Coordinator of the EU Joint Action on Vaccination (INSERM)</td>
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<td>• Mariano Votta, Director, Active Citizenship Network</td>
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<tr>
<td>17:25-17:35</td>
<td>Discussion with the audience</td>
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<tr>
<td>17:35-18:30</td>
<td>Concluding remarks</td>
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<td></td>
<td>• Pierre Coulie, Member of the Belgian Royal Academy of Medicine (ARMB)</td>
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<tr>
<td>18:30-18:45</td>
<td>Networking cocktail</td>
</tr>
</tbody>
</table>
Annex II - Speakers’ biographies

Moderator

Gary Finnegan
Health Journalist

Gary Finnegan is an award-winning journalist, editor and author. He has served as Editor of Irish Medical News and has edited the health and research sections of EurActiv.com. An experience science writer, Gary regularly writes for Horizon magazine, Vaccines Today, Break Dengue and ThistsMedTech, along with several specialist magazines. He has a degree in physiology from Trinity College Dublin and an MSc in science communication from Dublin City University. Gary has won two GSK Irish Medical Media Awards and is a three-time national winner of the EU Health Prize for Journalists run by the European Commission.

Jean-Michel Foidart
Perpetual secretary, Belgian Royal Academy of Medicine (ARMB)

J.M. Foidart is an MD, PhD trained in Obstetrics and Gynecology (Ob-Gyn), in part in the United States (1976-1979) at the Johns Hopkins University Hospital, Baltimore, and in Belgium, Finland and France. He spent 3 years as a biochemist at the National Institutes of Health in Bethesda, Maryland, USA. He became in 1988, professor and chairman of the Dept of Cell Biology at the University of Liege (ULg), Belgium. He then established a large and well renowned laboratory that owns many patents. He contributed from 1989 until 1996 to the clinical development of a new oral contraceptive containing Drospirenone. In 1996, he became chairman of the Dept of Ob-Gyn ULg, until 2012. From 2012 until 2015 he was extraordinary Professor at University of Liège, Belgium and chairman of the Interdisciplinary Group of Genomics and Proteomics (600 researchers). He is presently Board member and the chairman of the Scientific Board at MITHRA, a Belgian company that he created in 1999 with François Fornieri. His main research interest is in experimental reproductive endocrinology and oncology. He played a pivotal role in the development of Levosert, an intra-uterine system releasing small amounts of levonorgestrel.

Professor Foidart is a member of many national and international scientific committees. He is a past president of the Belgian Society of Biology and of the Belgian Society of Gynecology. He is past General Secretary of the European Society of Gynecology and a former Board member at the International Federation of Gynecology and Obstetrics in London (FIGO) and presently a member of the Board of the International Society of Gynecological Endocrinology. He has been an invited lecturer at the Universities of Paris VII and Paris XI and is the recipient of several international awards from Belgian (Chaires Francqui 1995 and 1996), and French Universities. He has received many honorary and scientific distinctions. He is Dr. Honoris Causae at the University la Sorbonne-Pierre et Marie Curie, (Paris 2010) and Paul Sabatier Toulouse (2012).

Professor Foidart was awarded in 2006, to the “Prix Maisin”, highest distinction for medical achievement of the National Research Foundation in Belgium and is Officier de l’Ordre de Léopold II and Commandeur de l’Ordre de la Couronne. He organized more than 30 International Congresses in the fields of Contraception, Reproductive Endocrinology and Menopause. He has published over 800 manuscripts, 26 chapters in books, and more than 40 invited reviews, in outstanding journals with a mean H index of 104, that were cited more than 40,000 times.

Professor Foidart is a member of the French and Belgian Academies of Medicine of which he is presently the Perpetual Secretary. He has been appointed in 2018, Treasurer of the European Federation of the Academies of Medicine.
George Griffin
President, Federation of European Academies of Medicine (FEAM)

Prof. George Griffin gained BSc in Pharmacology and Molecular Biology at King's College London Sciences, where he was awarded the Delegacy Prize for Excellence in Preclinical Science. He was awarded PhD in Cell Biology/Biochemistry, University of Hull, and returned to clinical studies at St George, University of London, where he was awarded the MBBS. Professor Griffin’s postgraduate training paralleled basic and clinical science. During this time, he was awarded a Harkness Fellowship of the Commonwealth Fund of New York at Harvard Medical School. On return to the UK, he continued clinical training at Royal Postgraduate Medical School where he was tutor in Medicine, and the National Hospital for Nervous Diseases. He then returned to St George’s as lecturer and was awarded a Wellcome Trust Senior Lectureship and became consultant physician on the Clinical Infection Unit where he was instrumental in developing an internationally renowned research unit twinned to the Clinical Unit. He held prestigious research fellowships in the University of Michigan and National Institutes of Health.

He has chaired scientific advisory boards in major pharmaceutical industry in the USA and UK. He has been chair and member of major Wellcome, Medical Research Council and Gates Foundation committees. He was censor at the Royal College of Physicians and was made a member of the Academy of Medical Sciences in which he has been elected to become foreign secretary and council member. He was appointed to the board of Public Health England where he will help shape strategy for research and clinical development. Professor Griffin was awarded the distinction of CBE in 2018 (Commander of the British Empire) for his research and its contribution to Public Health.

His research has focussed on the host response to infection at cell, molecular and whole body level. Such work involves immune and metabolic responses in vivo in humans. Furthermore cell and molecular studies include culture of human mucosal explants and definition of macrophage activation in vitro by microbial agents. A macrophage is a cell which ingests particles (microorganisms or host cells) for destruction and immune presentation. It is important in intracellular infection and also produces cytokines (a category of signaling molecules) as part of the immune response.

Professor Griffin’s principal clinical contributions to knowledge have been in the characterisation of intestinal disease in HIV infection, mechanism of weight loss in HIV and definition of loss of mucosal immune response in advanced HIV infection. The dominant cell and molecular achievements have been the characterisation of NF-kb, a crucial factor maintaining macrophage differentiation and the role this transcription factor plays during tuberculosis infection of the macrophage and the mechanism of enhanced HIV transcription in such cells. More recently he has characterised the role of co-infection of HIV infected cells with herpes virus in enhanced HIV transcription in the genital epithelium.

Jos van der Meer
Past President, European Academies’ Science Advisory Council (EASAC)

Jos WM van der Meer is emeritus Professor of Medicine at Radboud University Nijmegen, The Netherlands. Between 1992 and 2012 he was head of the Department of internal medicine at the Radboud University Medical Centre.

His major areas of expertise are host defence against infection, autoinflammation, immunodeficiency and antimicrobial therapy.

He is a member of the Royal Netherlands Academy of Arts and Sciences (KNAW), for which he served as a vice-president from 2005 to 2011. He is a member of Academia Europaea and he is currently past-president of EASAC, the European Academies Science Advisory Council. He is a honorary Fellow of the Royal College of Physicians in London and in Edinburgh and a fellow of the Infectious Diseases Society of America.

He is a member of the Dutch National Board for Research Integrity LOWI.

He received a number of prices and awards, such as the Gold Hijmans van den Bergh medal. He was awarded knighthood in the order of the Netherlands Lion in 2003.

He published more than 1000 scientific papers in peer-reviewed journals. His H index is > 100.
Mike Catchpole
Chief Scientist, European Centre for Disease Prevention and Control (ECDC)

Mike Catchpole is a medical doctor who has worked in infectious disease epidemiology and response at the national and international level since 1991. He is Chief Scientist at the European Centre for Disease Prevention and Control (ECDC). Prior to that he was Director of Public Health England’s national Centre for Infectious Disease Surveillance and Control, and was the UK member of the ECDC Advisory Forum from 2007 until 2014. He has over 20 years’ experience of management of communicable disease surveillance and response, including the management of many national outbreak investigations and leadership of the national epidemiological response to the 2009 influenza A(H1N1) pandemic in England, leading the public health follow up of those exposed to the terrorist bombings in London in 2005, developing and managing the surveillance systems for the 2012 London Olympics and the surveillance systems that were instrumental in driving the dramatic reductions in MRSA and C.difficile in England.

His primary research interests have included HIV and other sexually transmitted infections, the wider health effects of major incidents, and public health information systems development. He has also been a member of the steering groups for a number of European projects, and chaired the Steering Committee of the European Programme for Intervention Epidemiology Training (EPIET) from 2001 to 2006.

He has academic appointments, as a visiting professor, at Imperial College London and City University London.

Siff Malue Nielsen
Consultant, Vaccine-preventable Diseases & Immunization (VPI), WHO Regional Office for Europe

Siff holds a master in Public Health, with a focus on behavioural change- and social insights. This she has combined with a degree in journalism and behaviour change communications at the Rollins School of Public Health, Emory University.

Her experience ranges from research-based communication with a focus on social in-sights, qualitative research to production of tailored interventions, project management and journalism. At the same time, she has many years of field experience, and has been working in many different countries – mainly focusing on public health issues in developing- and middle-income countries.

Siff began consulting with WHO in 2014, working primarily on risk communications. For the last two years she has been part of the vaccine acceptance and demand team within VPI. She supports Member States in strengthening vaccine acceptance and demand. Support is focused on behavioral insight, qualitative research for targeted intervention and communication strategies, risk communication and building long-term resilience against vaccine safety scares. In addition she is coordinating the inter-sectoral project on developing a game-based educational module on vaccines and immunization.

Prior to joining WHO her professional experience includes positions as communications consultant focusing on health care; as press and communications consultant at the Danish Medical Association; and as a journalist at a Danish newspaper.
Heidi Larson  
Professor of Anthropology, Risk and Decision Science, London School of Hygiene and Tropical Medicine

Heidi J. Larson, PhD, is an anthropologist and Director of The Vaccine Confidence Project at the London School of Hygiene & Tropical Medicine, where she is a Professor of Anthropology, Risk and Decision Science. She is also the Director of European Initiatives and Clinical Professor, Institute for Health Metrics and Evaluation (IHME), University of Washington.  

Professor Larson previously headed Global Immunization Communication at UNICEF and chaired the GAVI Advocacy Task Force. Dr. Larson’s research focuses on the analysis of social and political factors that can affect uptake of health interventions and influence policies. Her particular interest is on risk and rumour management in health programmes, particularly around vaccines and immunization. She served on the FDA Medical Countermeasure (MCM) Emergency Communication Expert Working Group, and is Principle Investigator of the EU-funded (EBODAC) project on the deployment, acceptance and compliance of an Ebola vaccine trial in Sierra Leone.  

The Vaccine Confidence Project (www.vaccineconfidence.org) has developed multiple metrics to measure population confidence in vaccines, from a survey-based Vaccine Confidence Index to temporal analysis of media and social media, and qualitative research to understand the drivers of vaccine reluctance and refusal. The research also includes tracking the ecology of rumours and transnational influences on public trust in vaccines.  

The Vaccine Confidence Project has been named a WHO Centre of Excellence on addressing Vaccine Hesitancy.

Paolo Villari  
Professor, Department of Public Health and Infectious Diseases of Sapienza University of Rome

Paolo Villari is Full Professor of Hygiene and Director of the Department of Public Health and Infectious Diseases of Sapienza University of Rome. He obtained his MD degree at the University “Federico II” of Naples, where he gained also his specialization in Hygiene and Preventive Medicine. He completed his post-graduate training in the U.S. During the years 1991-1993 he was Visiting Scientist at the Department of Health Policy and Management of the Harvard School of Public Health (Boston – MA), where he obtained his Master Degree in Public Health in 1992. During the years 1995-1996, he was Guest Investigator at the Laboratory of Microbiology of the Rockefeller University (New York – NY). At present Paolo Villari is the President of the National Verification Committee for the elimination of measles and rubella in Italy.  

Scientific interests of Paolo Villari include systematic reviews and meta-analysis in public health, health care management and molecular epidemiology of infectious diseases. He co-authored more than 200 articles published on national and international peer-reviewed journals on different topics of Public Health, and his current H-index is 29.

Martin Seychell  
Deputy Director General for Health, European Commission, DG SANTE

A graduate in chemistry and pharmaceutical technology, Mr. Seychell specialized in Chemical analysis. He has held important positions on several government boards and commissions in Malta, including the Food Safety Commission and the Pesticides Board. Mr Seychell occupied the post of Head of Directorate at the Malta Standards Authority between 2001 and 2006.  

He has been responsible for the implementation of a number of EU directives in the areas of risk assessment, food safety, chemicals and cosmetic products legislation, and has actively participated in negotiations on major technical proposals such as the new chemicals legislation, REACH, and in screening processes in the areas of free movement of goods, environment and agriculture during the process leading to Malta’s accession to the EU. He held the post of Director of Environment in Malta between 2006 and 2011. As Director, he was responsible for a broad range of functions arising from the Maltese Environment Protection Act. He was appointed Deputy Director General for Health and Consumers at the European Commission in March 2011. Responsible for directorates dealing with Consumer affairs, Public health and Health systems and products (SANCO). 2014 - to date: Deputy Director-General for Health in the Health and Food Safety Directorate-General (SANTE).
Andrija Visic
Manager, Policy and Government Affairs, Vaccines Europe

Andrija Visic is a Manager, Policy and Government Affairs at Vaccines Europe in Brussels. He assists the Vaccines Europe Executive Director in organising the work of several Vaccines Europe Working Groups and Task Forces (External Affairs, Influenza, Access). Before joining Vaccines Europe, Andrija worked in the European Parliament and as a Head of Office in the Croatian Society of Lobbyists. He holds an MA in public policy with a focus on lobbying from the Central European University in Budapest and an MA in sociology from University of Zagreb.

Geneviève Chêne
Coordinator of the EU Joint Action on Vaccination (INSERM)

Professor of medicine in biostatistics and public health since 1999, Geneviève Chêne is currently the Director of the Bordeaux school of public health (institut de santé publique, d’épidémiologie et de développement, ISPED) at the university of Bordeaux. She currently serves as coordinator of the EU-joint action on vaccination led by France, an EU instrument to strengthen cooperation across EU countries and improve vaccine coverage (Inserm as coordinating institution, in close cooperation with the French ministry of health).

Since 2014, Geneviève is head of a platform for international clinical trials (“EUCLID”), funded by the investments for the future (« PIA ») through F-CRIN infrastructure. This platform is involved in many international vaccine trials for the prevention of Ebola, malaria or pneumococcus.

As a professor of public health at the Bordeaux university, Geneviève teaches clinical epidemiology and public health at the school of medicine and at the ISPED where she initiated an international distant-learning program (5000+ students since 2001). She is appointed as Adjunct professor of clinical epidemiology at the Harvard T.H Chan school of public health (department of epidemiology) since October 2017.

Between 2014 and 2017, she served as director of the Thematic Institute (ITMO) public health of the Inserm and the National Alliance for Life Sciences and Health (Aviesan), based in Paris. In 2013, she was nominated in the “Comité des Sages” by the Prime Minister for the preparation of the National Strategy for Health.
Mariano Votta
Director, Active Citizenship Network

Mariano Votta, public affairs professional and journalist, is the Director of Active Citizenship Network (ACN), the international branch of the Italian NGO Cittadinanzattiva, where he is responsible for European Affairs. Passionate about healthcare and consumer issues, he has more than 17 years of experience in the field of advocacy, stakeholder engagement, European projects, communication and civic information. Mariano's role is in Public Affairs and Project Management at EU level now, but he began his career working in journalism as Communication Officer at Cittadinanzattiva. In this position, he was involved for the first time at international level within the United Nation Development Programme, where he worked as consultant in Public Services and Communication in Colombia from 2010 to 2012. Then, he moved on to take up his current position within ACN in 2013. Since then, he has been actively involved as ACN stepped up its advocacy activities at the European Institutions, which in 2015 led to the opening of a representative office in Brussels and - above all - to the launch of the MEP Interest Group “European Patients' Rights & Cross-Border Healthcare”, promoted with the endorsement of almost 100 organizations across Europe. Furthermore, in 2016, Mariano won the Efhre International University Excellence Awards on patients' rights. Mariano Votta officially represents ACN abroad, with the European Commission DG Health, DG Consumers, DG Move, DG Migration and Home Affairs and with all the other stakeholders. He is also in the Board/ Executive Committee of Cittadinanzattiva (since 2013), Pain Alliance Europe (since 2014), Societal Impact of Pain (since 2016) and Health First Europe (since 2017). In 2016 he was appointed by the European Commission to represent Italian Consumer Associations in the European Consumer Consultative Group, and in 2017 he was appointed as Secretary General at European Consumer Union-ECU. Before joining Cittadinanzattiva-ACN in 2001, he worked in the credit sector for a multinational corporation. Mariano Votta holds a MSc in Political Science and two post-graduate courses in European Public Relations and in Corporate Social Responsibility. He has also volunteered in the post communist Albania. He has been for more than ten years a Boy Scout where he became assistant leader of the youngest groups (7-12 years old).

Pierre Coulie
Member of the Belgian Royal Academy of Medicine (ARMB)

Pierre G. Coulie, MD PhD, born in Brussels in 1957, is Full Professor at the Faculty of Medicine of the Université catholique de Louvain, located in Brussels, where he teaches immunology. Trained as an immunologist at the de Duve Institute in Brussels, he worked with Prof. Jacques Van Snick on rheumatoid factors and cytokines. In 1988 he joined the group of Prof. Thierry Boon human tumor immunology. Investigator at the Brussels branch of the Ludwig Institute for Cancer Research from 1989 to 1995, he made important contributions to the identification of human tumor-specific antigens recognized by T lymphocytes and to the understanding of the mechanisms of tumor regressions in the early days of cancer immunotherapy. Heading a research group at the de Duve Institute. P. Coulie is an expert on the antigenicity and immunogenicity of human tumors. His current research deals with the immunogenicity of breast carcinomas, including at the early stages of tumor development, with inflammatory cytokine production in the context of cancer and with the identification of antigens targeted by T cells in human autoimmune diseases.