

Proposal for an EU Joint Action on Vaccination: Cross-border challenges to be addressed

1. Background

Vaccination certainly constitutes one of the most cost-effective public health interventions implemented worldwide to prevent morbidity and mortality associated to several deadly diseases. As often noted, however, vaccination has become victim of its own success. Today, **growing hesitant behavior**¹ and **complacency towards disease** are putting at risk a proper implementation of the National Immunisation Programmes across the EU Member States.

As a result, over the past years, Europe has been experiencing a worrying surge in cases of vaccine-preventable diseases. Such a situation **puts avertable strains on healthcare systems**, as the necessary vaccines and infrastructures to deliver the programmes are often in place but remain **suboptimal in their use**². This represents a gap, as the investment in cost-effective vaccination programmes must be seen as instrumental to protect individual health on the one hand, but also to contribute to healthcare systems' sustainability, societal welfare and economic growth on the other.

Countries around the world are reflecting on ways forward to address this challenge, considering legal measures that could **prompt public health behaviour prone to vaccination**. The European Commission Expert Panel on Effective Ways of Investing in Health recently published a Preliminary Opinion on the application of the concept of **'Disruptive Innovation' to Healthcare**³. In the field of disease prevention, the panel highlights the innovative use of legislation to control tobacco consumption. A similar approach could be seen gaining ground in the field of vaccination. While several EU countries are promoting reflecting and debate on policy options that could be pursued in this regard (e.g. France, Italy, Germany), countries around the world have already enacted enforcement legislation to increase vaccination coverage rates. To illustrate, the Australian government recently announced the intention to cut child care benefits for parents refusing to vaccinate their children according to the immunisation schedule; In California, in the US, Senate Bill 277 approved in June 2015 eliminated parents' rights to refuse to vaccinate their children for personal or religious reasons. It requires that children receive a strict course of 10 immunisations to attend school or day care.

Vaccination also continues to still be primarily regarded as a childhood intervention, overlooking the fact that **a number of vaccines are fundamental across other age and risk groups**. The value of immunisation beyond childhood is currently not being sufficiently considered, leaving the healthcare system with a missed opportunity to comprehensively promote active and healthy aging policies in response to the demographic changes in Europe. The major changes to the social and demographic structure of the EU population call for immediate action to promote equitable access to the necessary vaccinations beyond childhood **through a life-course approach to immunisation**⁴.

The continuous **pressure on prices and the rigidity of current procurement systems** for vaccines in Europe has significantly impacted the presence of manufacturers in the last five years. This has **reduced the flexibility of securing a sustainable supply** to the few companies still operating on European soil.

While immunisation is a fundamental national public health competence, the recently adopted **Council Conclusions on vaccinations as an effective tool in public health** well highlight the **common challenges that are being faced by all of the EU Member States** at present,

¹ WHO (2015), Vaccine hesitancy: a growing challenge for immunisation programmes, <http://www.who.int/mediacentre/news/releases/2015/vaccine-hesitancy/en/>

² For more information on preventable disease cases and major outbreaks in Europe, please visit the following web links from official public health sources WHO, ECDC, DG SANTE as well as news agencies, e.g. BBC, Euronews.

³ http://ec.europa.eu/health/expert_panel/opinions/docs/011_disruptive_innovation_en.pdf

⁴ Council Conclusions (2014) on Vaccinations as an effective tool in public health, point 28f, <http://italia2014.eu/media/3789/council-conclusions-on-vaccinations-as-an-effective-tool-in-public-health.pdf>

including the ones briefly described above. Such challenges are **affecting the successful implementation of existing immunisation programmes** in Europe today, and are **multi-faceted** in nature, thus requiring strong political leadership to move forward from the status quo. More so in a climate of increasing uncertainties posed by **risks of supply shortages that could be further exacerbated** with the recent wave of **migration towards EU countries and the growth of “vaccine hesitancy” in Europe.**

Communicable diseases know no borders, and as such it seems appropriate that a public health strategy aimed at their prevention has EU-added value. A **strategic and forward-looking approach is key**. All of the challenges affecting the current vaccine and vaccination landscape in Europe require joint stakeholder reflection in view of putting in place a coherent **EU strategy for vaccination**

In these regards, the above-cited **Council Conclusions** already show the way forward by inviting the Member States and the Commission to **develop co-financed Joint Action programmes** to share best practice on national vaccination policies (paragraph 29i).

EU Joint Actions have a clear added value⁵ as, **provided the right political leadership**, they enable a significant number of actors from the Member States to cooperate together in identifying and developing the appropriate actions at EU level that can **help them meet their own public health objectives** according to their **National Immunisation Policies**.

2. Aim and scope

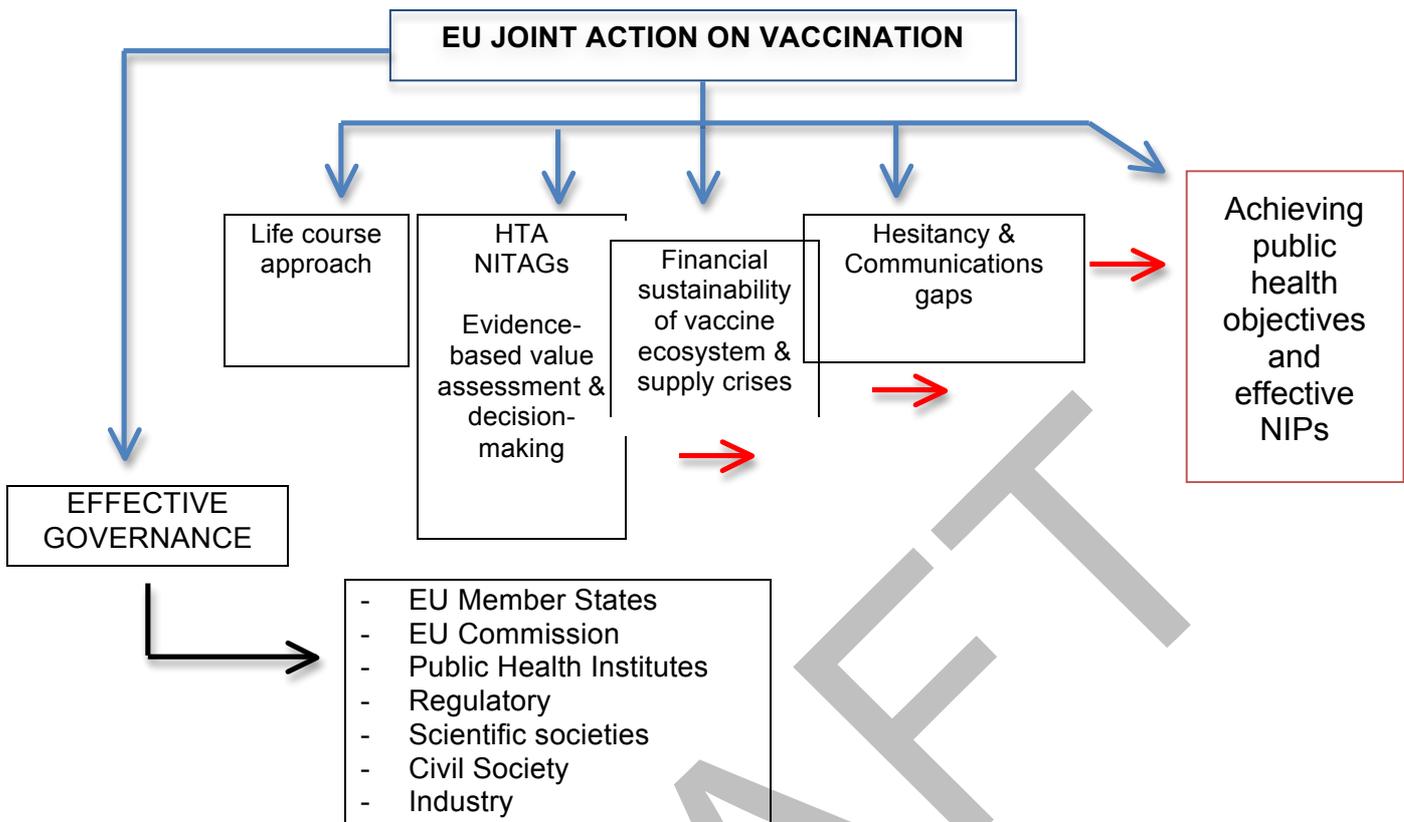
An **EU Joint Action on Vaccination should aim towards building an EU immunisation roadmap** through the development of effective guidance for the **establishment and implementation of effective national immunisation programmes in the Member States with clear immunisation targets (KPIs) throughout the life course** as well as the necessary capability and capacity to implement them with input from all actors concerned.

It is considered that an EU Joint Action (JA) on Vaccination should be **structured in reflection of the main common challenges faced by the Member States** in the implementation of their national immunisation programmes (NIPs), thus where the EU added value would be evident.

Key working areas under the scope of such a JA could be the following:

1. Set a European a life course approach to immunisation reflected in National vaccination programmes
2. Set a a framework for evidence-based HTA and decision-making specific to vaccines
3. Secure financial sustainability of vaccine ecosystem to avoid supply crises upstream and strengthen effective delivering of vaccines to healthcare systems
4. Effectively tackling ‘immunisation hesitancy’ to enable maximum level of protection to European citizens
5. Defining priorities for unmet medical needs and new vaccine development

⁵ http://ec.europa.eu/chafea/documents/health/hp-factsheets/joint-actions/factsheets-hp-ja_en.pdf



The following pages provide a brief description of the core issues where EU level action and cooperation could be considered to add value, and strengthen Member States' capacity to meet their public health objectives.

1. Encouraging a life course approach to immunisation

As recognised by the Council Conclusions (Art. 28 f) there is a need to “consider immunisation beyond infancy and early childhood by creating vaccination programmes with life-long approach”. The demographic shift and increase in the older age groups across the EU call for the implementation of systematic policies that can support active and healthy living across the entire life spectrum. The EU target of increasing life expectancy by two quality life years⁶ should include efforts to maximise opportunities for preventing debilitating diseases.

A number of vaccination exist that are of relevance to protecting health beyond childhood, targeting adolescents, adults, and the elderly as well as specific target groups such as pregnant women and at risk patients affected by chronic conditions. Such vaccinations however remain suboptimal in their implementation and often do not constitute part of the recommended and funded national immunisation programme. This creates disparities and inequities in the offering across countries but sometimes also within countries, where independent regional programmes are in place.

A life course approach to vaccination has the potential of contributing to meeting today's healthcare system challenges by maximising opportunities for prevention; making the fundamental albeit often forgotten link between chronic and infectious diseases; help

⁶ European Commission Directorate-General for Economic and Financial Affairs. Brussels: Directorate-General for Economic and Financial Affairs; 2009. The 2009 Ageing Report — Economic and budgetary projections for the EU-27 Member States (2008–2060). Joint Report prepared by the European Commission (DG ECFIN) and the Economic Policy Committee (AWG).

promoting a more rational use of antibiotics for the vaccines concerned (e.g. against influenza and pneumococcal diseases).

Appropriate reflection on how to create the right conditions and set up the needed infrastructures to allow such a shift towards a 'life course' approach to vaccination is thus of paramount importance for Europe today. More so as several new vaccines are to become available over the next years to target emerging and unmet medical needs often affecting specific target groups. This particularly includes vaccines against antimicrobial resistant bacteria, healthcare associated infections, and more personalised vaccines adapted to the age profile and immune system.

2. Improving and strengthening national capacity for carrying out evidence-based HTA and decision-making on immunisation

Building on the success and achievements of the EU-funded EUnetHTA JA, with specific focus on Relative Effectiveness Assessment (REA) in HTA, it is considered that prompting dialogue and reflection across key EU stakeholders to **develop specific HTA considerations relevant to vaccines** is of paramount importance. Being preventative in nature, vaccines present specific characteristics that set them apart from other medicinal products.

Indeed, in order to ensure rapid implementation of life-saving vaccination programmes there is a need to develop a specific, coordinated, comprehensive assessment framework that takes account of the **unique nature and value of vaccines**. Member States in the EU currently implement different approaches to their vaccination calendars based on local epidemiology and appraisal of recommendations from the relevant evaluation bodies informing the decision-making (e.g. NITAGs, HTA)⁷.

However, it is often experienced a **duplication in assessments** used by public health (NITAGs), payer, and regulatory bodies at European, national and regional levels. This often leads to **delays in access**, and it is estimated that in EU Members States, it takes around six years from marketing authorisation of a vaccine to implementation of a vaccination programme⁸.

There is also an important need to improve the **coordination of the different stakeholders** involved in vaccine assessment especially NITAGs and HTA bodies, in and among EU Members States, to avoid duplication and foster proper evidence-based policy decisions.

3. Financial sustainability of vaccine ecosystem and supply crises

In an environment characterised by a relatively limited number of vaccine manufacturers supplying for global public health needs, several factors on the supply and/or demand side of the vaccine market may intertwine and impact ability to keep supply steady.

These factors span across the public health, demand forecasting, procurement policies and legislation, regulatory, and production domains. The different national immunisation programs and increasing national and EU regulations certainly make it challenging for the vaccine manufacturers to meet the various and complex requirements and specifications.

This necessitates a **joint stakeholder dialogue** across EU actors and expertise and including the voice of the vaccine manufacturers. Only a joint dialogue can help first of all build the necessary understanding of the hurdles and challenges implicated, as well as pave

⁷ ECDC (2015), Current practices in immunisation policy-making in European countries, accessible [here](#).

⁸ Blank P. et al. (2013), Population Access to new Vaccines in European countries, Vaccine 31, 2862-2867, <http://dx.doi.org/10.1016/j.vaccine.2013.04.039>

the way to putting **in place the right mitigation strategies** that can either lower the risk of shortages or help addressing these situations timely when the need arises.

4. Effectively tackling the phenomenon of ‘immunisation hesitancy’

The recurring outbreaks of several vaccine preventable diseases experienced in several EU countries for a number of years now is a worrying trend showing a weakness in the capacity of vaccination programmes to fully attain their objectives. These outbreaks are posing unnecessary and avoidable costly strains on healthcare system sustainability, which is already challenged by cost-containment policies.

To illustrate, since 2010, the EU has seen a series of measles and rubella outbreaks, notably in the UK, France, Italy, Spain, Belgium, Romania, Bulgaria, and, more recently, Germany. The ECDC reported more than 4,000 cases of measles between July 2014 and July 2015⁹. The European Commission reported that only half of EU countries have achieved the 95% coverage target for two doses of the measles vaccine.¹⁰ Since the 2009 H1N1 pandemic experience, a decline in vaccination against seasonal flu has been reported for key target groups¹¹. All but two EU countries are falling short of the 75% coverage target set by the Council¹², leaving an estimated 60 million fragile adults unvaccinated every year.

As known, infectious diseases know no borders, and without a pan-European strategy to prevent the public health risks of communicable diseases, countries’ own national policy are at risk of being insufficient. **A discussion at EU level must take place on how to effectively tackle the barriers and drivers of hesitant behavior which affects both the general public as well as healthcare workers** in the broadest sense, from GPs to nurses, midwives etc.

It is thought that the rational approach to addressing such challenge is to set up appropriate EU level ‘infrastructure’ to enable a stratified monitoring of acceptance attitudes, baseline levels of risk awareness, as well as sentiments towards specific vaccines and vaccination programmes. This should help to support the appropriate measurement of the scope and extent of ‘vaccine hesitancy’. It would thus act as a tool than can inform the appropriate design of effective public health communication programmes.

5. Defining priorities for unmet medical needs and new vaccine development

With the changing demographic structure of the EU population and the rising threats of emerging medical needs such as antimicrobial resistance and healthcare associated infections, there is a fundamental need to define mechanisms capable of prioritising and advising on innovative vaccines needed to protect public health.

The development of innovative vaccines requires considerable investments in breakthrough technologies and is a lengthy process that can take up to 20 years from R&D through to availability on the market. Solid and comprehensive data should be available to assess unmet medical needs and prioritise new vaccine development. This would help identifying countries’ vaccination priorities in a long-range plan.

⁹ ECDC (2015), Measles and Rubella Monitoring, July 2015. Available online at <http://ecdc.europa.eu/en/publications/Publications/measles-rubella-quarterly-surveillance-july-2015.pdf>

¹⁰ DG SANCO (2012), Europe’s got measles, Presentation to the EU Health Policy Forum. Available at: http://ec.europa.eu/health/interest_groups/docs/ev_20120510_co04_en.pdf

¹¹ European Commission (2014), SWD (2014) 8 final, State of Play on the Implementation of the 2009 Council Recommendation on seasonal influenza vaccination, http://ec.europa.eu/health/vaccination/docs/seasonflu_staffwd2014_en.pdf

¹² Council Recommendation (2009/1019/EU), <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:348:0071:0072:EN:PDF>

Ultimately, the **impact of a Joint Action** and collaboration at EU level should be to foster innovation for a social purpose at least on **three levels**:

- I. Better prevention and health outcomes from diseases that can be avoided;
- II. Sustainable healthcare systems and freeing of resources for medical innovation; and
- III. Sustained research and industry investment in the interest of public health needs as to ensure the sustainability of immunisation programmes.

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