Making vaccine research & development more effective in the EU

1. INTRODUCTION

The purpose of this paper is to provide the basis for a discussion on where and how strengthened EU-wide collaboration on vaccine research & development (R&D) in Europe, can meet the needs and address public health challenges.

Public research programmes, from the European Commission and Member States, have invested substantially in vaccine research and development. The main instrument for funding vaccine research by the Commission has been the multiannual framework programmes for research and technological development, currently the Horizon 2020.

Horizon 2020 supports vaccine research and innovation by covering all aspects of vaccine research through a portfolio of funding instruments. Furthermore, the Commission has developed dedicated instruments for small and medium-size enterprises (SMEs) as well as public-public and public-private partnerships (e.g. the Innovative Medicines Initiative (IMI)). The Commission has also pursued innovative ideas to support vaccine research, including the award of H2020 prizes[1] and loans for vaccine research.

2. CHALLENGES

Despite substantial funding and policy initiatives, the European vaccine R&D field faces ever-evolving challenges related to advances in vaccinology, the emergence of new players in vaccine manufacturing and shifts in the public's attitude towards vaccines.

Europe is witnessing a rising trend in vaccine hesitancy, discrepancies of demand and supply for certain vaccines, and calls for the evidence-based reconfiguration of national vaccination programmes.

In response, the Commission has funded the "*Innovation Partnership for a Roadmap on Vaccines in Europe*" (IPROVE) to inform strategic decisions on the priorities for future vaccine investment in innovation and technological development at the level of the EU as well as for individual Member States. It particularly highlights the need to prioritize vaccine implementation research[2] as a major tool towards understanding and addressing vaccination hesitancy and informing public health policy decisions.

2.1 Barriers to vaccine development

The vast majority of the vaccines that are currently on the market have been developed through traditional research methods. The complexity of targets for vaccine development requires substantial financial investment and expertise, making the development of the next generation of innovative vaccines much more complex, challenging, costly and risky. When designing the R&D plans for a new vaccine, companies

[1] http://europa.eu/rapid/press-release_IP-14-229_en.htm

[2] Implementation research is devoted to understanding the bottlenecks around introduction and scaling up implementation of a proven public health intervention.http://www.who.int/immunization/research/implementation/en/

currently have to make their assumptions on the vaccine profile and future medical needs with no possibility to assess whether the candidate vaccine will actually meet the expectations from all relevant stakeholders. This means that vaccine developers have to take an increasingly high level of risks at a very early stage in development in the current challenging economic environment.

2.2 Vaccine implementation research

Understanding the bottlenecks around the introduction and scaling up of a new vaccine is an important research question. Implementation research addresses these issues and seeks to find practical solutions to overcome these barriers or constraints.[3] Such research activities could address shortcomings related to e.g. knowledge about reasons behind vaccine hesitancy, design of clinical studies or flexible manufacturing systems.

3. OPPORTUNITIES

3.1 Foster partnerships across sectors

R&D projects that support collaborations across countries, disciplines, and organisations can foster innovative and integrated approaches to meet challenges, e.g. the Innovative Medicines Initiative (IMI2). This could be complemented by respective stakeholder dialogue involving all relevant partners. This would allow exploring how barriers to the development of vaccines could be overcome. This is in particular relevant in the context of changing demographic structure of the EU population and rising threats of emerging medical needs such as antimicrobial resistance, which has been identified as a major public health priority at European and worldwide levels.[4] [5]

3.2 Establishment of European vaccine R&D Infrastructure

Based on the pilot European Vaccine R&D infrastructure TRANSVAC, the Commission is currently preparing the next generation of European Vaccine R&D Infrastructure, which is expected to further facilitate linking and aligning human and financial resources between research programmes with shared objectives. This infrastructure can create platforms and networks of excellence to overcome and avoid duplication of efforts and to improve efficacy and effectiveness of research efforts throughout Europe by providing access to critically needed R&D services.

3.3 Prioritization of vaccine implementation research

Implementation research in the field of vaccination could support countries in strengthening their routine vaccination programmes.[6] Prioritisation of such research at EU level would contribute to increased accuracy and effectiveness of EU funding according to public health needs.

Prioritisation of vaccine implementation research would help to leverage research needs related to:

---

[3] http://www.who.int/immunization/research/implementation/en/

[4] WHO's first global report on antibiotic resistance reveals serious, worldwide threat to public health - 30 April 2014

[5] http://ec.europa.eu/dgs/health_food-safety/docs/amr_factsheet_en.pdf

[6] http://ac.els-cdn.com/S0264410X13001369/1-s2.0-S0264410X13001369-main.pdf?_tid=0ebf54a6-0d7d-11e7-8497-00000aab0f6b&acdnat=1490021822_03df93b9a14507e7173d3e645814300d

i. Vaccine manufacturing and quality control (e.g.VAC2VAC[7]);
ii. Communication (e.g. EBODAC[8]); and
iii. Evidence-based vaccination programmes (e.g. i-MOVE+[9] and ADVANCE[10]).

Research on vaccine hesitancy could aim that drivers and barriers to immunization are correctly understood and taken into account. Furthermore, such research could explore how to increase the effectiveness of communication, e.g. of health care workers, to counter vaccine hesitancy and better advocate vaccination.

Research on innovative manufacturing processes would allow shortening production times, raising production yields, increasing production predictability, and improving timelines, especially in epidemic or pandemic settings. Research could also focus on flexible manufacturing systems to decentralise manufacturing capacity through a more localised supply base that could avoid supply interruptions in case of manufacturing issues and shorten transport as well as delivery times. Furthermore, such research could explore how to support the adoption of single use systems and technologies to minimise variations between sites.

To this end, concerted action in the area of vaccine implementation research would also facilitate addressing gaps with regard to emergency preparedness and capacity to respond timely and rationally to the need to develop vaccines and medical countermeasures in health threats situations in order to protect populations from emerging cross-border health threats such as bioterrorism or pandemic influenza.

DISCUSSION

- In which areas would you consider it important to continue/strengthen and support new EU actions to address key challenges in vaccine R & D?

Urgent R&D for epidemic viruses is pushing forward vaccinology (e.g. tap new genomics technology to reduce the long R&D process, or the emergence of vaccine platform technologies), and helping modernise manufacturing and force regulatory authorities 'catch up' with the scientific advances in vaccinology and modernise their regulation. All these would be of considerable benefit to classic vaccine R&D by reducing the length of the R&D process for a new vaccines, reducing the effort and cost associated with the licensing of vaccines, or streamlining and modernising manufacturing to reduce vaccine shortages.

- The recent outbreaks of Ebola and Zika shifted political priority and funds towards urgent vaccine R&D against emerging pathogens. Would you consider this as an imposition upon traditional vaccine R&D or an opportunity to energize vaccine R&D, and drive production and regulatory modernization?

- What would the most appropriate framework be for the collaboration of Public Health Authorities and civil society with the vaccine industry on issues related to implementation research?

[7] http://www.vac2vac.eu/
[8] http://www.ebovac.org/ebodac/
[9] http://www.i-moveplus.eu/
[10] http://www.advance-vaccines.eu/?page=home