



Ad hoc expert audio conference on vaccine shortages

3 June 2016 - 11:00 to 12:30 (CET)

Flash report

The teleconference was attended by representatives from: AT, DE, DK, ES, IE, IT, FR, HU, HR LV, LT, NL, NO, UK, PT, SE, SANTE B4, ECHO, GROW, WHO EURO, ECDC, EMA and Vaccines Europe (in an open session).

Meeting objectives

- The European Commission convened an ad hoc expert audio meeting in order: to continue discussions at expert level on action to address vaccine shortages and to exchange with industry representatives (Vaccines Europe) on issues related to vaccine shortages.

Exchange with Vaccines Europe

- Vaccines Europe (VE) gave an overview on existing problems and underlined that scarcity and shortages of vaccines have to be seen in the context of the complexity of biological production and very long production times. There are problems related to different packaging/product presentation, diverging definitions/understanding of the term "shortages", and diverging regulatory requirements. In addition, tender demands related to stockpiling would often be challenging.
- The situation for manufacturers has worsened over the last few years as less and less Europe-based producers would have to serve an increasingly globalized vaccine market ("new vaccine eco system"). Increasing global vaccine demand would hinder proper priority setting of manufacturers. Consequently, concerted action of stakeholders would be needed to accelerate the solution of existing problems.
- The European Medicines Agency (EMA) highlighted the need for an agreed definition of medical shortages taking into account the problem of diverging specifications of vaccine shortages in national and sub-national tenders. Simple and transparent mechanism for notification would be needed for timely notification to both national authorities and EMA.
- VE see solutions mostly in administrative and regulatory flexibility. They suggested that industry and Member States could agree on a "to-do" list with a view to agreeing on changes to be addressed in order to improve vaccine supply without major changes of current regimes. In this context VE offered support as regards: i) Workload of Official Medicines Control Laboratories (OMCLs) related to in-vivo testing; ii) Sending of sera from animal to testing laboratories, aiming at shortening timelines as regards release of products.

- SANTE noted industry's commitment and interest to engage and cooperate with Member States to address vaccine shortages. The Commission will continue to provide opportunities for such dialogue to feed industry's point of view in the discussion. In this respect it will be important taking into account that issues related to supply and shortages are discussed under different perspectives and (legal) frameworks. Consequently, it will be important to explore synergies between discussions in different fora.

Draft concept paper on vaccine shortages

- The expert meeting discussed a revised concept paper on vaccine shortages aiming at specifying possible actions related to vaccine demand forecasting and vaccine research & development priority-setting.

Vaccine demand forecasting

- The European Commission provided background to the proposal to run a feasibility study in order to identify basic principles of demand forecasting and to develop a concept for a vaccine demand/supply data warehouse, with a view to establishing a central vaccine demand and supply data repository.
- SANTE referred to possible benefits of such an action as regards e.g. highlighting key demand and supply-side constraints; improved planning (budgeting) and implementation (supply chain logistics) of vaccination programmes; precondition for scaling of production capacities; justification for investments in product development; best use of limited forecasting resources within the EU; or increased efficiency and effectiveness of both national and joint procurements of vaccines.

Priority setting of vaccine research & development

- The European Commission provided background to the proposal to run a feasibility study in order to identify and agree on common stages and criteria for prioritizing vaccine R&D basic principles and to develop a concept for a respective decision-making-support system, with a view to establishing a vaccine R&D priority setting framework.
- SANTE referred to possible benefits of such an action as regards e.g. increased accuracy and effectiveness of EU funding of vaccine development, securing public health needs in vaccine R&D, contribution to strengthened EU crisis preparedness or enhancing Europe's impact on a strategic plan for globally coordinated vaccine R&D.
- SANTE will further revise content and structure of the draft concept paper according to the findings of the discussion and ask Member States experts for comments in a written procedure. The aim is to finalize the concept paper and agree on actions to be proposed to the HSC in another ad hoc expert meeting in September. SANTE will inform HSC Members about the state of play of discussion on this important topic at the HSC Plenary meeting on 7 and 8 June.

Other business

- Ireland gave a brief update on a national measles outbreak which was posted on 2 June in the EWRS.