Summary report on the

Second consultative meeting on strengthening coordination between national regulatory authorities and national immunization technical advisory groups

WHO-EM/VAC/004/E

Hammamet, Tunisia
5–6 June 2012

World Health Organization
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1. Introduction

Interactions between national drug regulatory authorities (NRAs) and national immunization technical advisory groups (NITAGs) are missing in many countries of the WHO Eastern Mediterranean Region and this may lead to negative impact on the proper use of vaccines. In order to strengthen coordination between NRAs and NITAGs, a first consultative meeting was organized by WHO in October 2011, with support from the SIVAC Initiative (Supporting National Independent Immunization and Vaccine Advisory Committees). The meeting aimed to discuss the differences between NRAs and NITAGs, share efficient models of coordination and draft a plan to optimize the interactions between NRAs and NITAGs. The meeting concluded with a series of action points for countries to improve coordination between their NRA and NITAG. It was decided that WHO and SIVAC would continue to support NRAs and NITAG strengthening and that a follow-up meeting would be convened within 10 months.

The second consultation on strengthening coordination between national regulatory authorities and national immunization technical advisory groups was held on 5–6 June in Hammamet, Tunisia. The objectives of the meeting were as follows:

- Share country experiences in the implementation of the agreed activities according to the specific country situation;
- Explore the feasibility of extending these activities to other countries of the Region;
- Provide to country representatives updated information on WHO NRA strengthening programme, WHO prequalification process and WHO procedure for the fast-track registration of imported WHO prequalified vaccines.

The meeting was attended by representatives of 12 countries of the Region: Bahrain, Egypt, Islamic Republic of Iran, Iraq, Jordan, Morocco, Oman, Pakistan, Saudi Arabia, Sudan and Syrian Arab Republic. Participants included national immunization programme officers, NRA and NITAG members, WHO staff from headquarters and the Regional Office, Director of the SIVAC Initiative as well as an expert in vaccine regulation.

The meeting was opened by Dr Philippe Gasquet, WHO Mediterranean Vulnerability Centre, on behalf of the WHO Representative in Tunisia. The programme of the consultation was developed to allow country participants to present the progress in implementing the action points from the first meeting. Following the country presentations, a discussion was held on the issues identified as constraints both in NRA and NITAG in relation to their roles and responsibilities that had an impact on the coordination mechanism, followed by a discussion on how to improve the coordination mechanism and the next steps. Participants were also updated on the WHO NRA strengthening programme, prequalification process and the procedure for expedited review of imported WHO prequalified vaccines for use in national immunization programmes.

2. Summary of discussions

Three of the countries that started implementing the action points immediately after the first meeting reported positive changes as a result of enhanced interaction between the NRA and the NITAG, with more exchange of information especially in terms of adverse events for vaccines used in immunization programmes and addition of a NRA representative as a non-core member in the NITAG. Bahrain has developed a draft standard operating procedure (SOP) for definition of

roles and responsibilities of NRAs and NITAGs and interactions that will be approved shortly. They also have a new regulatory authority for vaccines, so some of the activities previously managed by the drug control authority have been transferred.

Countries that recently started implementing the action points from the first meeting reported progress in terms of successful advocacy for coordination, designation of representatives as ex-officio members, more information sharing, drafting of confidentiality agreements and memoranda of understanding, and enhanced composition of committees to improve the scientific basis for decisions on use of vaccines. In some cases, the national manufacturers are members of the NITAG, which represents a conflict of interest and is not recommended by WHO.

All participants who attended the first meeting reported that they debriefed relevant stakeholders upon return and had a positive response at the ministerial level, and in NRA and NITAGs.

With regard to NRAs, two issues were highlighted. The first was the lack of provision to register vaccines that are not used in the country of origin: this applies not only to the case of scientific opinions of the European Medical Association (EMA) but also, most importantly, to cases of vaccines manufactured in India or other developing countries. In those cases, the national immunization programme or NITAG exercises the power to authorize use of a vaccine that is not registered, thus giving permission to violate existing legislation. Participants were encouraged to establish contact with EMA in the cases of vaccines produced in Europe since there is experience of successful cases of direct communication and collaboration. It was explained that EMA scientific opinions follow a thorough evaluation process in

collaboration with WHO. To date, no vaccine has been given a positive opinion, therefore there are no cases yet of vaccines not used in Europe that have been evaluated through the centralized procedure and are manufactured for exclusive use outside of the European Community. Countries emphasized that their main concern is with vaccines from other sources. In some cases the name of the product is not the same as the one used in the domestic market, or the production process may even differ.

The second issue was the lack of registration of vaccines resulting from the lack of existence of a unit responsible for vaccines in the NRA. It was emphasized that WHO recommends building on existing drug control authorities, rather than establishing a separate regulatory authority for biologicals.

Issues observed among NITAG presentations were the absence of NRA representative, the membership of manufacturers as members – conflict of interest, and the position of the Ministry of Health in the NITAG.

Regarding NRA–NITAG coordination, participants noted a need to clarify the type of documents and data requested by the NITAG from the NRA. In some cases the information requested by the NITAG was too extensive or was confidential. It was noted that the NITAG may ask specific questions about quality, safety or efficacy from the NRA in order to clarify points during the deliberations regarding the use of a product. The formalization of coordination through SOPs is very important in this respect.

Among successes reported, there was ample evidence that countries have taken the initiative to implement improvements in both NRAs

and NITAGs without waiting for help from SIVAC or WHO. Advocacy was successful, through debriefing to ministries, NRAs and NITAGs and other stakeholders. Participation of NRA members in NITAG meetings, and vice versa, has improved and responsibilities clarified and published. Some countries developed SOPs for better shared management of adverse events following immunization (AEFI), through harmonization of AEFI forms, collaboration for AEFI surveillance and exchange of AEFI information.

Lastly, one important aspect of the improved coordination is the influence of the NITAG on the NRA prioritization of marketing authorization dossier review based on public health needs. In some cases, they are considering the acceptance of dossiers for review, if the NITAG is planning to remove the use of a given vaccine (i.e. switching from oral poliovaccine to inactivated poliovaccine).

Participants reviewed the steps of the prequalification, requirements for acceptance of vaccines to be prequalified and the procedure for expedited review of imported WHO prequalified vaccines used in national immunization programmes. This procedure is of particular benefit to initiate registration of vaccines when the capacity to review a particular vaccine is lacking or weak or when the vaccine is needed for an emergency.

3. Next steps

Participants agreed that there is a need to move forward with the development of model documents for countries to adopt or adapt. For this purpose, the meeting decided that a working group would be established. Among other things, the working group will:

- Prepare a list of SOPs and other documents
- Collect existing models from other countries
- Prepare draft documents as models for countries to adopt/adapt

The group will be composed of members from Bahrain (Dr Jaleela Jawad plus a member from the NITAG), Jordan (Dr Ali Musa Muhaidet and Dr Mohammad Ratib Suror), Oman (Dr Bader Rawahi, Dr Idris Abaidani) and Saudi Arabia (Dr Bandar Al Hammad, Dr Hmoud Bin Saadf Al Qani). WHO will coordinate the operation of this group, which will become functional very soon.

Participants agreed that NRA assessment indicators should be used to make a self-assessment of the NRA to identify strengths, areas to improve and develop or review the institutional development plan of the NRA.

The meeting recommended that the WHO procedure for expedited review of imported WHO prequalified vaccines used in national immunization programmes be used to fast-track registration or the first step of vaccine registration until developing relevant NRA capacities.

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