

Proposal to change Section 19.03.00.00 - Vaccines

Currently vaccines are included under section 19.3 of the WHO Model list. Sub-section 19.3.1 lists vaccines "for universal immunization" and sub-section 19.3.2 Vaccines for specific groups of individuals. Both sections are seriously outdated and cannot be left as they are. As an example 7 vaccines are listed for universal immunization (BCG, diphtheria, hepatitis B, measles, pertussis, poliomyelitis and tetanus) whereas routine immunization with BCG is no longer recommended in a number of countries and a number of other vaccines have been recommended for routine vaccination for a number of years e.g. routine yellow fever vaccination has been recommended for many years in endemic countries. Having vaccine on a list falls short of allowing introduction of a vaccine in a national immunization scheme for universal or at risk vaccination. This list seems for vaccine of limited value and impact in the context of national immunization programs and governments, immunization managers and national regulatory authorities rather turn to other sources of information and in particular recommendations from the immunization Strategic Advisory Group of Experts (SAGE), the WHO vaccine position papers, and the Expert Committee on Biological Standardisation. Government need to be provided with specific information on immunization schedules, target groups, vaccine availability and so on.

Each country should have a National Regulatory Authority Advisory Committee and an Immunisation Practice Advisory Committee that can provide the specific expertise required for regulatory decisions and make recommendations on use of vaccines at the national level. These committees may also be used for prioritisation at the country level. Prioritisation at the global level is not appropriate. WHO's role is to provide information and guidance to enable regions and countries to develop their own priorities.

WHO has a dual mandate of providing global policies, standards and norms and support member countries in applying such policies and standards to national programmes.

The WHO core functions have been defined as:

1. Providing leadership on matters critical to health and engaging in partnerships where joint action is needed
2. Shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge
3. Setting norms and standards and promoting and monitoring their implementation
4. Articulating ethical and evidence-based policy options
5. Providing technical support, catalysing change and building sustainable institutional capacity
6. Monitoring the health situation and assessing health trends.

Over the past decade, the global immunization landscape has changed substantially. There are many more stakeholders in the vaccines and immunization arena than was previously the case. At the same time, the scope of immunization efforts has broadened, with the need to target other age groups, an increased number of new vaccines and technologies becoming available, and emphasis on provision of other critical health interventions (e.g. malaria control and nutrition) at immunization contacts.

The Global Vaccines and Immunizations Strategy (GIVS) 2006 – 2015 is a joint UNICEF/WHO plan which has been developed through extensive consultation with partners. It has been endorsed by WHA (WHA 58.15) and the UNICEF EB (2005/7).

The Department of Immunizations, Vaccines and Biologicals (IVB), WHO HQ is advised by a number of advisory committees , that provide external expert opinions to the Department. This assists WHO in formulating global vaccine and immunization policies and strategies.

Three main cross-cutting committees are involved in providing information to WHO in the policy/normative area: the Strategic Advisory Group of Experts (SAGE), which has recently been completely restructured in view of the above, the Expert Committee on Biologicals Standardization (ECBS), and the Global Advisory Committee on Vaccine Safety (GACVS).

The Strategic Advisory Group of Experts (SAGE) was established in 1999 by the Director-General of WHO to provide guidance on the work of the Department of Immunization, Vaccines and Biologicals (IVB). A review of the structure and function of SAGE was undertaken in 2005 and the structure and modus operandi was adjusted to make it more relevant to WHO in formulating global immunization strategies and policies in the light of the Global Immunization Vision and Strategy. SAGE reports to the Director-General on issues ranging from vaccine research and development to immunization delivery, and extending beyond childhood immunization to all vaccine-preventable diseases. SAGE would therefore evolve into a body overarching global immunization.

The GACVS, an expert clinical and scientific advisory body, was established by WHO to deal with vaccine safety issues of potential global importance independently from WHO and with scientific rigour. It was established in 1999 and has developed into a high-powered committee widely respected for its independent, scientific work. It provides scientific advice to SAGE and a report is delivered at each SAGE meeting on the activities of GACVS.

The ECBS establishes global norms and standards published in the the Technical Report Series (<http://www.who.int/biologicals/publications/trs/areas/vaccines/en/index.html>) that help define biological medicinal products of assured quality, including the quality, efficacy and safety specifications that are used for pre-qualification of vaccines. It deals with vaccine standardizations and the work is highly specialized and technical. It provides global standards and biological reference materials. Its work is considered essential to vaccine development and production.

In accordance with its mandate to provide guidance to Member States on health policy matters, WHO is now issuing a series of regularly updated position papers on vaccines and vaccine combinations against diseases that have an international public health impact. These papers, which are concerned primarily with the use of vaccines in large-scale immunization programmes, summarize essential background information on the respective diseases and vaccines, and conclude with the current WHO position concerning their use in the global context. The papers have been reviewed by a number of experts within and outside WHO and since April 2006 they are reviewed and endorsed by WHO's Strategic Advisory Group of Experts on immunization. The position papers are designed for use mainly by national public health officials and immunization programme managers. However, they may also be of interest to international funding agencies, the vaccine manufacturing industry, the medical community and the scientific media.

These papers are published in the Weekly Epidemiological Record and available at the following web page:
http://www.who.int/immunization/documents/positionpapers_intro/en/index.html.

Since the format of this publication does not allow for references, a separate list of key references is provided on the web site for each vaccine position paper. A total of 5 full new position papers or updates are released every year and additional updates are provided as needed on a timely basis.

More information can be found at the following web site:
<http://www.who.int/immunization/en/>

In view of the vaccine specific mechanisms established to provide recommendations on vaccine use, it is proposed that vaccines be removed from the list and that section 19 be replaced with a brief paragraph of information on processes in place for recommendations on vaccine use and how to access this information i.e. conclusions and recommendations from the SAGE, conclusions from the GACVS, position papers, and Technical Report Series publications