



REPUBLIC OF MOZAMBIQUE
MINISTRY OF HEALTH
Committee of Experts on Immunization (CoPI)

First Meeting

Maputo, 26 to 28 April 2011.

Recommendation R003/01/2011 Eng.

Recommendation on needs and priorities for the introduction of new and underutilized vaccines

Preamble

CoPI found that:

- A. Although infant mortality remains very high in Mozambique, its reduction is evident and the leading role of EPI in this area is unquestionable, as shown by the drastic decrease in the occurrence of measles and neonatal tetanus and more recently of meningitis due to *Haemophilus influenzae* type B
- B. Currently in Africa, apart from the neonatal causes, pneumonia and meningitis associated with diarrheal diseases account for the largest number of deaths in the first year of life (37%) and even in the subsequent four years
- C. Evidence at the national and international levels point to *pneumococcus* as the principal cause of pneumonia and invasive pneumococcal disease (including sepsis and bacterial meningitis) in children under 5 years old. Invasive pneumococcal disease has a very high fatality rate
- D. The introduction of the pneumococcal conjugate vaccine in Mozambique is URGENT. It will no doubt significantly reduce morbidity from pneumococcal disease and Infant and Juvenile Mortality Rates (mortality of children under 5 years), as well as costs related to treatment of pneumococcal disease, contributing to achieving the Millennium Development Goal number 4.
- E. The reduction in EPI coverage rates in 2010 are related to the breakdown of stocks of pentavalent vaccine (DTP + HB + Hib), which are not attributable to the country, and therefore should not be considered as a general trend, as evidenced by the coverage rates of polio vaccine (in which there has been no suspension of vaccination). Therefore, COPI believes that these results, because they are unrelated to the performance of EPI, must not, in any way, hamper the introduction of pneumococcal vaccine in the country.

- F. CoPI considers that the conditions and logistics of the cold chain so that we can introduce the pneumococcal conjugate vaccine are already met, and therefore rejoices that the application process for the introduction of this vaccine is already in advanced stage.
- G. Data from the region and the country show that the 13 valiant pneumococcal conjugate vaccine has evidenced better coverage to reduce the incidence of pneumonia, meningitis and pneumococcal invasive disease in children under 5 years old.
- H. *Rotavirus* has been identified as an important agent in the etiology of diarrheal diseases in Africa and, even in Mozambique; some studies have corroborated this information.
- I. In some countries, the introduction of the *Rotavirus* vaccine showed a significant reduction in the number of severe episodes of gastroenteritis. An increasing number of countries are introducing this vaccine into their immunization schedule.
- J. The vaccine against *human papiloma virus* (HPV) was approved by WHO in 2006 and presents an unreasonably high price, but its value in the prevention of Cervical Cancer is undeniable, therefore they must begin to envision the steps towards the introduction of this vaccine in the future in our Vaccine Schedule.
- K. Finally, COPI has noted, with great satisfaction, that studies for the development of a malaria vaccine are progressing satisfactorily and there are hopes that the vaccine can be licensed by the end of 2013.
- L. The COPI also noted that there are other vaccines already licensed and that may be candidates for introduction in the National Program of Immunization: Typhoid Fever, Cholera, Triple viral (Measles / Mumps / Rubella), among others.
- M. The COPI also noted a deficit of epidemiological information in the country before the introduction of a vaccine, and especially the lack of mechanisms for surveillance of disease after the introduction of vaccines into EPI. These deficiencies also reflect the fact that Mozambique does not have a hierarchical network of laboratories and epidemiological surveillance system has a fragile system of reference of surveillance samples.

Operative Paragraphs

Accordingly, COPI recommends:

1. The introduction in routine EPI, of the Pneumococcal Conjugate Vaccine 13 Valiant, in 2012. For this purpose the COPI considers essential and indispensable that the application process for co-financing from GAVI to be submitted, before

the deadline of submission of the applications, that is, until the 15th of May 2011. CoPI also recommends that all procedures required should be complied with by September 2011, in order that this application to be successful.

2. That the introduction in the routine EPI of the *Rotavirus* Vaccine is done as soon as possible (ideally in 2013) and strongly urges MoH to create the logistics conditions, in 2012, for its introduction.
3. CoPI expresses the conviction that the Mozambican adolescents have the RIGHT to receive immunization with HPV vaccine, as recommended by GIVS. Thus, COPI appeals to the international bodies that have an important role in the commercialization of vaccines, to pressure manufacturers to reduce sharply the price of this vaccine.
4. Given the promising results already published and in course of publication, COPI recognizes as critically important that Mozambique should be one of the first countries worldwide to introduce the vaccine against malaria. Therefore, CoPI, recommends to the MoH and Cooperating Partners to make an additional financial effort for the introduction of this vaccine as soon as it is licensed, eventually with own financial resources of the government, its national and international partners and other organizations of civil society, public and private, if the support of the habitual international institutions will not be not available.
5. The strengthening of epidemiological surveillance system and the establishment of a hierarchical and coordinated network of laboratories for epidemiological surveillance (using the laboratory infrastructure already existing in the country), which will provide quick and quality information on disease burden and the impact of preventive measures implemented, such as the introduction of vaccines into EPI.

Finally, COPI decided that the theme of the Introduction of new underutilized vaccines will again be included in the agenda of one of its meetings, in 2012. For this purpose, COPI recommends that, in the meantime, studies shall be carried out on the opportunity to introduce underutilized vaccines, including the possibility of introduction of the 0 Dose of *Hepatitis B* vaccine.

Monitoring Indicators:

- ▶ That the application process for the GAVI co-financing has actually been submitted until May 15, 2011;
- ▶ That all necessary procedures for this application to succeed have been completed by September 2011;
- ▶ That the pneumococcal 13 valiant conjugate vaccine is effectively introduced into routine EPI, in 2012;

- ▶ That in 2012, were created the logistic conditions and have been completed all procedures for the introduction into routine EPI of the *Rotavirus Vaccine*;
- ▶ That the introduction in the routine EPI of the vaccine against *rotavirus* has been done, as soon as possible (ideally in 2013);
- ▶ That effective actions of Advocacy have been developed in relation to the International agencies which have an important role in the marketing of vaccines, in order to pressure manufacturers to reduce sharply the price of the human papiloma virus vaccine (HPV);
- ▶ That actually the price of *human papiloma virus* vaccine (HPV) has reached levels affordable to their introduction into the routine EPI;
- ▶ That Mozambique is actually one of the first countries worldwide to introduce the vaccine against malaria, as soon as it is licensed;
- ▶ That actions of effective advocacy for partnership that have developed with the Government, its partners and other national and international civil society organizations (public and private) for the creation of a national vaccine fund that will allow the introduction, in our routine EPI, of this and other vaccines, if the usual support of international institutions, will not be not available;
- ▶ That the issue of introduction of new and underutilized vaccines has actually been included on the agenda of one of CoPI meetings of 2012;
- ▶ That for that purpose, in the meantime, has been carried out studies on the opportunity to introduce underutilized vaccines, including the possibility of introduction of the 0 Dose of *Hepatitis B* vaccine;
- ▶ That by late 2012, have been identified sentinel posts for integrated disease surveillance and its staff trained and have been established the structure, operating mechanisms and referral system for the hierarchical network of epidemiological surveillance laboratories, in order to demonstrate in a more efficient way, the burden of disease and the impact of the preventive measures introduced.

Maputo, 28th April 2011