3. CONCLUSIONS AND RECOMMENDATIONS

3.1 Conclusions

The conclusions of the meeting were as follows:

3.1.1 Preventing perinatal transmission

The group strongly endorsed the *Operational Field Guidelines for Delivery of the Birth Dose of Hepatitis B Vaccine* published by the WHO Western Pacific Regional Office and strongly encouraged that they be implemented further in the Region’s weakest countries. Different countries and areas in the Region are at different stages in terms of antenatal care coverage, capacity and resources to carry out antenatal screening and provide HBIG to HBsAg-positive mothers. However, the literature review suggests that HBIG does provide some additional protection than that conferred by the vaccine alone. There is not much empirical evidence on vaccine efficacy in preventing perinatal infection if given late, after 24 hours of birth, and randomized prospective studies to answer this question are not ethically possible. However, the efficacy of vaccine in preventing perinatal infection if given with 24 hours of birth is well documented.

3.1.2 Review and finalization of draft protocols for conducting serological surveys

Countries with low vaccination coverage should devote their limited resources to raising vaccine coverage and should undertake national serosurveys only after achieving sustained high vaccine coverage, including birth-dose coverage, for at least four to five years. The choice between school-based or household-based serosurveys will depend on the country context, including the school enrolment rates. The sample size needed is dependent on the precision desired. Ideally 95% confidence intervals should be the aim. The protocols for serosurveys should undergo review by countries’ ethical review boards, and the decision to communicate HBsAg results will be taken by countries based on their local situations (e.g. ability and resources to provide counselling and antiviral treatment). The single necessary test for serosurveys is HBsAg testing, but additional tests (anti-HBs and anti-HBc) can be undertaken depending on the resources available. Rapid tests with documented sensitivities and specificity may be used in serosurveys.

3.1.3 Monitoring and achievement of the regional goal: certification process

While an HBsAg seroprevalence rate <2.0% (with a confidence interval of preferably 0.5%) at national level should be the main criterion for certification, vaccine coverage data will be used to determine the sustainability of control efforts. If a country were certified as having a
rate lower than the 2% milestone at the first attempt, a second serosurvey would be needed to
determine the achievement of less than the 1% seroprevalence goal. After certification, vaccine
coverage data will be used to monitor the maintenance of control status.

3.1.4 Acute hepatitis B surveillance

Acute hepatitis surveillance allows a country to identify risk factors for HBV transmission
in various age groups and may be useful to document the impact of vaccination programmes for
older age groups. However, it is not as useful for evaluating the impact of infant vaccination
programmes. In addition, it does require a very well functioning surveillance system and a high
level of laboratory and epidemiological resources. Thus it is only appropriate for countries with
more mature infant vaccination programmes that are ready to start addressing the need to
vaccinate older age groups.

3.1.5 Vaccination of groups other than infants

Achieving high vaccination HepB3 coverage for infants, including a timely birth dose,
remains the first priority. Countries that are yet to achieve sufficient coverage for infants should
not be distracted by vaccination for older age groups. However, countries with mature infant
vaccination programmes should consider catch-up or patch-up immunization strategies for older
children, prioritizing children up to five years of age first, followed by children of six to 15 years.
In addition, vaccination for health care workers may be prioritized along with infant vaccination
programmes.

3.1.6 Finalization of the regional hepatitis B plan 2007

The regional plan developed in 2003 needs to be revised to reflect the regional goal set up
in 2005 and the progress made by countries since then. The two key strategies remain the same—
high infant vaccination coverage with three doses of hepatitis B vaccine by age one and with a
timely birth dose within 24 hours for all newborn infants. However, it was concluded, that the
scope of regional plan should be expanded to include more explicitly the strategies for countries
that have more mature infant immunization programmes and that are already near to or have
achieved the regional goal. Hence, those countries with more resources and with mature infant
hepatitis B programmes are encouraged to consider providing HBIG in addition to vaccine at
birth, to vaccinate older children and adolescents, and to set up acute hepatitis B surveillance
systems. In addition, vaccination for health care workers should be prioritized along with infant
vaccination in all the countries.
3.2 **Recommendations**

The working group made the following recommendations:

3.2.1 **Preventing perinatal infection**

(1) Universal provision of a birth dose of hepatitis B vaccine within 24 hours of birth should be the key regional strategy to prevent perinatal transmission. In addition, high coverage with HepB3 by age one needs to be achieved for both prevention of perinatal transmission and horizontal transmission.

(2) Countries with high coverage of antenatal care and the resources to provide antenatal screening and HBIG, might also consider providing HBIG in addition to the vaccine at the time of birth.

(3) WHO Headquarters and the Western Pacific Regional Office should provide strong guidance for using hepatitis B vaccine out of the cold chain with proper VVMs and should work with manufacturers towards appropriate labelling of such vaccines for use out of the cold chain. However, use of vaccine out of the cold chain should be recommended strongly and encouraged where it is needed to increase coverage with the timely birth dose and where it is acceptable to countries while waiting for specific labelling of the vaccine by manufacturers for out-of-cold-chain use.

(4) Studies on the impact of antiviral drugs on prevention of perinatal infection, especially among pregnant women with high HBV DNA titers, should be encouraged, especially in countries with higher resources and an advanced-stage hepatitis B control programme.

3.2.2 **Review and finalization of draft protocols for conducting serological surveys**

(5) The WHO Western Pacific Regional Office should designate a WHO regional collaborating laboratory network to provide technical support for countries performing serosurveys.

(6) Countries should conduct representative serosurveys, either household-based or school-based surveys sampling children of at least five years of age using laboratory tests with documented sensitivity and specificity, measuring at least HBsAg and aiming at 95% confidence intervals.

3.2.3 **Monitoring and achievement of the regional goal: certification process**

(7) An expert resource panel may be set up and should, in turn, be used to draw members for a certification panel as and when a request is received from a country. The serosurvey data documenting HBsAg levels of less than 2% at national level, preferably with 95% confidence, will be the mainstay for certification, but vaccination coverage data will be used to monitor the sustainability of control efforts. As an indication of their continued efforts in controlling hepatitis B, countries should present plans for accelerating hepatitis B control to meet the next goal of HBsAg prevalence of 1% at the time of certification for the less than 2% goal. The current certification guidelines developed by the WHO Western Pacific Regional Office may be modified accordingly.
3.2.4 Hepatitis B surveillance

(8) Countries with mature infant hepatitis B programmes and with adequate resources may be encouraged to consider establishing acute hepatitis B surveillance, with laboratory confirmation and case investigation in sentinel or population-based sites, to guide their programmes at advanced stages of hepatitis B control.

3.2.5 Vaccination of groups other than infants

(9) Immunization of older children (first priority - children through five years of age, and second priority- children six to 15 years of age) should be instituted in countries with mature infant immunization programs and additional resources. Either a catch-up or patch-up or a combination of both may be used depending upon the local context of a country.

(10) Countries should aim to provide free vaccination for all health workers at the time of entry into training schools or at job entry, as well as for all health workers currently on the job, prioritizing it along with infant immunization.

3.2.6 Regional plan for 2007

(11) The eight key strategies presented in the draft regional plan 2007, along with the monitoring and evaluation framework, are endorsed, with recommendations for a few modifications as described under Section 2. The two key strategies will be achieving and maintaining high coverage with HepB3 and timely delivery of the birth dose within 24 hours of birth for all infants. Under the monitoring and evaluation framework, it is recommended that the WHO Western Pacific Regional Office should designate one or more regional hepatitis reference laboratories or collaborating centres to provide laboratory expertise throughout the Region.