

April 2010 meeting of the Strategic Advisory Group of Experts on Immunization: preliminary statements on H1N1 and Rotarix vaccines

The meeting of the Strategic Advisory Group of Experts on Immunization (SAGE) was held on 13-15 April, 2010.

As part of its agenda, updates on pandemic H1N1 vaccine were presented.

No new safety signals have arisen with more than 570 million doses distributed worldwide, and 350 million doses administered.

There are no changes necessary to the current recommendations on priority vaccination target groups or number of doses^{1,2}.

SAGE received a routine update of the December 2009 meeting of the Global Advisory Committee on Vaccine Safety (GACVS)³ and of a special teleconference of GACVS held on 25 March 2010⁴. This special teleconference addressed a recent communication about the presence of DNA from porcine circovirus type 1 (PCV1) in an oral rotavirus vaccine (Rotarix). On the latter topic, SAGE also received an update from regulatory authorities and virologists that are currently conducting investigations into this finding, as well as from the manufacturer.

SAGE noted that PCV1 is not known to cause disease in animals or humans. PCV1 DNA is often found in food products and has been detected in human stool specimens from healthy children who have not received Rotarix vaccine. The safety of Rotarix is supported by both large prelicensure clinical trials (more than 50,000 subjects) and an extensive postlicensure safety experience (over 60 million doses of vaccine administered).

SAGE noted the conclusions of GACVS indicating that the extensive clinical data support the safety of Rotarix and that GACVS was of the view that the benefits of rotavirus vaccination for children far outweigh any known risk associated with use of Rotarix. Rotavirus gastroenteritis is the most common cause of severe diarrheal disease in young children throughout the world and rotavirus immunization is recommended by WHO^{5,6}. Given the absence of any known risk, SAGE strongly recommends the continued use of Rotarix for immunization programs, in particular in those parts of the world with elevated under-5 mortality associated with rotaviruses. SAGE requested to be regularly updated by GACVS as new information becomes available.

Other topics *inter alia* discussed at the meeting included: the revision of the vaccine prequalification procedure for countries, the impact of new vaccines introduction on

¹ See WER No 30, 2009, pp 301-308

² See WER No 49, 2009, pp 505-516

³ See WER No 5, 2010, pp 29-36.

⁴ http://www.who.int/vaccine_safety/topics/rotavirus/rotarix_statement_march_2010/en/index.html

⁵ See WER No 51-52, 2009, pp 533-537.

⁶ See WER No32, 2007 pp 285-296.

immunization and health systems, pandemic H5N1 vaccines, pertussis vaccines, the results of the Thai RV144 HIV vaccine trial, the process of grading and review of quality of scientific evidence, and poliomyelitis eradication.

The final report of the SAGE meeting will be published in the Weekly Epidemiological Record on 28 May 2010.