

influenza viruses evolve constantly, it is impossible to carry out a complete clinical analysis of seasonal influenza vaccines yearly because the composition changes each year to adapt to the virus and so you are always a year behind. A complete clinical evaluation is not needed also because manufacturers produce seasonal influenza vaccines using the same procedure and equipment, but for a different virus each year. In the USA, vaccines for seasonal influenza are licensed without clinical trials on the basis of a "strain change". The US regulatory authorities consider the change from seasonal to pandemic H1N1 influenza vaccine production (using the same procedure) as a change in the strain and therefore will not request clinical trials before registration. Having said that, all manufacturers will perform clinical trials to find out whether one or two doses are necessary, to test it in special populations and to administer it jointly with other vaccines. In Europe, a strain change is accompanied by a small clinical trial requested by the European Medicines Agency. In the last couple of years, manufacturers in the European Union registered "mock-up" or prototype H5N1 bird flu vaccines as nobody knows which H5N1 strain might become a pandemic strain. Manufacturers made clinical batches of an H5N1 vaccine with virus stocks from China, Indonesia and Viet Nam. They carried

out clinical trials and submitted the results to the regulatory authorities who said the vaccines were fine. They are not allowed to sell H5N1 vaccines, since there is no H5N1 pandemic, but they can use the same procedure to make H1N1 pandemic vaccine. That way they can get a licence in a few days. This is another way vaccines can be licensed without clinical trials, while still ensuring safety on the basis of what is known about influenza vaccines. Based on the extensive knowledge available on seasonal vaccines and the results obtained through evaluation of H5N1 avian influenza vaccines, there is no doubt that it will be possible to make effective H1N1 pandemic vaccines.

*Q: What's been done to ensure that developing countries get enough vaccine?*

A: It depends on what we mean by "enough". Some countries want to vaccinate every member of the population, but there is no way we can do this for the whole world. WHO has a cross-organizational operation that is in place to secure vaccines for developing countries. This is spearheaded by the Director-General's Office and the legal and vaccine departments. We are engaged in three types of activities. The first is to negotiate donations with manufacturers. Two have been announced: 100 million doses by sanofi-aventis and 50 million doses from GlaxoSmithKline. Second, we

are working with other manufacturers to reserve a portion of their vaccine production for WHO at a reduced price. Third, we are working with governments to raise funds to purchase vaccines. We are also working with 11 vaccine manufacturers based in developing countries, providing them with seed financing and technical expertise to help them produce influenza vaccine domestically. We have also helped them access technology and given them sub-licences to use technology for producing live attenuated vaccine. These 11 companies will be manufacturing some of the 30 different expected vaccines.

*Q: What happens if developing countries have only partial coverage?*

A: Coverage will be partial and not only in developing countries. But we should not be "hypnotized" by vaccines. There are other measures, such as social distancing, school closure, avoidance of large gatherings, antibiotics and personal hygiene. This is not like rabies, which is 100% fatal: we are talking about a disease from which most people recover very well. We will try to help countries to gain access to as much vaccine as possible, at least to preserve their health systems functioning, but there is just not enough vaccine for every country in the world to vaccinate every member of the population twice. ■

### Recent news from WHO

- Elimination of **onchocerciasis** is feasible after a multicountry study found that treatment with ivermectin stopped further infections and transmission in three areas in Africa where the disease is endemic, WHO announced on 21 July. More than 37 million people are infected with onchocerciasis, also known as river blindness. The blackfly that transmits the disease breeds in rivers; it often blinds people, as well as causing debilitating skin conditions. The study was coordinated by TDR, a Special Programme for Research and Training in Tropical Diseases.
- The first **World Humanitarian Day** was held on 19 August to recognize humanitarian workers who provide life-saving care in the field, to pay tribute to those who have died in the course of carrying out their humanitarian work and to call for continued commitment to provide care to people affected by war, natural disasters and other humanitarian crises.
- A key document was released highlighting measures to reduce the impact of the **influenza A (H1N1) pandemic**, particularly in vulnerable, low-resource and humanitarian settings. Call to action 17 August 2009 is a joint initiative by WHO, the International Federation of Red Cross and Red Crescent Societies, the United Nations Children's Fund (UNICEF), United Nations' Office for the Coordination of Humanitarian Affairs (OCHA), the UN System Influenza Coordination (UNSIC) and nongovernmental organizations. The document is available at: [http://www.who.int/csr/resources/publications/swineflu/20090817\\_call\\_to\\_action\\_en.pdf](http://www.who.int/csr/resources/publications/swineflu/20090817_call_to_action_en.pdf)

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