

Recommendations regarding H1N1 vaccination of subjects involved or likely to be involved in clinical trials.

November 2, 2009

In the context of the influenza A (H1N1)v pandemic, it is anticipated that a vaccine against this virus will be made available to physicians in the coming weeks.

However, medicinal product clinical trial protocols may include limitations regarding the administration of vaccine therapies in the weeks preceding inclusion in a clinical trial, or over the course of a trial.

Such limitations may be included in the inclusion or non-inclusion criteria, and in the section describing prohibited concomitant medications.

This situation has led Afssaps to clarify the course of action in this context.

1. The High Council of Public Health has issued recommendations on public health priorities for the use of vaccines against the pandemic influenza A (H1N1)v virus. These recommendations, available on the Ministry of Health's website (<http://www.santesports.gouv.fr>), advise starting a campaign of vaccination against the pandemic A (H1N1)v virus as soon as possible when the vaccine becomes available and define a priority order for the vaccination of French population.
2. For protocols that may have limitations on the administration of vaccines in the weeks preceding the inclusion and/or during the trial, Afssaps advises to postpone inclusion in the trial, or even to encourage a reassessment of the benefit/risk of inclusion in the trial considering the patient's wish to be vaccinated, when vaccination is part of the non-inclusion criteria.
3. For patients already included in such a trial and willing to be vaccinated, Afssaps advises to collect this information for pharmacovigilance purposes.

This information will be collected by indicating the vaccine lot in the case report form or in the patient's medical record and shall be referred, where appropriate, by investigators and sponsors in the declaration forms of adverse reactions that might occur during the trial.

In this regard, it is recommended that investigators ask their patients about the realisation of this vaccination on the occasion of inclusion or follow-up visits of patients likely to participate or already included in the trials.

4. However, this course of action may be adjusted at the discretion of the investigator, depending on the situation of the patient, taking into account the benefit of participating to the trial and the risk of possible infection by the influenza A (H1N1)v virus.

It is also advised that investigators contact trial sponsors, if they have doubts about what to do, when protocols do not explicitly state limitations relating to the administration of vaccine therapies.