Influvac 15 mikrog HA / 0,5 ml suspension for injection in prefilled syringe

6.7.2016, Version 3.0

PUBLIC SUMMARY OF THE RISK MANAGEMENT PLAN

VI.2 Elements for a Public Summary

VI.2.1 Overview of Disease Epidemiology

Seasonal influenza is an acute viral infection that causes annual epidemics that peak during winter in temperate regions. It affects most countries for one to two months. Influenza spreads easily from person to person. Influenza can affect anybody in any age group, but people most at risk of complications (e.g., pneumonia, inflammation of the heart (myocarditis) and neurologic complications (encephalitis)) include the elderly, those with pre-existing medical conditions (such as chronic heart or lung disease), and pregnant women. The number of affected people and most affected age groups varies considerably from year to year depending on circulating virus strains and immunity in the population. On average, approximately 10% of Europe's population is infected each year, and influenza-related complications cause hundreds of thousands of hospitalizations across Europe. Each year, there are many avoidable deaths from influenza, between 8 and 44 per 100,000 population in milder and more severe influenza seasons

VI.2.2 Summary of Treatment Benefits

Influenza vaccination is the primary method for preventing seasonal influenza and its severe complications. However, influenza vaccination is used as a prophylactic and it does not have any immediate obvious health benefit for the vaccinated (healthy) individual.

Influenza vaccination may reduce the risk of infection, need for medical visits and hospitalization and may avoid medical complications and deaths due to influenza. Onset of protection after influenza vaccination is generally obtained within two to three weeks with an expected duration of protective immunity for six to twelve months.

Abbott's trivalent influenza vaccine can be given to adults and children from the age of six months onwards. The quadrivalent influenza vaccine has not yet been tested in children and therefore currently may only be given to adults. The vaccine works by helping the body to produce its own antibodies in order to protect against the diseases that influenza virus causes. People who run an increased risk of associated complications of influenza, such as elderly people, pregnant women and patients with chronic diseases, may particularly benefit from vaccination. Clinical studies have been performed to evaluate the safety of influenza vaccine (surface antigen, inactivated) and the ability of this vaccine to cause the production of antibodies (protection against disease).

VI.2.3 Unknowns Relating to Treatment Benefits

During its clinical development, Abbott's trivalent influenza vaccine has been studied in adults and also in healthy children from six months of age, which adequately reflects the currently approved indication for this vaccine. It has not been studied in children younger than six months and therefore treatment benefits are unknown for this population. The quadrivalent influenza vaccine has not yet been tested in children of any age below 18 years.

Persons with a disease or under medical treatment, which affects the immune system (immunodeficiency), and pregnant and breast-feeding women were excluded from the clinical

studies. Information on the use of Abbott's influenza vaccine in these groups is thus limited, but there is also no evidence of a safety concern with the use of this type of vaccine. As these groups are at particular risk to acquire influenza or to develop complications, they are particularly recommended to have influenza vaccination.

VI.2.4 Summary of Safety Concerns

The following tables summarize the safety concerns (important identified risks, important potential risks and missing information) of Abbott's trivalent and quadrivalent influenza vaccine.

Important Identified Risks

Risk	What Is Known	Preventability
Allergic reactions (Hypersensitivity to the active substances or to any of the excipients)	Allergic (hypersensitivity) reactions are extremely rare, but may evolve to a serious allergic reaction that affects the entire body, which can be life-threatening (anaphylactic reaction). Such reactions are usually caused by extreme sensitivity to certain components of the vaccine, probably to trace amounts of egg protein left over from the manufacturing process. Influenza vaccine (surface antigen, inactivated) is made in eggs; therefore this vaccine should not be given to anyone who has a known allergy to chicken eggs or egg products, especially if the allergic reaction was severe (anaphylactic reaction). This vaccine should also not be given to people who have known allergies to any component resulting from the manufacturing process that may be present as traces in the product (formaldehyde, cetyltrimethylammonium bromide, polysorbate 80, or gentamicin).	Yes, by avoiding use in individuals with known allergy or previous intolerance to a dose of influenza vaccine. Vaccination should be preceded by a review of the medical history. Appropriate medical treatment and supervision should be available in case of a rare anaphylactic event following administration of the vaccine.

Important Potential Risks

Risk	What is Known (Including Reason Why It Is Considered a Potential risk)
Seizures without fever (Non-febrile convulsions)	Seizures without fever may occur in children and other age groups following influenza vaccination. Although it is rare, brain injury may occur if a seizure is very prolonged.
Diseases where the immune system attacks normal structures in the body (Adverse events following immunization of possible autoimmune nature (e.g., GuillainBarré syndrome, neuritis, encephalitis/ encephalomyelitis, demyelinating disease, vasculitis, thrombocytopenia))	Some diseases that are thought to be caused by the immune system attacking normal structures in the body, such as nerves, the brain, blood vessels or blood platelets (autoimmune disorders) have been observed following influenza infections and have also been associated with vaccination including influenza vaccines. This might result in serious complications.
Vaccination failure	Influenza vaccination does not always result in full protection from influenza infection, mainly because influenza viruses are constantly changing. It is not possible to tell in advance who will be protected and who will not. People aged 65 years and above and people of any age whose immune system is not working properly (for example because of HIV infection, certain other underlying diseases, or because of certain medicines such as many anti-cancer drugs) are less likely to obtain full protection. However, as influenza infection might be particularly dangerous in such patient groups, the relevant authorities of many countries, including all European countries, recommend to influenza vaccination in particular for older people and people with immune system problems.

Missing information

Risk	What Is Known
Safety in patients whose immune system does not work properly (Safety in immunocompromised patients)	Influenza vaccination helps to protect people whose immune system is not working properly (for example because of HIV infection, certain other underlying diseases, or because of certain medicines such as many anti-cancer drugs) from influenza infection, although protection might be less than in people with a healthy immune system. Influenza vaccination also protects many people with immune system problems from serious complications that influenza infection might cause. There is no

	indication that this medicine might be less safe in people with immune system problems. The relevant authorities of many countries, including all European countries, recommend influenza vaccination in particular for patients with immune system problems.

VI.2.5 Summary of Risk Minimization Measures by Safety Concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, and also describe the risks and recommendations for minimizing them. Information for patients is available in lay language in the package leaflet (PL). The measures in these documents are known as 'routine risk minimization measures'.

The SmPC and the PL are part of the medicine's product information. The product information is publicly available in national databases of human medicines at the Regulatory Authorities.

This medicine has no 'additional risk minimization measures' in place (i.e., there are no special conditions and restrictions for its safe and effective use).

VI.2.6 Planned Post-Authorization Development Plan

This section is not applicable. Safety and effectiveness of influenza vaccine (surface antigen, inactivated) is well established by long-standing use in clinical practice and there are no pertinent gaps which must be addressed in the post-authorization development. Thus, no studies are currently planned or ongoing with influenza vaccine (surface antigen, inactivated).

VI.2.6.1 Studies which are a Condition of the Marketing Authorization

This section is not applicable. There are no studies imposed as a condition of the Marketing Authorization of influenza vaccine (surface antigen, inactivated). Also other small annual clinical trials so far requested will no longer be requested in the EU and not conducted starting from the northern hemisphere 2015-2016 influenza season.

VI.2.7 Summary of Changes to the Risk Management Plan over Time

List of Major Changes to the Risk Management Plan

Version	Date	Safety Concerns	Comment
3.0	06 JUL 2016	Important identified risks: • No changes Important potential risks: • "Vaccination failure" newly added • "Autoimmune disorders" renamed to "Adverse events following immunization of possible autoimmune nature (e.g., Guillain-Barré syndrome, neuritis, encephalomyelitis, demyelinating disease, vasculitis, thrombocytopenia)" Missing information: • "Safety in immunocompromised patients" newly added	Addition of safety concerns per request of a regulatory authority, unrelated to newly received or analyzed safety data. Data on quadrivalent product added.