# Screening Questionnaire for Influenza HA Vaccine

For voluntary vaccination

#### This screening questionnaire cannot be used for routine vaccinations. For routine vaccinations, the questionnaire provided by the municipal government should be used.

<ul> <li>Please fill out information or Please circle the appropriate</li> <li>If a child is to be vaccinated should fill out the questionname</li> </ul>	nly within the 'bolded' frames if you wish to receive the vaccina one of the two options in the answer columns. , a parent/guardian who is familiar with the child's health cond aire.	tion. ition	Body te examin	emperatur ation	e before		C
Address			TEL (	)		-	
Name of the recipient		Male		Day	Month	Ye	ar
Name in English (if needed)		Female	Date of birth		/	/	
(Name of the guardian)				(	Age:	years	months)

Questions	Answer	Doctor's Use	
1. Have you read and understood the explanation about the flu shot (on the back) that you are about to receive today?	No	Yes	
2. Do you have any concerns about your health condition today?	Yes, please specify ( )	No	
3. Currently, are you under treatment by a doctor for any disease? Has the doctor told you if it is OK to receive the vaccination today?	Yes, Name of disease ( ) Yes/No/Haven't talked in particular.	No	
4. Have you been ill within the past month?	Yes, Name of disease ( )	No	
5. Do you have any significant past medical history to declare (any congenital anomaly, any disease of the heart, kidneys, liver or cranial nerves, any immunodeficiency, any blood dyscrasia, etc.)?	Yes, Name of disease ( )	No	
6. Have you ever experienced a skin rash/urticaria or felt ill after taking certain medications or eating certain foods (especially, egg, poultry, other poultry- derived foods)?	Yes Name of medication(s)/foods ( )	No	
7. Have you ever suffered from convulsions?	Yes (about episode[s]) (Date of the last episode: Around <sup>Month</sup> / <sup>Year</sup> )	No	
8. Have you ever been diagnosed as having a respiratory disease(s), such as interstitial pneumonia or bronchial asthma?	Yes	No	
9. Is the vaccine that you are about to receive today your first this season?	No, Date of the last vaccination $(^{\text{Day}} / ^{\text{Month}})$	Yes	
10. Have you ever felt unwell after receiving a flu shot?	Yes	No	
11. Have you ever felt unwell after receiving any vaccine other than a flu shot?	Yes, Name of vaccine ( )	No	
12. Have you received any vaccine within the past month?	Yes, Date of vaccination ( <sup>Day</sup> / <sup>Month</sup> ) Name of vaccine ( )	No	
13. Do you have any close relatives with congenital immunodeficiency?	Yes	No	
14. Has anyone among your close relatives or other contacts been diagnosed as having measles, rubella, varicella, mumps, etc., in the last month?	Yes Name of disease ( )	No	
15. [Females only] Are you currently pregnant?	Yes	No	
16. [If the person about to be vaccinated is a child] Were any abnormalities detected in the child during delivery, at birth, or during infant checkups? Birth weight ( ) g	Yes Please specify ( )	No	
17. Please specify any other concerns or questions you might have about your health condition that you want to share with the doctor.			

#### Doctor's Comments

Based on the above information and results of medical examination, I believe that today's vaccine (can be administered/should be postponed). I have explained to the recipient/guardian about the effects of the vaccination, the possible adverse reactions, and the relief services available to the recipients for any adverse reactions, in accordance with the Pharmaceuticals and Medical Devices Agency Act.

Signature, or name and seal of the doctor

	Patient/Guardian's Use		
I (agree/disagree) to be v	accinated, after having undergone a medical checkup by the docto	or, as well as	received and understood the doctor's
explanation about the vac	cination and its effects and possible adverse reactions.		
	<i>//</i>	,	Note if the recipient is unable to sign the form, a proxy should sign it and indicate his/her
Signature	(if you are a proxy: relationship to the vaccine recipient	)	relationship to the recipient.

Name of vaccine to be used	Dosage and Administration	Institution/Doctor's name/Date and time of vaccination
□Influenza HA Vaccine "KMB"	Subcutaneous	Institution:
Lot No.:	$\Box 0.5~mL$ (3 yrs. old and older)	Doctor's name:
Medical record No.:	$\Box 0.25~mL$ (6 months to under 3 yrs. old)	Date and time of vaccination:
(Seller: Meiji Seika Pharma Co., Ltd.)		Hours ininutes Day /Month /Year

Your provided personal information will be used only for the screening examination performed prior to the influenza vaccination.

For influenza HA vaccination, the health condition of the recipient must be clearly known. Therefore, please fill out the Screening Questionnaire on the front page as much in detail as possible. If a child needs to be vaccinated, a parent/guardian who is familiar with the health condition of the child should fill out the form.

#### Effects and Adverse Reactions of the Vaccine =

Influenza HA vaccination is expected to prevent influenza or minimize the symptoms of influenza. It is also expected to prevent complications of and death from influenza.

In general, adverse reactions to this vaccine are minor. The injection site may become red, swollen, hard, warm, painful, numb, or show blisters, but these reactions usually resolve spontaneously within a few days. Fever, chills, headache, fatigue, transient loss of consciousness, dizziness, lymphadenopathy, cough, vomiting/nausea, abdominal pain, diarrhea, decreased appetite, joint pain, myalgia, and/or muscular weakness may also occur. Hypersensitivity reactions such as rash, urticaria, eczema, erythema, erythema multiforme, itching, and/or angioedema may also occur. Other possible reactions include cellulitis, paralysis such as facial nerve paralysis, peripheral neuropathy, syncope, vasovagal reaction, uveitis, and tremor. People with strong egg allergies or other allergies should notify their doctor prior to the vaccination because of the possibility of a strong hypersensitivity reaction(s). Significant adverse reactions may include the following: (1) Shock, anaphylaxis (urticaria, dyspnea, angioedema, etc.), (2) acute disseminated encephalomyelitis (fever, headache, convulsions, movement disorder, disturbed consciousness, etc., that appear within a few days to two weeks after vaccination), (3) encephalitis/encephalopathy, myelitis, optic neuritis, (4) Guillain-Barre syndrome (numbness in both hands and feet, gait disorder, etc.), (5) convulsions (including febrile convulsions), (6) hepatic function disorder, jaundice, (7) asthmatic attack, (8) thrombocytopenic purpura, thrombocytopenia, (9) vasculitis (IgA vasculitis, eosinophilic granulomatosis with polyangiitis, leucocytoclastic vasculitis, etc.), (10) interstitial pneumonia, (11) oculomucocutaneous syndrome (Stevens-Johnson syndrome), acute generalized exanthematous pustulosis, (12) nephrotic syndrome (the frequency of any of these is unknown). If other unknown or worrisome symptoms appear, or if any of the aforementioned diseases are suspected, please consult the doctor in charge of the vaccination or your local medical institution.

### Persons who are ineligible for the vaccination =

A person:

- 1) with obvious fever (37.5°C or higher)
- 2) evidently suffering from a serious acute illness
- 3) with a history of anaphylaxis (a severe allergic reaction with dyspnea, generalized urticaria, etc., that usually appears within 30 minutes after vaccination) upon receiving the influenza HA vaccine in the past
- Note that any person with a history of developing an anaphylactic reaction after receiving another drug should inform his/her doctor and seek the doctor's judgment about the appropriateness of receiving the vaccination.
- 4) Other than those listed above whose doctor has determined that he/she is an inappropriate candidate to receive the vaccination

## People who must consult a doctor before receiving vaccinations

A person:

- 1) with a cardiac, renal, hepatic or vascular disease
- 2) who is developmentally immature and under the care of a doctor or health nurse
- 3) with a history of fever, rash, urticaria, or other allergic symptoms within 2 days of receiving a vaccination in the past
- 4) with a history of skin rashes or other physical problems due to medications or foods (chicken eggs, poultry, etc.)
- 5) with a history of convulsions in the past
- 6) with a history of having been diagnosed to have immunodeficiency, or having a close relative suffering from congenital immunodeficiency
- 7) who may be pregnant
- 8) with respiratory problems, such as interstitial pneumonia or bronchial asthma

#### Post-vaccination precautions =

- 1) Acute adverse reactions (breathlessness, urticaria, cough, etc.) may occur within 30 minutes of receiving influenza HA vaccine. Therefore, people should stay at the medical facility for a short while after receiving the vaccination to enable their condition to be monitored, and be advised to contact the doctor immediately upon the emergence of any adverse reactions.
- 2) On the day of the vaccination, keep the injection site clean and go about your life as usual. Avoid strenuous exercise and heavy drinking.
- 3) Bathing on the day of the vaccination is allowed, but rubbing the injection site should be avoided.
- 4) In the unlikely event of development of unusual symptoms such as high fever or convulsions, seek medical attention immediately.

	Day	Month	Day of	the week	
Scheduled date of	/		(	)	Name of
vaccination	Please come to				Institution
	at around ( <sup>Hour</sup>	rs mir	nutes	) on the day of the vaccinatior	

With regard to voluntary vaccination with influenza HA vaccine, there is a system providing relief services under the Pharmaceuticals and Medical Devices Agency Act for persons or their family members with health problems related to adverse reactions developing despite proper use of the vaccine, that are sufficiently serious to necessitate hospitalization. For more information, please visit the website of the Pharmaceuticals and Medical Devices Agency. For inquiries, please contact us (contact details on the right).

Consultation Center for Relief Services, Pharmaceuticals and Medical Devices Agency

Shin Kasumigaseki Building, Kasumigaseki 3-3-2, Chiyoda-ku, Tokyo 100-0013, Japan

Phone: 0120-149-931 (Toll free)

URL: https://www.pmda.go.jp/relief-services/adr-sufferers/0020.html