

About Clinical Trials conducted by the members of the IFPMA & IFPMA Influenza Vaccine Supply International Task Force (IVS ITF)

Last Update (May 26, 2008)

Company (Site Location)	Strain	Type	Culture	Adjuvant	Doses (µg)	Trials # subjects	Timing S=Start E= End	Additional Information	
Acambis Inc (USA)	All A strains	Conserved protein (M2e)	Cell	None Alhydrogel QS-21	2 doses IM 50	Ph I Adult: 18-40 y 80	S: July 2007 E: Jan 2008		
Baxter (Czech Republic/ Austria)	H5N1 WT -Clade 1	Inactivated Whole virion	Cell	Alum	2 doses IM 3.75 / 7.5 / 15 / 30	Ph I/II Adult: 18-45 y 270	S: June 2006 E: Oct 2007		Mock-up dossier submitted to EMA in Q1 2008
				None	7.5 / 15				
Baxter (Czech Republic/ Austria)	H5N1 WT -Clade 1	Inactivated Whole virion	Cell	None	2 doses 7.5	Ph III Adults and Elderly 560	S: Apr 2007		
Baxter (Czech Republic/ Austria)	H5N1 WT -Clade 2	Inactivated Whole virion	Cell	None	2 doses 3.75 / 7.5	Ph I/II Adult: 21-45 y 110	S: Aug 2007		
Baxter (Czech Republic/ Austria)	H5N1 WT -Clade 2	Inactivated Whole virion	Cell	None	1 booster dose 7.5	Phase II Adults	S: Sep 2007		
Baxter (Czech Republic/ Austria)	H5N1 WT -Clade 1	Inactivated Whole virion	Cell	Alum	2 doses IM 7.5 / 15 / 45	Ph I/II* Adult 300	S: Oct 2006	* with NAID	
				None	2 doses 7.5 / 15				
Baxter (Czech Republic/ Austria)	H5N1 WT -Clade 1	Inactivated Whole virion	Cell	None	2 doses 7.5	Ph III Adults, Elderly, Risk groups Ca 3500	S: Q2 2008		

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Baxter (Czech Republic/ Austria)	H5N1 WT -Clade 1	Inactivated Whole virion	Cell	None	2 doses 7.5	Ph I/II Peds : 6m – 17y 900	S: Q1 2009		
Biken (Japan)	H5N1 -Clade 1	Inactivated Whole virion	Egg	Alum	2 doses IM / SC 1.7 / 5 / 15	Ph I/II* Adult: 20-40 y 120	S: Mar 2006 E: Sep 2006	* with NIID	Mock-up & H5N1 pre- pandemic vaccine files approved by MHLW in Oct. 2007
Biken (Japan)	H5N1 -Clade 1	Inactivated Whole virion	Egg	Alum	2 doses SC 5 / 15	Ph II/III* Adult: 20-64 y 300	S: Sep 2006 E: Jan 2007	* with NIID	
Crucell (Switzerland/ Netherlands)	H9N2	Inactivated Whole virion	Egg	Alum	2 doses IM 1.7 / 5 / 15 / 45	Ph I* Adult: >18 y 353	S: Aug 2006 E: Jan 2007	* with University of Leicester	
		Inactivated Whole virion	Egg	None	2 doses IM 1.7 / 5 / 15 / 45				
		Inactivated Whole virion	Egg	None	2 doses ID 5 / 15				
		Virosome	Egg	Virosomes as carrier/ adjuvant system	2 doses IM 1.7 / 5 / 15 / 45				
Crucell (Switzerland/ Netherlands) Solvay Pharmaceuticals (Netherlands)	H9N2	Inactivated Whole virion/ Subunit	Egg	None	2 doses IM 7.5 / 15 / 30	Ph I Adult: 18-60 y 60	S: 2000 E: 2000	* Lancet 2003; 362: 1959-66	

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CSL Limited (Australia)	H5N1 -Clade 1	Inactivated Split virus	Egg	AIPO ₄	2 doses IM 3 rd dose booster (after 6 months) 7.5 / 15	Ph I/II* Adult: 18-45 y 400	S: Oct 2005 E: Feb 2006	* Results presented in May 2006	Mock-up file submitted to TGA in mid 2007
CSL Limited (Australia)	H5N1 -Clade 1	Inactivated Split virus	Egg	AIPO ₄	2 doses IM 30 / 45	Ph I/II* Adult: 18-64 y 392	S: Oct 2006 E: Jun 2007	* Results presented in Feb 2007	
CSL Limited (Australia)	H5N1 -Clade 1	Inactivated Split virus	Egg	AIPO ₄	2 doses IM 30 / 45	Ph II* Elderly: > 65 y 221	S: Oct 2006 E: Aug 2007	* Results presented in Feb 2008	
CSL Limited (Australia)	H5N1 -Clade 1	Inactivated Split virus	Egg	AIPO ₄	2 doses IM 30 / 45	Ph II* Child: 6 m – 8 y 220	S: Oct 2006 E: Dec 2007	* Results being analyzed	
Denka Seiken* (Japan)	H5N1 -Clade 1	Inactivated Whole virion	Egg	Alum	2 doses IM / SC 1.7 / 5 / 15	Ph I/II Adult: 20-40 y 120	S: Feb 2006 E: Jul 2006	*with NIID	Mock-up file submitted to MHLW in Jan 2007
Denka Seiken* (Japan)*	H5N1 -Clade 1	Inactivated Whole virion	Egg	Alum	2 doses SC 5 / 15	Ph II/III Adult: 20-64 y 300	S: Sep 2006 E: Dec 2006	* with NIID	

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GSK Biologicals (Belgium)	H2N2	Inactivated Whole virion	Egg	Al(OH) ₃ AlPO ₄	2 doses IM 1.9 / 3.8 / 7.5 / 15	Ph I/II Adult 18-30 y 201	S: Sep 1999 E: Dec 1999	
						Adult >30 y 143 Elderly: >60 y 56		
GSK Biologicals (Belgium)	H2N2	Inactivated Whole virion	Egg	Al(OH) ₃ AlPO ₄	2 doses IM 1.9 / 15	Ph I/II Adult 18-30 y 100	S: Oct 2000 E: Nov 2001	Mock-up file submitted to EMEA in Dec 2005
	H9N2				2 doses IM 1.9 / 3.8 / 7.5 / 15	Adult 18-30 y 200		
GSK Biologicals (Belgium)	H9N2	Inactivated Whole virion	Egg	Al(OH) ₃ AlPO ₄	2 doses IM 3.8	Ph II Adult 18-30 y 50	S: Jan 2001 E: Apr 2001	
GSK Biologicals (Belgium)	H9N2	Inactivated Whole virion	Egg	Al(OH) ₃ AlPO ₄	2 doses IM 1.9 / 3.8 / 7.5 / 15	Ph I/II Elderly >60 y 385	S: May 2005 E: Aug 2005	
GSK Biologicals (Belgium)	H5N1 -Clade 1	Inactivated Whole virion	Egg	Al(OH) ₃ AlPO ₄	2 doses IM 3.8 / 7.5 / 15 / 27	Ph II Adult 18-60 y 400	S: Mar. 2006 E: Jul 2006	

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GSK Biologicals (Belgium)	H5N1 -Clade 1	Inactivated Split virus	Egg	AS03	2 doses IM 3.8 / 7.5 / 15 / 30	Ph I/II Adult 18-60 y 400	S: Apr 2006 E: Jun 2006	Lancet 2007; 370:580-589	Pre-pandemic & Pandemic Mock-up file received EU approval May 2008
GSK Biologicals (Belgium)	H5N1 -Clade 1	Inactivated Split virus	Egg	AS03	2 doses IM 15	Ph III Adult > 18 y 5,052	S: May 2006 E: Feb 2007		
GSK Biologicals (Belgium)	H5N1 -Clade 1	Inactivated Split virus	Egg	AS03	2 doses IM 3.8 / 7.5	Phase II Elderly > 60 y 480	S: Nov 2006 ongoing		
GSK Biologicals (Belgium)	H5N1 -Clade 1	Inactivated Split virus	Egg	AS03	2 doses IM 3.8	Phase III Adult 18-60 y 1090	S: Mar 2007 ongoing		
GSK Biologicals (Belgium)	H5N1 -Clade 1 & Clade 2.1.3	Inactivated Split virus	Egg	AS03	1 or 2-dose + booster IM 3.8	Phase II Adult 18-60 y 504	S: Feb 2007 ongoing		
GSK Biologicals (Belgium)	H5N1 -Clade 2.1.3	Inactivated Split virus	Egg	AS03	1 or 2 doses booster IM in primed subjects 3.8	Phase II Adult 19-61 y 450	S: Aug 2007 ongoing		
GSK Biologicals (Belgium)	H5N1 -Clade 1	Inactivated Split virus	Egg	AS03	2 doses IM 1.9 / 3.8	Phase II Children 3-9 y 400	S: Jul 2007 ongoing		
GSK Biologicals (Belgium)	H5N1 -Clade 2.1.3	Inactivated Split virus	Egg	AS03	2 doses IM 1.9 / 3.8	Phase I-II Adults 18-64 680	S: Aug 2007 ongoing		

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GSK Biologicals (Belgium)	H5N1 -Clade 2.1.3	Inactivated Split virus	Egg	AS03	2 doses IM 3.8	Phase III Adults \geq 18 y 4440	S: Jan 2008 ongoing		
Kaketsuken (Japan)	H5N1 -Clade 1	Inactivated Whole virion	Egg	Alum	2 doses SC 1.7 / 5 / 15	Ph I/II* Adult: 20-40 y 120	S: Feb 2007 E: Jun 2007	* with NIID	Mock-up & H5N1 pre- pandemic vaccine files submitted to MHLW in Apr 2008
Kaketsuken (Japan)	H5N1 -Clade 1	Inactivated Whole virion	Egg	Alum	2 doses IM 5 / 15	Ph II/III* Adult: 20-64 y 300	S: Aug 2007 E: Dec 2007	* with NIID	
Kitasato Institute (Japan)	H5N1 -Clade 1	Inactivated Whole virion	Egg	Alum	2 doses IM / SC 1.7 / 5 / 15	Ph I/II* Adult: 20-40 y 120	S: Mar 2006 E: Jul 2006	* with NIID	Mock-up & H5N1 pre- pandemic vaccine files approved by MHLW in Oct. 2007
Kitasato Institute (Japan)	H5N1 -Clade 1	Inactivated Whole virion	Egg	Alum	2 doses IM 5 / 15	Ph II/III* Adult: 20-64 y 300	S: Aug 2006 E: Nov 2006	* with NIID	

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MedImmune (AstraZeneca) (USA)*	H5N1 (-Clade 1, First Strain)	Live attenuated, intranasal	Egg	None	2 doses, Intranasal $10^{7.5}$ TCID ₅₀	Ph I* Adult: 18-49 y 16	S: 2007 E: 2007 Completed	* CRADA with NIAID * Preliminary results presented in Feb 2007 and Feb 2008 ** born after 1968	
MedImmune (AstraZeneca) (USA)*	H5N1 (-Clade 1, Second Strain)	Live attenuated, intranasal	Egg	None	2 doses, Intranasal $10^{6.7}$ TCID ₅₀	Ph I* Adult: 18-49 y 18	S: 2006 E: 2006 Completed		
MedImmune (AstraZeneca) (USA)*	H5N1 (-Clade 1, Second Strain)	Live attenuated, intranasal	Egg	None	2 doses, Intranasal $10^{7.5}$ TCID ₅₀	Ph I* Adult: 18-49 y 19	S: 2007 E: 2007		
MedImmune (AstraZeneca) (USA)*	H9N2	Live attenuated, intranasal	Egg	None	2 doses, Intranasal 10^7 TCID ₅₀	Ph I* Adult:18-37/38 y** 24 Seronegative	S: 2005 E: 2006 Completed		
MedImmune (AstraZeneca) (USA)	H7N3	Live attenuated, intranasal	Egg	None	2 doses, Intranasal $10^{7.5}$ TCID ₅₀	Ph I* Adult: 18-49 y 17	S: 2007 E: 2007		
MedImmune (AstraZeneca) (USA)	Strain to be chosen	Live attenuated, intranasal	Cell	None		Pre-clinical	Clinical start date to be determined		
Merck & Co. Inc (USA)	M-2*	Conserved Protein Recombinant	Cell	Alum & New adj	3 doses IM	Ph I Adult 190	S: 2007 ongoing		

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Nobilon* (Schering-Plough) (Netherlands)	H5N1 -Clade 1	Inactivated Whole virion	Cell	CoVaccine, HT™	Dose finding	Pre-clinical		* EU-FP6 project FluVac	
Nobilon* (Schering-Plough) (Netherlands)	H5N1 & H2N2 ts,ca,att	Live Attenuated	Cell	None	Intranasal	Pre-clinical		* CRADA with CDC (USA)	

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Novartis V&D (Italy)	H5N3	Inactivated Surface antigen	Egg	MF59	2 doses IM 3 rd dose booster (after 16 months) 7.5 / 15 / 30	Ph I Adult: 18-40 y 65	Trial finished in 2000	- Lancet 2001 357: 1937-1943 - Vaccine 2003 21: 1687-1693 - JID 2005 19 1: 1210-1215	Mock-up file approved by EMA in May 2007
Novartis V&D (Italy)	H9N2	Inactivated Surface antigen	Egg	MF59	2 doses IM 3.75 / 7.5 / 15 / 30	Ph I/II* Adult: 18-34 y 96	Trial finished in 2005	* Trial conducted by NIAID - Clinical Inf Dis 2006 43(9):1135-42	
Novartis V&D (Italy)	H5N1 -Clade 1	Inactivated Surface antigen	Egg	MF59		Ph II* Adult: 18-60 y 321 Ph II* Elderly: >60 y 173	Trials finished in 2007	Analysis ongoing	
Novartis V&D (Italy)	H5N3 & H3N2 & B	Inactivated Surface antigen	Egg	LTK63	2 doses Intranasal (7 days) 7.5	Ph I Adult: 18-40 y 100	Trial finished in 2002	- J. Virol. 2006 10: 4962-4970	
				MF59	2 doses IM 15	Ph I Adult: 18-40 y 100	Trial finished in 2002		

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Novartis V&D (Italy)	H5N1 -Clade 1	Inactivated Surface antigen	Egg	MF59	2 doses IM 3 rd dose booster (after 6 months) 7.5 / 15	Ph II Adult: >18 y 250	Trial finished in 2007	Analysis ongoing	
Novartis V&D (Italy)	H5N1 -Clade 1	Inactivated Surface antigen	Egg	MF59	2 doses IM 3 rd dose booster (after 6 months) 7.5 / 15	Ph II Adult: 18-40 y 40	Trial finished in 2007	Analysis ongoing	
				None	2 doses IM 3 rd dose booster (after 6 months) 15				
Novartis V&D (Italy)	H5N1 -Clade 1	Inactivated Surface antigen	Egg	MF59	2 doses IM 7.5	Ph III Adult: >18 y 4250	Trial finished in 2007	Analysis ongoing	
Novartis V&D (UK)	H5N1 -Clade 1	Inactivated Surface antigen	Egg	None	2 doses IM 15 / 30 / 45	Ph I/II* Adult: 18-64 y 390	S: Mar 2006 E: Oct 2006	* Trial conducted by NIAID	
				Alum	2 doses IM 7.5 / 15 / 30				
				MF59	2 doses IM 7.5 / 15				

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sanofi pasteur (France)	H5N1 -Clade 1	Inactivated Split virus	Egg	Alum	2 doses IM 7.5 / 15 / 30	Ph I Adult: 18-40 y 300	E: 2005	- Lancet 2006 367:1657-1664	Mock-up file submitted to EMEA in May 2007
					2 doses IM 7,5 / 30	Ph II Elderly: > 60 y 600	S: June 2006		
sanofi pasteur (France)	H5N1 -Clade 1	Inactivated Split virus	Egg	New Adjuvant	2 doses IM 1,9 / 3,8 / 7,5 / 15	Ph I Adult: 18-40 y 266	S: Jan 2007	Analysis ongoing	
sanofi pasteur (USA)	H5N1 -Clade 1	Inactivated Split virus	Egg	None	2 doses IM 7.5 / 15 / 45 / 90 (04-063)	Ph I/II* Adult: 18-64 y 118	S: Apr 2005 E: Nov 2005	* Trial conducted by NIAID	Vaccine approved by FDA in Apr 2007
						Ph II* Adult: 18-64 y 333	S: Oct 2005 E: Jan 2006		
sanofi pasteur (USA)	H5N1	Inactivated Split virus	Egg	None	Optional 3 rd dose booster (6 months) 7.5 / 15 / 45 / 90 (05-0090)	Ph II* Adult: 18-64 y 339	S: Oct 2005 E: July 2006	* Trial conducted by NIAID	
sanofi pasteur (USA)	H5N1 -Clade 1	Inactivated Split virus	Egg	None	3 doses IM 45 / 90 (04-076)	Ph I/II* Elderly: > 65 y 259	S: Oct 2005 E: Feb 2007	* Trial conducted by NIAID	

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sanofi pasteur (USA)	H5N1 -Clade 1	Inactivated Split virus	Egg	Alum	2 doses IM 3.75 / 7.5 / 15 / 45 (05-0141)	Ph I/II* Elderly: > 65 y 600	S: Mar 2006 E: Mar 2007	* Trial conducted by NIAID	
sanofi pasteur (USA)	H5N1 -Clade 1	Inactivated Split virus	Egg	None	2 doses IM Optional 3 rd dose booster (6 months) 45 μ g in 0,5 ml (04-077)	Ph I/II* Child: 2-9 y 125	S: Jan 2006 E: Apr 2007	* Trial conducted by NIAID	
sanofi pasteur (USA)	H5N1 -Clade 1	Inactivated Split virus	Egg	None	2 doses IM 45 μ g in 0,5 ml (06-0072)	Ph I/II* Child: 2-10 y 35	S: Feb 2007 E: Oct 2007	* Trial conducted by NIAID	
sanofi pasteur (USA)	H5N1 -Clade 1	Inactivated Split virus	Egg	Alum	2 doses IM 3.75 / 7.5 / 15 / 45 (05-0127)	Ph I* Adult: 18-49 y 600	S: Mar 2006 E: Dec 2006	* Trial conducted by NIAID	
sanofi pasteur (USA)	H5N1 -Clade 1	Inactivated Split virus	Egg	None	2 doses ID 3 / 9 3 rd dose booster (after 7month) 2 doses IM 15 / 45* 3 rd dose booster 77 μ g (after 7 months) (05-0015)	Ph I* Adult: 18-40 y 100	S: July 2005 E: Oct 2006	* Trial conducted by NIAID	
sanofi pasteur (USA)	H7N7	Inactivated Split virus	Egg	None	2 dosed IM 7.5 / 15 / 45 / 90	Ph I* Adult: 18-40 25	S: Mar 2008 E: Ongoing	* Trial conducted by NIAID	

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sanofi pasteur (USA)	H5N1 -Clade 1, Clade 0*	Inactivated Split virus	Egg	None	Single dose IM (H5 primed subjects) 90 μ g (05-0043)	Boosting Adult: 18-64 y 37	S: Oct 2005 E: Mar 2006	*Clade 0, Protein Sciences baculovirus purified HA (clade 3) priming	
					Compared against subjects who received 2 IM doses of clade 1 in a previous trial				
sanofi pasteur (USA)	H5N1	Inactivated Split virus	Egg	None	2 doses, 0.1 ID (30 μ g) (06-0089)	Adult: 18-49 y 226	S: Mar 2007 E: Feb 2008		
					2 doses, 0.1 IM (30 μ g)				

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Note: where an adjuvant is employed, standard practice is to evaluate it against the same vaccine without an adjuvant. Where alum is indicated as adjuvant, this refers to aluminum salt; AIPO₄ is aluminum phosphate. The dose, in μ g, refers to the amount of haemagglutinin (HA).

ID: Intradermal

IM: Intramuscular

SC: Subcutaneous

WT: Wild Type

ca: cold adopted

NIAID: National Institute of Allergy and Infectious Diseases

(USA) <http://www3.niaid.nih.gov/>

NIID: National Institute of Infectious Diseases

(Japan) <http://www.nih.go.jp/niid/index-e.html>

CRADA Collaborative Research & Development Agreement

About Clinical Trials conducted by the members of the IFPMA & IFPMA Influenza Vaccine Supply International Task Force (IVS ITF)

Last Update (May 26, 2008)

Company (Site Location)	Strain	Type	Culture	Adjuvant	Doses (µg)	Trials # subjects	Timing S=Start E= End	Additional Information	
Sinovac Biotech (China)	H5N1 -Clade 1	Inactivated Whole virion	Egg	Alum	2 doses IM 1,25 / 2,5 / 5 / 10 Optional 3 rd dose booster (after 12 months) 1,25 / 2,5 / 5 / 10	Ph I Adult: 18-60 y 120	S: Dec 2005 E: Jun 2006	- Lancet 2006 368:991-997	Mock-up file approved by SFDA in Apr 2008
Sinovac Biotech (China)	H5N1 -Clade 1	Inactivated Whole virion	Egg	Alum	2 doses IM (14 days) 5 / 10 / 15	Ph Ib Ado, Adult & Elderly 12-70 y 70	S: Aug 2007 E: Jan 2008		
Sinovac Biotech (China)	H5N1 -Clade 1	Inactivated Whole virion	Egg	Alum	2 doses IM 5 / 10 / 15	Ph II Adult: 18-60 y 400	S: Sep 2007 E: Jan 2008		
					2 doses IM (14 days) 10				
Sinovac Biotech (China)	H5N1 -Clade 1	Inactivated Split virus	Egg	Alum	2 doses IM 5 / 10 / 15 / 30	Ph I Child, Ado. Adult & Elderly 3-70 y 160	S: Aug 2007 E: Jan 2008		
Solvay Pharmaceuticals (Netherlands)	H5N1 -Clade 1	Inactivated Surface antigen	Egg	Alum	2 doses IM 10 / 30	Ph I Adult: 18-49 y 400	S: July 2007 E: Dec 2007	Analysis ongoing	
Solvay Pharmaceuticals (Netherlands)	H5N1 -Clade 1	Inactivated Surface antigen	Cell	Alum	2 doses IM 2 / 5 / 10	Ph I Adult: 18-49 y	S: May 2008		

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Note: where an adjuvant is employed, standard practice is to evaluate it against the same vaccine without an adjuvant. Where alum is indicated as adjuvant, this refers to aluminum salt; AIPO₄ is aluminum phosphate. The dose, in µg, refers to the amount of haemagglutinin (HA).

ID: Intradermal

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CRADA Collaborative Research & Development Agreement

About the Pandemic R&D table:

The table lists all the prototype avian / pandemic influenza vaccines under development by the member companies of the IFPMA and IFPMA Influenza Vaccine Supply International Task Force. As such, it covers the vast majority of R&D projects being undertaken in this field. The number of projects and the commitment of these companies to undertake the necessary clinical trials underline the innovative vaccine industry's commitment to help minimize the global health impact of avian and pandemic influenza.

About the IFPMA (www.ifpma.org):

The International Federation of Pharmaceutical Manufacturers & Associations is the global non-profit NGO representing the research-based pharmaceutical, biotech and vaccine sectors. Its members comprise 25 leading international companies and 44 national and regional industry associations covering developed and developing countries. The industry's R&D pipeline contains hundreds of new medicines and vaccines being developed to address global disease threats, including cancer, heart disease, HIV/AIDS and malaria. The IFPMA Clinical Trials Portal (www.ifpma.org/clinicaltrials), the IFPMA's Ethical Promotion online resource (www.ifpma.org/EthicalPromotion/) and its Health Partnerships information (www.ifpma.org – Developing World) help make the industry's activities more transparent. The IFPMA strengthens patient safety by improving risk assessment of medicines and combating their counterfeiting. It also provides the secretariat for the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

About the IFPMA Influenza Vaccine Supply International Task Force:

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Influenza Vaccine Supply International Task Force (IPMA IVS), established in February 2002, brings together research-based influenza vaccine manufacturers from around the world, who are developing vaccines against influenza threats from seasonal, avian and a pandemic. The IFPMA IVS provides its expertise in R&D, logistics and manufacturing to help governmental and intergovernmental bodies in pandemic planning and decision-making.

For more information, please see www.ifpma.org/influenza

As of May 2008, IFPMA IVS ITF members are: Baxter, Biken, CSL Limited, Crucell (including Berna Biotech), Denka Seiken, GlaxoSmithKline Biologicals, Kaketsuken, Kitasato Institute, MedImmune (AstraZeneca), Nobilon (Schering-Plough), Novartis Vaccines and Diagnostics (former Chiron Vaccines), PowderMed (Pfizer), sanofi pasteur, Sanofi Pasteur MSD, Sinovac and Solvay Pharmaceuticals.

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