

चाचा नेहरू बाल चिकित्सालय एवं अनुसंधान केन्द्र, इंदौर

क्रमांक / 3416 / सू.आ. / 10

इंदौर दिनांक 13/12/2010

प्रति,

डॉ. आनंद राय
C/o सुभाष उपाध्याय
118, रेडियो कॉलोनी, रेसीडेंसी एरिया
इन्दौर

द्वारा:—प्राध्यापक एवं विभागाध्यक्ष, शिशु रोग विभाग।

विषय:—सूचना के अधिकार के अंतर्गत चाही गई जानकारी के संबंध में।

संदर्भ:—आपका रसीद क्रं. 1661 दिनांक 21.10.2010

उपरोक्त विषयांतर्गत लोक सूचना अधिकार अधिनियम 2005 की धारा (6)(1) के अंतर्गत आपके द्वारा चाही गई वांछित जानकारी इस पत्र के साथ प्रपत्र "अ" में संलग्न है।

संलग्नानुसार:— प्रपत्र "अ"

डॉ. हेमन्त जैन
Hemant

प्राध्यपक शिशु रोग विभाग
म.गा.स्मृ.चिकि.महाविद्यालय, इन्दौर
इंदौर दिनांक 13-12-10

क्रमांक / 3416-17 / सू.आ. / 10

प्रतिलिपि:—

लोक सूचना अधिकारी, महात्मा गांधी स्मृति चिकित्सा महाविद्यालय, इन्दौर की ओर
सूचनार्थ।

डॉ. हेमन्त जैन
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प्राध्यपक शिशु रोग विभाग
म.गा.स्मृ.चिकि.महाविद्यालय, इन्दौर

DEPARTMENT OF PEDIATRICS
M.G.M. MEDICAL COLLEGE & CHACHA NEHRU BAL CHIKITSALAYA
AVUM ANUSANDHAN KENDRA INDORE

Date: 13/12/2010

Kindly find details of the Adjuvants used in the under mentioned vaccine trials done in the Department of Pediatrics Chacha Nehru Bal Chikitsalaya, Indore.

To the best of my knowledge none of the adjuvants used to boost the immunity of vaccines has any clinically significant side effects

Table - 1

Year	Vaccine Name	Sponsor Company	DCGI No. & Date	Adjuvant Name
2006	1. Hib Vaccine	Panacea Biotech	12-40/04DC 30-01-2006	Thiomerosal Aluminium Content Sodium Chloride : 0.025 mg : 0.30 mg : 4.25mg
	2. Easy Five Vaccine	Panacea Biotech	12-20/02DC 04-08-2006	Aluminium (Al ³⁺) (as aluminium phosphate gel) Thiomerosal Physiological saline : 0.025 mg : q.
	3. I/v Montelukast	Merck & Co. USA	4-191/05DC 05-10-2006	Not Applicable (Pharma Trial)
2007	1. Quadrivalent Study	LG Life Science, Korea	12-05-/96DC	Aluminium hydroxide gel (as aluminium ion) Thiomerosal Formalin (as formaldehyde) Tween 80 ≤ 0.39 mg ≤ 0.004 w/v% ≤ 0.01 w/v% 5 µg
			19-04-2006	

	2. MenACWYTT Conjugate Vaccine	Glaxo smith Kline	04/24/GSK/2007 DC 26-07-2007	No Adjuvant	
	3. DTWP	Panacea Biotech	04-193/06DC 07-05-2007	Inactive Ingredients 2-phenoxyethanol Aluminium Content Sodium Chloride	: Quantity/dose of 0.5 ml : 2.5 mg : 0.25 mg : 4.25 mg
	4. MOPV-1 Vaccine	WHO Sponsored	H/PBL- 45/MTOPV07 17-07-2007	MgCl ² Phenol red Kanamyacin & Neomycin Sulphate	
2008	1. Valsartan	Novartis, USA	CT/53/07-DCG 29-05-2007	Not Applicable (Pharma Trial)	
	2. Valsartan	Novartis, USA	CT/54/07-DCG 29-05-2007	Not Applicable (Pharma Trial)	
	3. Bivalent OPV	WHO Sponsored	4/PBL- 26BOPV/08DC 11-06-2008	MgCl ² Phenol red Kanamyacin & Neomycin Sulphate	
2009	1. Pentavalent on 100 Trial Subjects	LG Life Science	4/LGK/29/PEN/ OTDC 01-05-2010	Aluminium hydroxide gel (as aluminium ion) Thiomerosal Formalin (as formaldehyde) Tween 80	≤ 0.39 mg ≤ 0.01 w/v% ≤ 0.01 w/v% 5 µg
	2. Rabeprazole	Johnson & Johnson, USA	CT/759/09-DCG 06-07-2009	Not Applicable (Pharma Trial)	
	3. IMOVAX Polio Vaccine	Panacea Biotech	4/PBL- 31/PPV/07DC 19-01-2010	2-Phenoxyethanol Formaldehyde Concentrated Sodium Phosphate Buffer	2.5 mg 12.5 µg 0.04 ml
	4. Pentavalent on 60 Trial Subjects	LG Life Science	4/LGK- 29/PEN07DC 31-09-2008	Aluminium hydroxide gel (as aluminium ion) Thiomerosal Formalin (as formaldehyde) Tween 80	≤ 0.39 mg ≤ 0.01 w/v% ≤ 0.01 w/v% 5 µg

<p>5. Meningococcal – ACWY Conjugate Vaccine</p>	<p>Glaxo Smith Kline</p>	<p>CT/799/09DCG 11-09-2009</p>	<p>No Adjuvant Added</p>
<p>2010</p> <p>12A, H1N1 Vaccine Serum Institute of India Ltd. (Inactivated)</p> <p>12B, H1N1 Vaccine Serum Institute of India Ltd.</p> <p>1. (Live Attenuated)</p> <p>2. H1N1 Vaccine</p>	<p>Serum Institute of India</p>	<p>12-76/SERUM/10B D 01-01-2010</p>	<p>Phosphate buffer saline : Base : 0.6 mg/dose</p> <p>AKOH³ gel : < 1 ug/dose</p> <p>Ovalbumin : <100 ug/dose</p> <p>Protein : < 100 EU/dose</p> <p>Endotoxin : < 100 EU/dose</p> <p>Partially hydrolysed gelatin : 2.5%</p> <p>Sorbitol : 5.0%</p> <p>L-Alanine : 0.1%</p> <p>L-Histidine : 0.21%</p> <p>Tricine : 0.3%</p> <p>L-Arginine hydrochloride : 1.6%</p> <p>Lactalbumin hydrolysate : 0.35%</p> <p>Phosphate buffer saline : Base</p>
<p>3. HPV Vaccine</p>	<p>Panacea Biotech</p>	<p>12-PBL/10-BD 04-01-2010</p>	<p>Thiomersal Adjuvant (Squalene based emulsion) : 0.025 mg</p> <p>Squalene : 9.75 mg</p> <p>Polysorbate 80 : 1.175 mg</p> <p>Soritan trioleate : 1.175 mg</p> <p>Amorphous Aluminium Hydroxyphosphate Sulfate (AAHS)</p>
<p>4. Hepatitis A</p>	<p>Merck & Dom, USA</p>	<p>CT/9111/09-DCG 29-01-2010</p>	<p>Crucell, Switzerland</p> <p>1/PMMS/P10BD 18-01-2010</p> <p>5 µg influenza hemagglutinin, 50 µg phospholipids (40 µg lecithin and 10 µg cephalin), 2.25 mg sodium chloride, water for injection ad 0.25 ml.</p>

Table -2

Year	Vaccine Name	Sponsor Company	CTRI No. & Date	Adjuvant Name
2007	1. Combination Vaccine Diphtheria, Tetanus whole cell pertussis, Hepatitis B	LG Life Science, Korea	CTRI/2009/091/000394 02-07-2009	Aluminium hydroxide gel (as aluminium ion) ≤ 0.39 mg Thiomerosal ≤ 0.004 w/v/% Formalin (as formaldehyde) ≤ 0.01 w/v/% Tween 80 5 µg
2009	2. Combination Vaccine Diphtheria, Tetanus whole cell pertussis, Hepatitis B, LBV/F0101	LG Life Science, Korea	CTRI/2009/091/000843 15-10-2009	Aluminium hydroxide gel (as aluminium ion) ≤ 0.39 mg Thiomerosal ≤ 0.01 w/v/% Formalin (as formaldehyde) ≤ 0.01 w/v/% Tween 80 5 µg
2010	1. V503 Multivalent HPV Vaccine	Merck & Co, USA	CTRI/2009/091/000767 02-02-2010	Amorphous Aluminium Hydroxyphosphate Sulfate (AAHS)
2010	2A, H1N1 Vaccine Serum Institute of India Ltd. (Inactivated)	Serum Institute of India	CTRI/2010/091/000093 11-03-2010	Posphate buffer saline : Base Al(OH) ₃ gel : 0.6 mg/dose Ovalbumin : < 1 ug/dose Protein : <100 ug/dose Endotoxin : < 100 EU/dose

2010	1. BOPV Polio Vaccine	Panacea Biotech	CTRI/2010/091/000591 15-07-2010	MgCl ₂ Phenol red Kanamycin & Neomycin Sulphate
2010	2. Hepatitis –A Vaccine in 18-47 month old Children Havpur	Crucells Switzerland	CTRI/2010/91/000246 26-03-2010	5 µg influenza hemagglutinin, 50 µg phospholipids (40 µg lecithin and 10 µg cephalin), 2.25 mg sodium chloride, water for injection ad 0.25 ml.
2010	3. A/H1N1 Influenza Vaccine in 6 to 35 months old Children	Panacea Biotech	CTRI/2010/91/000029 23-04-2010	Thiomersal : 0.025 mg Adjuvant (Squalene based emulsion) Squalene : 9.75 mg Polysorbate 80 : 1.175 mg Sorbitan trioleate : 1.175 mg
2010	4. LA-H1N1 Vaccine phase II/III Trial	Serum Institute of India	CTRI/2010/91/000092 15-02-2010	Partially hydrolysed gelatin : 2.5% Sorbitol : 5.0% L-Alanine : 0.1% L-Histidine : 0.21% Tricine : 0.3% L-Arginine hydrochloride : 1.6% Lactalbumin hydrolysate : 0.35% Pospbate buffer saline : Base
2009	5. IMOVAX Polio Vaccine with Inactivated Polio	Panacea Biotech	CTRI/2010/91/000887 25-01-2010	2-Phenoxyethanol : 2.5 mg Formaldehyde

	Vaccine of Panacea Biotech in Infants			12.5 µg Concentrated Sodium Phosphate Buffer 0.04 ml
2010	6. Monovalent H1N1 Influenza Vaccine in Healthy pediatrics population 3-9 years of age	Panacea Biotech	CTRI/2010/091/000031 23-04-2010	Thiomersal : 0.025 mg Adjuvant (Squalene based emulsion) Squalene : 9.75 mg Polysorbate 80 : 1.175 mg Sorbitan trioleate : 1.175 mg



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