LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Datum: 2012-02-09 Dnr: 2911:2011/513086

Inspektionsenheten
Gunilla Anheller

Dr Tore Persson
Box 17214
104 62 Stockholm

E-post: Tore.Persson@ki.se

Beträffande Pandemrix/GSK med adjuvans AS03

Ni har per brev frågat om rationalen för oannonserad närvaro av arsenik och tenn i Vaccin Pandemrix/GSK med adjuvans AS03.

Läkemedelsverket har genomfört en oberoende analys av prover från er med jämförande referensprover av samma tillverkningssats från tillverkaren GSK.

Analyssvaren från det oberoende laboratoriet överensstämmer med de analyser som GSK gjort, och visar betydligt lägre halter av arsenik och tenn än de som ni erhållit vid analyser på laboratoriet på KTH i Stockholm. Erhållna halter redovisas i bifogad bilaga.

På Läkemedelsverkets vägnar

Gunilla Anheller
Utredare

Peter Stjärnkvist
Senior Expert

Bilaga :Test Report NI-1743-11 från National Medicines Institute, Warsaw, Poland

Kopia skickad till GSK, Att: Gunilla Jonsson

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@mpa.se

NATIONAL MEDICINES INSTITUTE

OFFICIAL MEDICINES CONTROL LABORATORY

Chełmska Str. 30/34 , 00-725 Warsaw, Poland

http://www.il.waw.pl
Board of Directors
secretary: (+48-22) 851-13-69
(+48-22) 851-14-96
Fax: (+48-22) 841-06-52

Main Accountant: (+48-22) 851-13-76
ext. 130
Bureau for Medicines Control and Research Organization: (+48-22) 841-36-51
ext. 338

Name and address of the customer:

Medical Products Agency
77500, Box 26
SE-751 03 Uppsala, Sweden

TEST REPORT : NI – 1743-11	Copy number 1	page 1 / 3
	Date of issue: 8th December 2011	

Date of the sample receipt in the Institute: 16th November 2011

Code of the sample: NI- 1743-11 **Code of the Leading Laboratory: W- CF/S/246/11**

Type of testing: expertise

The purpose of testing: determination of As and Sn

SAMPLE'S IDENTIFYING DATA:

Name of the product : Pandemrix (Pandemic)

Dosage form : see the table

Dose: - **Batch: see the table**

Production date: - **Date of expire: -**

The marketing authorization holder: -

The manufacturer responsible for the batch release: -

The amount of the sample obtained: 14 vials

Description of the package and the content: 12 colourless glass vials with rubber stoppers, aluminium overseals and plastic caps (6 of them contain white emulsion and 6 clear, colourless solution), 2 vials with plastic screw caps (one with white emulsion, second with blue clear solution).

Evaluation of the compliance with the approved standard of: not applicable
Primary packaging: -
Secondary packaging: -
Information leaflet: -

TESTS RESULTS:
The document containing requirements for the product: -

Testing method: ICP-MS; Ph. Eur. 7.0, 2011: 2.2.58

As: LOQ - 0.000358 ppm Sn: LOQ - 0.000050 ppm

Label MPA No	Dosage form	Sample	Lot	As (ppm)	Sn (ppm)
1.	Emulsion for injection	Adjuvant	AA03B020AA	below LOQ	below 0.004
2.			AA03B026AA	below LOQ	below LOQ
3.			AA3BA041A	below LOQ	below LOQ
4.			AA03A135A	below LOQ	below LOQ
5.			AA03A253A	below LOQ	below LOQ
6.			AA03B020AA	below LOQ	below 0.005
7.	-	White emulsion	-	**0.157** *	below 0.010
8.	Solution for injection	Antigen	AFLSA081A	below 0.019	below 0.018
9.			AFLSA160A	below 0.005	below 0.009
10.			AFLSA162A	below LOQ	below 0.003
11.			AFLSA166A	below LOQ	below 0.018
12.			AFLSA167A	below LOQ	below 0.008
13.			AFLSA167AB	below LOQ	below LOQ
14.	-	Blue solution	-	**0.046** *	below LOQ

Notice:
* tests of the vials **7 and 14** were performed using single portion of sample because of the small amount of them, the repetition wasn't possible.

Additional information:
The tests were performed using ICP-MS X Series II with a quadrupole system (Thermo Electron Corporation).

CONFIRMATION OF THE PRODUCT COMPLIANCE with the suitable requirements: -

NOTICES (opinions, interpretations): The results obtained for 14 samples of the product in the range of tested parameters are summarized in the table above.

(part of the report not covered by quality system according to PN-EN ISO/IEC 17025)

Tests results and confirmation concern exclusively the tested samples

The tests beginning date: 24th November 2011 The tests completion date: 2nd December 2011

Signature and stamp of a person preparing the report: **Signature and stamp of a person approving the report:**

p.o. KIEROWNIKA PRACOWNI
mgr inż. Monika Kiljan

Z-ca KIEROWNIKA
ZAKŁADU CHEMII FARMACEUTYCZNEJ
dr n. farm. Agata Błażewicz

Signature and stamp of the Director of the Institute

DYREKTOR
NARODOWEGO INSTYTUTU LEKÓW
Prof. dr hab. Zbigniew E. Fijałek

THE END

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