From: Nazaryan, Nona <Nona.Nazaryan@pfizer.com>
Sent: 12 May 2020 21:16
To: Brian Howes; Leah McBride; Nikita Harika; Katie Pearce; Kelly Wells
Subject: Blair PDF Legalization 13/May/NN-CST- 46364-84900
Attachments: GMP 277 H Aseptic South 2020-009.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Brian and Team,

Please can you arrange for the enclosed documents to be legalised.

All required details are below:

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Chile	GMP	PBG (IMB)	ALPROSTADIL	Apostille	UK	03-Jun-2020	46364-84900	**Name:** Juan Ignacio Donoso **Address:** Av. Cerro el Plomo 5680, Torre 6, Piso 16, Las Condes, Santiago, Chile, **Telephone:** +5622412998 **Email:** juanignacio.donoso@pfizer.com

When the document is despatched, please send a PDF copy to nona.nazaryan@pfizer.com and recipient details identified above, including the tracking details.

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BE IT KNOWN that I, Sunita Kumeri of, 268 Bath Road, Slough, Berkshire United Kingdom a duly authorised Notary Public

CERTIFY that

1. The signature set and subscribed to the certificate at the foot of the first page of the copy document annexed hereto is genuine having been subscribed thereto by Zoe Bruce whose identity I the Notary attest and who is duly authorised by Pfizer Limited ("the Company") to represent them in this matter, and
2. Zoe Bruce has thereby certified on behalf of the company that the Certificate of GMP Compliance of a Manufacturer issued to Pfizer Manufacturing Belgium NV annexed hereto is a true copy of the original document.

SIGNED and sealed at 268 Bath Road, Slough, Berkshire aforesaid on 13th May 2020.

Sunita Kumeri
Notary Public
England and Wales

Protocol No. 13/20

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

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2. Has been signed by a été signé par / ha sido firmado por	Sunita Kumeri
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Certified
Attesté / Certificado

5. at á / en: London	**6. the** le / el día: 14 May 2020
7. by par / por	Her Majesty's Principal Secretary of State for Foreign and Commonwealth Affairs
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209378

Federal Agency for Medicines and Health Products

CERTIFICATE NUMBER: ***BE/GMP/2020/009***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Belgium confirms the following:
The manufacturer: ***Pfizer Manufacturing Belgium NV***
Site address: ***Rijksweg 12, Puurs, 2870, Belgium***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***277 H*** in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:
Article 12 bis, § 1 of the Law of 25th March 1964 related to the Medicinal Products

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2020-01-29*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

I, Zoe Bruce, on behalf of Pfizer, certify this document to be a true copy of the original

rt 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates Special Requirements 7 Other: highly potent products/certain hormones(en) 1.1.1.3 Semi-solids Special Requirements 7 Other: highly potent products(en) 1.1.1.4 Small volume liquids Special Requirements 7 Other: highly potent products/ certain hormones(en)
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids
	1.1.3 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.2 Immunological products 1.3.1.5 Biotechnology products 1.3.1.6 Human or animal extracted products Special Requirements 7 Other: low molecular weight heparin(en)
	1.3.2 Batch Certification (list of product types) 1.3.2.2 Immunological products 1.3.2.5 Biotechnology products 1.3.2.6 Human or animal extracted products

Clarifying remarks (for public users)

Inspected area: 'Aseptic Area South" / 1.3.1.2: formulation and filling only 1.3.1.5: formulation and filling only 1.3.1.6: formulation and filling only

2020-04-22

Name and signature of the authorised person of the Competent Authority of Belgium

in name of

afmps fagg

Séverine Brasseur
(Signature)
2020.04.23 09:57:03
+02'00'

Mr. Xavier De Cuyper
Federal Agency for Medicines and Health Products
Tel: *+32 2 5284000*
Fax: *+32 2 5284001*