BE IT KNOWN that I, Sunita Kumeri of, 18-24 Stoke Road, Slough, Berkshire United Kingdom a duly authorised Notary Public

CERTIFY ONLY that Brian Michael Howes who is well known to me and who is duly authorised by Pfizer Limited ("the Company") to represent them in this matter has today caused the annexed Certificate of Pharmaceutical Product to be produced to me and has represented to me on behalf of the Company that the said document is an original document signed by Dhipon Islam on behalf of the Swedish Medical Products Agency.

SIGNED and sealed at 18-24 Stoke Road, Slough, Berkshire aforesaid on 12th February 2019

Sunita Kumeri
Notary Public
England and Wales

Protocol No. 39/19

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: Pays / Pais:	United Kingdom of Great Britain and Northern Ireland
This public document Le présent acte public / El presente documento público	
2. Has been signed by a été signé par ha sido firmado por	Sunita Kumeri
3. Acting in the capacity of agissant en qualité de quien actúa en calidad de	Notary Public
4. Bears the seal / stamp of est revêtu du sceau / timbre de y está revestido del sello / timbre de	The Said Notary Public

Certified

Attesté / Certificado

5. at á / en: London	**6. the** le / el día: 13 February 2019
7. by par / por	Her Majesty's Principal Secretary of State for Foreign and Commonwealth Affairs
8. Number sous no / bajo el numero	APO-1309015
9. Seal / stamp Sceau / timbre Sello / timbre	**10. Signature** Signature Firma: N. Larrier

FOREIGN AND COMMONWEALTH OFFICE LONDON

This Apostille is not to be used in the UK and only confirms the authenticity of the signature, seal or stamp on the attached UK public document. It does not confirm the authenticity of the underlying document. Apostilles attached to documents that have been photocopied and certified in the UK confirm the signature of the UK official who conducted the certification only. It does not authenticate either the signature on the original document or the contents of the original document in any way.

If this document is to be used in a country not party to the Hague Convention of the 5th of October 1961, it should be presented to the consular section of the mission representing that country

To verify this apostille go to www.verifyapostille.service.gov.uk

Certificate of a Pharmaceutical Product[1]

This certificate conforms, in general, to the format recommended by the World Health Organisation *(explanatory notes are attached)*

No. of Certificate: **5.8.1-2018-461**

Exporting (certifying) country: **Sweden**

Importing (requesting) country: **Chile**

1. Name, dosage form and strength of the medicinal product:
Salazopyrin®, tablet, 500 mg

1.1 Active ingredient(s)[2] and amount(s) per unit dose:[3]

Active ingredient	
sulfasalazine	500,000 mg

For complete qualitative composition including excipients, see attached.[4]

1.2 Is this product authorised to be placed on the market for use in the exporting country?[5] ☑ Yes ☐ No

If No, why is Marketing Authorisation lacking?

☐ *under consideration* ☐ *refused* ☐ *withdrawn*

2A.1 Marketing Authorisation number:[6] **3017**

Date of Marketing Authorisation: **27 September 1945**

2A.2 Marketing Authorisation Holder (name and address):

Pfizer AB
191 90 Sollentuna
Sweden

2A.3 Status of the Marketing Authorisation Holder:[7]

☐ *a* ☐ *b* ☐ *c* ☑ *d (key in appropriate category as defined in note 7)*

2A.3.1 For categories b, c and d the name and address of the manufacturing site producing the dosage form are:[8]
Recipharm Uppsala AB
Björkgatan 30
751 82 Uppsala
Sweden

2A.4 Is Summary Basis of Approval appended?[9] ☑ No

2A.5 Is the attached, officially approved product information complete and consonant with the Marketing Authorisation?[10] ☑ Yes ☐ Not provided
The applicant assumes the whole responsibility for the accuracy of the translation of the text from Swedish into English.

2A.6 Applicant for certificate if different from the Marketing Authorisation Holder (name and address):[11]
FMD KL Europe LLC
3a Hakob Hakobyan Str.
Yerevan 0031
Republic of Armenia

3. Does the certifying authority arrange for periodic inspection of the manufacturing site in Sweden in which the dosage form is produced?[12] ☑ Yes ☐ No ☐ N/A

If no or not applicable proceed to question 4.

3.1 Periodicity of routine inspections: Every two to three years

3.2 Has the manufacture of this type of dosage form been inspected? ☑ Yes

3.3 Do the facilities and operations in Sweden conform to GMP in the European Community. (The Commission: Guide to Good Manufacturing Practice for Medicinal Products in the European Community and directives 2003/94/EEC and 91/412/EEC) and as recommended by the World Health Organisation?[13] ☑ Yes ☐ No

Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?[14]

☑ Yes ☐ No

If no, explain:

Address of certifying authority:
Medical Products Agency
Box 26
Dag Hammarskjölds väg 42
751 03 Uppsala
Sweden
Telephone number: ***+46 (0)18-17 46 00*** Fax number: ***+46(0)18-54 85 66***

On behalf of the Medical Products Agency

Signature:

LÄKEMEDELSVERKET · SWEDISH MEDICAL PRODUCTS AGENCY ·

Dhipon Islam
Stamp and date: ***5 December, 2018***