Chambre des notaires

Certificate

CANADA
PROVINCE OF QUÉBEC

I, the undersigned, Danielle Gagliardi, Secretary of the *Chambre des notaires du Québec*, a professional order duly established under the *Notarial Act* and the *Professional Code*, having its Head Office in the City of Montréal, Province of Québec, hereby certify under my oath of office:

THAT M^tre^ Anne Hamelin, Notary in the City of Montréal, is a member of the *Ordre des notaires du Québec* since June 28th, 1985, date of her registration on the Roll of the said professional Order;

THAT since that date, M^tre^ Hamelin has always been entered on the Roll of the *Chambre des notaires du Québec*;

THAT her signature affixed to the attached document corresponds to that filed in my office in accordance with the *Notarial Act*.

IN WITNESS WHEREOF, I have signed the present certificate in the City of Montréal, this Wednesday, August 14, 2019.

Danielle Gagliardi, Notary

Danielle Gagliardi, Notary
Secretary

"Note: The present certificate only gives evidence of the signature of the notary, but not the contents of the annexed document."

101-2045, rue Stanley, Montréal QC H3A 2V4 Tel.: 514-879-1793 Toll free: 1-800-263-1793 www.cnq.org

600020938

CONSULADO GENERAL DE CHILE
EN MONTREAL, CANADÁ

Se legaliza la firma de Danielle Gagliardi,
Secretaria de la Cámara de Notarios de Quebec.

Actuación N° 2031 Arancel N° 4-10

Derechos Percibidos US$ 12.-

Montreal, 22 AGO 2019

CONSULADO GENERAL DE CHILE ☆ MONTREAL ☆

JAIME CONTRERAS NOGUEIRA
Cónsul General

SERVICIO CONSULAR 10 2019 2019 2

BAUSCH Health

Bausch Health Companies Inc.
2150 St. Elzear Blvd. West, Laval, Quebec, Canada, H7L 4A8
Tel. 514-956-6135
www.bauschhealth.com

Quality Assurance and Compliance

CANADA

PROVINCE OF QUEBEC

DISTRICT OF MONTREAL

I, the undersigned, Mrs. Annick Bouchereau-Meunier, QA and Compliance Specialist, of the company BAUSCH HEALTH COMPANIES INC. of Laval, do herby solemnly declare and certify on my honor:

That the documents herewith represent the:

- Certificate of Change of Name, dated July 13, 2018;
- Attestation of Administrative Change, dated 2018-07-26
- Declaration of Company Name Change, dated 2018-10-22, referencing:
  - Establishment Licence 101880-B, dated 2018-10-09
- Declaration of Good Manufacturing Practices (GMP), dated 2019-07-19;
- Certificate of Pharmaceutical Product (CPP) 2019 for ***Mestinon 60 mg Tablets - Chile***

IN WITNESS WHEREOF, I have signed in the City of Laval

On this 9 *day of* AUGUST *2019*

Signature: Annick B.M.

Annick Bouchereau-Meunier, QA and Compliance Specialist
Quality Assurance and Compliance

Solemnly declare before me in the City of Laval

On this 9th *day of* August *2019.*

Signature: Anne Hamelin

Anne Hamelin, Notary

Reference: Mestinon 60 mg Tablet - Chile

BRITISH COLUMBIA

Number: C0977395

CERTIFICATE
OF
CHANGE OF NAME

BUSINESS CORPORATIONS ACT

I Hereby Certify that VALEANT PHARMACEUTICALS INTERNATIONAL, INC. changed its name to BAUSCH HEALTH COMPANIES INC. on July 13, 2018 at 05:00 AM Pacific Time.

Issued under my hand at Victoria, British Columbia
On July 13, 2018

CAROL PREST
Registrar of Companies
Province of British Columbia
Canada

ELECTRONIC CERTIFICATE

BAUSCH Health
2150 St-Elzear Boulevard West
Laval, Quebec H7L 4A8
514-956-6135
bauschhealth.com

Date: July-26-2018

ATTESTATION OF ADMINISTRATIVE CHANGE

TO WHOM IT MAY CONCERN

This is to notify you that, effective July 13, 2018 Valeant Pharmaceuticals International Inc. (Laval manufacturing site) located at 2150 Saint-Elzear Blvd. West, Laval, QC, H7L 4A8, changed its name to "Bausch Health Companies Inc" (the "Name Change"). As a result of this change, the Laval facility now bears the name of **Bausch Health Companies Inc.**, which is considered a name change of an administrative nature only.

It is confirmed that the quality systems, equipment, procedures and processes at Bausch Health Companies Inc., located at 2150 Saint-Elzear Blvd. West, Laval, QC, H7L 4A8, remain unchanged due to this administrative company name change, and that the documentation provided continues to reflect and support **Bausch Health Companies Inc**, Laval Canada manufacturing facility.

Thomas Laing
Director, Quality and Compliance

2018-07-26

Date

BAUSCH Health
2150 St-Elzear Boulevard West
Laval, Quebec H7L 4A8
514-956-6135
bauschhealth.com

Date: October-22-2018

DECLARATION AND PROOF OF NAME CHANGE

TO WHOM IT MAY CONCERN

This is to certify that on July 13, 2018 Valeant Pharmaceuticals International Inc. (Laval manufacturing site) located at 2150 Saint-Elzear Blvd. West, Laval, Quebec, H7L 4A8, Canada, changed its name to "Bausch Health Companies Inc" (the "Name Change"). As a result of this change, the Laval facility now bears the name of **Bausch Health Companies Inc.** as confirmed by the attached Establishment License issued by Heath Canada on October 9th, 2018 (ref. Licence number 101880-B).

Thomas Laing
Director, Quality and Compliance

2018·10·22
Date

Health Canada / Santé Canada

Establishment Licence / **Licence d'établissement**

Licence No. / No. de la licence
101880-B

Bausch Health Companies Inc.

2150 Boul. St. Elzear Ouest
Laval QC H7L 4A8

This licence is issued in accordance with the *Food and Drugs Act and Regulations* (Division 1A) for the following activities /
Cette licence est délivrée conformément à la *Loi et au Règlement sur les aliments et drogues* (titre 1A) pour les activités et les catégories de drogues suivants :

Category / Catégorie	Activity / Activité	Non-Sterile / Non-Stérile	Sterile / Stérile
Pharmaceutical / Pharmaceutique	Fabricate / Manufacturer	X	
Pharmaceutical / Pharmaceutique	Package / Emballer	X	X
Pharmaceutical / Pharmaceutique	Label / Étiqueter	X	X
Active Pharmaceutical Ingredients / Ingrédient actif pharmaceutique	Test / Analyser	X	
Pharmaceutical / Pharmaceutique	Test / Analyser	X	X
Active Pharmaceutical Ingredients / Ingrédient actif pharmaceutique	Import / Importer	X	
Pharmaceutical / Pharmaceutique	Import / Importer	X	X

1 - If applicable / s'il y a lieu
«Biological» includes drugs listed in Schedule D to the Act, other than vaccines or whole blood and its components / « Biologique » inclut les drogues visée à l'annexe D de la Loi, autre que les vaccins ou le sang total et ses composants
«Radiopharmaceutical» includes drugs listed in Schedule C to the Act / « Radiopharmaceutique » inclut les drogues visée à l'annexe C de la Loi

2 - If applicable / s'il y a lieu
«Distribute» as set out in paragraph C.01.A.003 (a) and/or (b) / « Distribuer » à titre de distribuer au sens de l'alinéa C.01A.003 (a) et/ou (b)
«Test» includes any tests and examinations required under Division 2 / « Analyser » conformément au titre 2

This licence contains the following additional annex(es) / Cette licence contient les annexes suivantes :

Foreign Building Annex / Annexe concernant les bâtiments étrangers
Active Pharmaceutical Ingredient Foreign Building Annex /Annexe concernant les bâtiments étrangers d'ingrédients pharmaceutiques actifs

Date of last GMP inspection / Date de la dernière inspection BPF : 2016-11-28

MINISTER OF HEALTH / MINISTRE DE LA SANTÉ	Countersigned Director General, Regulatory Operations and Regions Branch or designated official Contresigné par Directeur général, Direction générale des opérations réglementaires et des régions ou responsable désigné
Establishment Licence Licence d'établissement Health Canada / Santé Canada Canada	Kimby N Barton Kimby Barton Issued on / Émise le : 2018-10-09

This licence is the property of the Regulatory Operations and Regions Branch and must be returned upon demand.
Cette licence appartient à la Direction générale des opérations réglementaires et des régions et doit être retournée sur demande.

Canada

BAUSCH Health
2150 St-Elzear Boulevard West
Laval, Quebec H7L 4A8
514-956-6135
bauschhealth.com

DECLARATION OF GOOD MANUFACTURING PRACTICES (GMP)

This is to certify that Bausch Health Companies Inc. (formerly known as Valeant Pharmaceuticals International Inc.) operates pharmaceutical manufacturing facilities located at 2150 St-Elzear Blvd. West, Laval, Québec, Canada, H7L 4A8.

The facilities are routinely inspected by the Health Products and Food Branch Inspectorate of Health Canada under the authority of the Food and Drugs Act to verify compliance with Part C, Division 2 of the Food and Drug Regulations (Good Manufacturing Practices) or any other pertinent regulation of the said Act and also under the authority of the Controlled Drugs and Substances Act and its regulations.
The facilities have been granted an overall rating of "C" (Recommended for the continuation or issuance of the Establishment License). The most recent inspection was conducted on November 29, 2018.

Additionally, Inspections of the facilities are routinely carried out by the US FDA under the authority of the Food and Drug Act to verify compliance with US (21 CFR Parts 210 and 211) current Good Manufacturing Practices guideline. The most recent FDA GMP audit, held on February 13 to February 17, 2017, was deemed as acceptable.

2019.07.19

Thomas Laing
Director, Quality and Compliance

Health Canada Santé Canada

CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

This certificate conforms to the format recommended by the World Health Organization
(Superscript numbers refer to explanatory notes located at the end of the certificate)

Exporting (certifying) country: **CANADA** No. of Certificate: **72555**

Importing (requesting) country: **CHILE**

1. Name and dosage form of the product:
MESTINON **TABLET**

1.1 Active ingredient(s)[2] and amount(s) per unit dose:[3]
PYRIDOSTIGMINE BROMIDE 60 MG

For complete composition including excipients, see attached:[4] **No**

1.2 Is this product licensed to be placed on the market for use in the exporting country?[5] **Yes**
If YES, continue with section 2A and leave section 2B blank
If NO, leave question 1.3 and section 2A blank and continue with section 2B[6]

1.3 Is this product actually on the market in the exporting country? **Yes**

2A.1 Number of product license and date of issue:[7] **00869961** **1990-12-31**

2A.2 Product license holder (name and address):
VALEANT CANADA LP/VALEANT CANADA S.E.C.
2150 BOUL. ST-ELZEAR OUEST
LAVAL,QUEBEC
CANADA,H7L 4A8

2A.3 Status of license holder:[8] **C**

2A.3.1 For categories (B) and (C) the name and address of the manufacturer producing the dosage form is:

BAUSCH HEALTH COMPANIES INC.
2150 BOUL. ST-ELZEAR OUEST
LAVAL,QUEBEC
CANADA,H7L 4A8

2A.4 Is a summary basis for approval appended ?[10] **Not Applicable**

2A.5 Is the attached product information complete and consonant with the license?[11] **Not Required**

2A.6 Applicant for certificate, if different from license holder (name and address):

Canada

2019 Health Canada Santé Canada Canada

Health Canada / Santé Canada

Applicant for certificate (name and address):

2 Status of applicant:[8]

2.2.1 For categories (B) and (C) the name and address of the manufacturer producing the dosage form is:[9]

2B.3 Why is marketing authorization lacking?

2B.4 Remarks:[13]

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?[14] **Yes**

If NO or NOT APPLICABLE, proceed to question 4

3.1 Periodicity of routine inspections (years): **2**

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

3.3 Do the facilities & operations conform to GMP as recommended by the WHO?[15] **Yes**

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?[16] **Yes**

If NO, explain:

Address of certifying authority

Regulatory Operations and Enforcement Branch
Health Product Compliance Directorate
200 Eglantine Driveway, Tunney's Pasture
Ottawa, Ontario K1A 0K9

Signature: _____

Name of authorized person **HARVIN KOMAL**

Date: 2019-06-27

This certificate expires 1 year from the date of issue

Canada

2019 Health Canada Santé Canada Canada

Komal, of the City of Ottawa, in the ce of Ontario, Public Servant, SOLEMNLY M AND DECLARE AS FOLLOWS:

1. I have been employed by the federal government at Health Canada since September 31st, 2016. I am currently Acting Supervisor within the Drug Establishment Licensing Unit, Health Product Compliance Directorate, Regulatory Operations and Enforcement Branch, Health Canada.

2. My duties as Acting Supervisor within the Drug Establishment Licensing Unit include the signing of Certificates of a Pharmaceutical Product conforming to the format recommended by the World Health Organization.

3. Reproduced immediately below is a copy of my employee identification card (Expiry 2027/04/10) issued by Health Canada:

SWORN BEFORE ME at the City of Ottawa, in the province of Ontario, this 22nd day of May, 2019.

Tina Marie Aubin, a Commissioner, etc., Province of Ontario, for the Government of Canada, Department of Health Expires July 05, 2020

AFFIDAVIT

Je soussignée, Harvin Komal, de la Ville d'Ottawa, dans la province de l'Ontario, fonctionnaire fédérale, DÉCLARE SOUS SERMENT CE QUI SUIT :

1. Je suis employée du gouvernement fédéral, à Santé Canada, depuis 31 septembre 2016. J'occupe actuellement le poste de superviseure par intérim de l'Unité des licences d'établissement de médicaments, Direction de la conformité des produits de santé, Direction générale des opérations réglementaires et de l'application de la loi, Santé Canada.

2. Dans le cadre de mes fonctions à titre de superviseure par intérim de l'Unité des licences d'établissement de médicaments, je suis appelée à signer des certificats de produit pharmaceutique conformes à la formule recommandée par l'Organisation mondiale de la Santé.

3. Ma carte d'identité d'employée (expiration le 2027/04/10) délivrée par Santé Canada est reproduite ci-dessous :

FAIT SOUS SERMENT DEVANT MOI dans la ville d'Ottawa, province de l'Ontario, le 22 mai 2019.

HARVIN KOMAL

EXPLANATORY NOTES

www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/modelcertificate/en/ (dated 2018)

This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.

02 Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.

03 The formula (complete composition) of the dosage form should be given on the certificate or be appended.

04 Details of quantitative composition are preferred but their provision is subject to the agreement of the product-licence holder.

05 When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.

06 Sections 2A and 2B are mutually exclusive.

07 Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.

08 Specify whether the person responsible for placing the product on the market:
a. manufactures the dosage form;
b. packages and or labels a dosage form manufactured by an independent company; or
c. is involved in none of the above.

09 This information can only be provided with the consent of the product-licence holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product licence. If the production site is changed, the licence has to be updated or it is no longer valid.

10 The Regulatory Operations and Enforcement Branch (ROEB) does not issue a document to the licence holder that summarizes the technical basis on which the product has been licensed. This information is contained in the detailed marketing application submitted by the licence holder and maintained by Health Product and Food branch (HPFB). In those instances where the licence holder has provided certified technical information for the product, it is appended to the certificate.

11 Product information (eg. product monographs, labelling, patient information sheet) is approved at the time of product registration and periodically thereafter when the need arises. Product information submitted by the applicant is not systematically reviewed prior to the issuance of the certificate. The applicant is required to provide written certification regarding the accuracy, completeness and concordance of the information with the currently approved version.

12. When the applicant is different from the licence holder, permission for issuing the certificate is required from the product licence holder. The applicant must provide evidence of the licence-holder's permission to Health Canada.

13 Please indicate the reason that the applicant has provided for not requesting registration.
a. the product has been developed exclusively for the treatment of conditions — particularly tropical diseases — not endemic in the country of export;
b. the product has been reformulated with a view to improving its stability under tropical conditions;
c. the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
d. the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
e. any other reason, please specify.

14 Not applicable means the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

15 The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No. 823, 1992, Annex 1. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).

16 This section is to be completed when the product-licence holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.