F.No. X-11026/186/2018-BD
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
O/o Licensing Authority cum Drugs Controller General India

Kotla Road, Near Bal Bhawan,
ITO, New Delhi-110002
Dated 01 APR 2019

ORDER

Subject: Cancellation of Registration Certificate No. SV-101 and Import License SV-101-112- regarding

WHEREAS, in terms of sub clause (i) of clause (b) of section 3 of the Drugs and Cosmetics, Act 1940, import, manufacture and sale of drugs is regulated with a view to ensure their safety, efficacy and quality.

AND WHEREAS, Rules 23 to 27 A of the Drugs and Cosmetics Rules, 1945 specify the provisions for grant of Registration Certificate and Import License for import of Drugs.

AND WHEREAS, M/s G.C. Chemie Pharmie Ltd. 5/C, Shree Laxmi Indl. Estate, New Link Road, Andheri (West), Mumbai 400053 India (herein after to referred as Authorized Indian Agent) was granted Registration Certificate No. SV-101 dated 08 Sep 2017 having validity upto 09/08/2020 for the drug Inactivated Influenza vaccine (Split Virion) I.P. suspension for injection(0.5ml & 0.25ml) in prefilled syringe manufactured by M/s Changchun Changsheng Life Sciences Ltd.,1615,Yueda Road, Changchun Jilin Province, China (herein after to referred as Registered manufacturer) under the Rule 27A of Drugs and Cosmetics Rules 1945.

AND WHEREAS, M/s G.C. Chemie Pharmie Ltd. 5/C, Shree Laxmi Indl. Estate, New Link Road, Andheri (West), Mumbai 400053 India was granted Import License No. SVH-101-112 dated 21 Sep 2017 having validity upto 09/08/2020 for the drug Inactivated Influenza vaccine (Split Virion) I.P. suspension for injection(0.5ml & 0.25ml) in prefilled syringe manufactured by M/s Changchun Changsheng Life Sciences Ltd., 1615,Yueda Road, Changchun Jilin Province, China under the Rule 27 of Drugs and Cosmetics Rules 1945.

AND WHEREAS, It has come to the notice of this office that during its inspection, China's State Drugs Administration have observed that the manufacturer, M/s Changchun Changsheng Life Sciences limited, 1615, Yueda road, Changchun, China was involved in falsification of production records for its Vero cell based Rabies Vaccine and has taken regulatory actions including order to stop production of the vaccine. Further this office has cancelled the registration certificate and Import license of Vero cell based Rabies vaccine issued to importer M/s. Synergy Diagnostics Pvt Ltd., 127-128, Laxmi Commecial Complex (Laxmi Market), Vartak Nagar,Thane (West)-400 606, India vide letter of even number dated 18 Oct 2018 due to violations of relevant requirements of good manufacturing practices by the said manufacturer.

AND WHEREAS, it has come to the notice of this office vide letter reference no. ADC/AC/IMP/DCGI/2018/007/1592 dated 04/12/2018 that it was communicated to CDL Kasauli by the importer M/s G.C. Chemie Pharmie Ltd., 5/C, Shree Laxmi Indl.

Estate,New Link Road, Andheri (West),Mumbai 400053 was not in position to supply the relevant documents related to the batch of Inactivated Influenza vaccine (Split Virion) I.P. suspension for injection(0.5ml & 0.25ml) in prefilled syringe as the licence of the principal manufacturer at China i.e. M/s Changchun Changsheng Life Sciences limited, 1615, Yueda road, Changchun, China has been suspended by China FDA.

AND WHEREAS, as per the Registration Certificate Condition No. 4 "*the manufacturer or his authorised agent in India shall inform the licensing authority forthwith in the event of any administrative action taken due to adverse reaction, viz. market withdrawal, regulatory restrictions, or cancellation of authorisation, and/or not of standard quality report of any drug pertaining to this Registration Certificate declared by the Regulatory Authority of the country of origin or by any Regulatory Authority of any other country, where the drug is marketed/sold or distributed*"

AND WHEREAS, Authorized agent in India was directed to stop immediately the import of the said vaccine & to submit the details of current status of manufacturing license and GMP certificate of registered manufacturer & recall the unsold stock of the drug Inactivated Influenza vaccine (Split Virion) I.P. suspension for injection(0.5ml & 0.25ml) in prefilled syringe from the market with intimation to this office.

AND THEREFORE a show cause notice was issued by the Licensing Authority under rule 21 (b) of Drugs and Cosmetics Act 1940 & Rules 1945 vide letter of even number dated 04.02.2019.

AND WHEREAS, The Authorized Indian Agent has informed vide letter Ref no. GCCPL/RA/Influenza/003 dated 08 Feb 2019 that there was no active unsold stock available in the market and the unsold expired stock was also retrieved completely from the market.

AND WHEREAS, The Authorized Indian Agent has informed vide letter Ref no. GCCPL/RA/Influenza/003 dated 08 Feb 2019 that they have communicated to CDL, Kasauli that manufacturing unit of registered manufacturer is currently been temporarily suspended by Chinese FDA for recall of Rabies.

AND WHEREAS, The Authorized Indian Agent has informed vide letter Ref no. GCCPL/RA/Influenza/004 dated 25th Feb 2019 that China FDA and State FDA of China has found the falsification of testing records of Human Rabies vaccine and has cancelled the manufacturing license of registered manufacturer, and GMP certificate of drug Inactivated Influenza vaccine (Split Virion) I.P. suspension for injection(0.5ml & 0.25ml) in prefilled syringe is expired on 23rd January 2019 and registered manufacturer has not provided the clarity on when they will be able to renew the GMP certificate. Further, Authorized Indian Agent also informed that plant operations are completely closed and manufacturer and employees are under the scrutiny of China FDA and State FDA of China and requesting this Office to provide 6 months to 9 months time period for obtaining the final opinion of registered manufacturer pertaining to registration of said drug based on the final regulatory action of China FDA & State FDA of China.

In view of the above, it is observed that Authorized agent in India or registered manufacturer have not intimated forthwith to this Directorate about the regulatory actions on M/s Changchun Changsheng Life sciences limited, 1615, Yueda road, Changchun, China for the drug Inactivated Influenza vaccine (Split Virion) I.P. suspension for injection (0.5ml & 0.25ml) in prefilled syringe taken by China's State

Drugs Administration. Further, manufacturing license of the registered manufacturing facility has been cancelled by China FDA and no clarity provided on renewal status of GMP certificate for said drug. Further, plant operations of registered manufacturing site are completely closed & registered manufacturer and their employees are under the scrutiny of China FDA and as per condition 2 of the Registration Certificate, *"no drug shall be registered unless it has a free sale approval in the country of origin, and /or in other major countries."*

AND THEREFORE, the undersigned being the licensing authority empowered under Rule 21 (b) of Drug and Cosmetic Rules, keeping in the view of contravention of the condition 2 & 4 of the registration Certificate in Form 41 under Drug and Cosmetic Rules 1945 hereby cancel the Registration Certificate No. SV-101 granted by this Directorate vide letter of F.No. 4/GCC-75/IVC/07-DC (Part-1) Renewal 2017 dated 08 Sep 2017 having validity up to 09/08/2020 for the drug Inactivated Influenza vaccine (Split Virion) I.P. suspension for injection (0.5ml & 0.25ml) in prefilled syringe under the provision of Rule 27A of Drugs and Cosmetics Rules with immediate effect.

Consequently, Import License No. SV-101-112 dated 21 Sep 2017 valid up to 09/08/2020 granted on aforesaid Registration Certificate also stands cancelled.

(Dr. S. Eswara Reddy)
Licensing Authority
Cum Drugs Controller General (India)

F.No. X-11026/186/2018-BD

o/c Sahi

To:

1. M/s G.C. Chemie Pharmie Ltd. 5/C, Shree Laxmi Indl. Estate, New Link Road, Andheri (West), Mumbai 400053 India to surrender original aforesaid Registration certificate and Import License.
2. M/s Changchun Changsheng Life Sciences Ltd., 1615, Yueda Road, Changchun, China

Copy to:

1. The Joint Secretary (R) MOH & FW, Nirman Bhavan, New Delhi
2. All Port Offices Of CDSCO
3. Order/File

(Dr.S. Eswara Reddy)
Licensing Authority
Cum Drugs Controller General (India)

o/c Sahi