

**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. SVH-9 and Import License SVH-9-131-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 Wockhardt limited, Plot no. C-2, Wockhardt Towers, Bandra Kurla complex, Bandra (East) Mumbai 400051, India (herein after to referred as Authorized Indian Agent) was granted Registration Certificate No. SVH-9 dated 05 Apr 2017 having validity upto 27/07/2020 for the drug Varicella vaccine (Live) I.P., Freeze dried along with sterile water for injection (as diluent) manufactured by M/s Changchun Changsheng Life Sciences Ltd., 1615, Yueda Road, Changchun, China (herein after to referred as Registered manufacturer) under the Rule 27A of Drugs and Cosmetics Rules 1945.

AND WHEREAS, M/s Wockhardt limited, Plot no. C-2, Wockhardt Towers, Bandra Kurla complex, Bandra (East) Mumbai 400051, India was granted Import License No. SVH-9-131 dated 09 Oct 2017 having validity upto 27/07/2020 for the drug Varicella vaccine (Live) I.P., Freeze dried along with sterile water for injection (as diluent) manufactured by M/s Changchun Changsheng Life Sciences Ltd., 1615, Yueda Road, Changchun, 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 Commercial Complex (Laxmi Market), Vartak Nagar, Thane (West)-400 606, India vide letter even number dated 18 Oct 2018 due to violations of relevant requirements of good manufacturing practices by the said manufacturer.

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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) IP 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 and recall the unsold stock of Varicella vaccine (Live) I.P., Freeze dried along with sterile water for injection (as diluent) 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 to this office vide letter Med-Aff/2019 -008 dated 13<sup>th</sup> Feb 2019 that they have initiated the process to recall the unsold stock in India; however no response has been received pertaining to quantities of said drug withdrawn from the market.

AND WHEREAS, The Authorized Indian Agent has informed to this office vide their letter Med-Aff/2019 -008 dated 13<sup>th</sup> Feb 2019 that due to the influence of Rabies vaccine incident, the manufacturing license is not valid, it has been revoked. For the GMP certificate of varicella vaccine, it is not revoked but renewal work is suspended and M/s Changchun Changsheng Life sciences limited is under control by the Chinese Government.

AND WHEREAS, The Authorized Indian Agent has informed to this office vide letter Med-Aff/2019 -012 dated 08<sup>th</sup> Mar 2019 that no batches of said drug have been imported after June 2018 by them & they have stopped the sale of said drug and submitted batch wise quantities of the said drug recalled from the Indian market.

In view of the above, it is observed that Authorized agent in India or 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 Varicella vaccine (Live) I.P., Freeze dried along with sterile water for injection (as diluent) taken by China's State Drugs Administration. Further, the manufacturing license for the registered manufacturer has been revoked

by China's State Drugs Administration and renewal of GMP certificate of said drug is suspended & registered manufacturer is under control by the Chinese Government 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. SVH-9 granted by this Directorate vide letter of F.No. 6-8/SV-7/2014-Bio. Div.(Vaccine Sera) Renewal 2016 dated 05 April 2017 having validity up to 27/07/2020 for the drug Varicella vaccine (Live) I.P., Freeze dried along with sterile water for injection (as diluent) under the provision of Rule 27A of Drugs and Cosmetics Rules with immediate effect.

Consequently, Import License No. SVH-9-131 dated 09 Oct 2017 valid up to 27/07/2020 granted on aforesaid Registration Certificate also stands Cancelled.



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

*o/c Sanku* *HN* *M*


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To:

1. M/s Wockhardt limited, Plot no. C-2, Wockhardt Towers, Bandra Kurla complex, Bandra (East) Mumbai 400051, 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 Sanku* *o/c*