

**7-5/2019/Misc/101**  
**Government of India**  
**Directorate General of Health Services**  
**Central Drugs Standard Control Organization**  
(International Cell)

9/9/2019

**Circular**

European Union has mandated through directives No. 2001/83/EC dated 08<sup>th</sup> June, 2011 that every consignment of Active Pharmaceutical Ingredient (API) from Non-EU/non-listed countries must be supported by a "Written Confirmation" Certificate (WCC) issued by the Competent Authority of that Country, stating that the consignment conforms to the standards of Good Manufacturing Practices (GMP) as laid down in the EU guidelines or equivalent thereof. This is effective from 2<sup>nd</sup> July 2013.

This directorate issues Written Confirmation Certificate on the basis of recommendation received from the concerned CDSCO zonal office and the standards shall be applicable for issue of "Written Confirmation Certificate" for active substances exported to the EU for medicinal products for Human use, in accordance with Article 46 (2)(b) of Directives No. 2001/83/EC and the documents required should be as per: "Good Manufacturing Practices guide for Active Pharmaceutical Ingredients ICH harmonized Tripartite Guideline stated as per ICH Q7".

The WCC issued by this directorate is valid for three years from the date of issue and as per the SOP "EP-INS-001" published by this office, if grant of "Written Confirmation" is recommended before the expiry of valid "Written Confirmation" the renewed "Written Confirmation" shall be issued from the date of expiry of previous "Written Confirmation".

However, it has come to notice of this office that the recommendations for the renewal of WCC are being received after the expiry of the previous WCC and this has caused non-continuity in the validity of WCC, though the firms are maintaining the compliance to the standards referenced in paragraph 2 stated above.

Hence, in order to maintain the continuity in the validity of WCC, it has been decided that the validity for the renewed WCC shall be deemed to be valid from the date of the expiry of the previous WCC.



**(Dr. V. G. Somani)**  
**Drugs Controller General (India)**

To,

1. All Stake Holders (CDSCO website)
2. All Zonal and Sub-Zonal Offices, CDSCO

Copy to:

1. PS, JSER, MOHFW, NB, New Delhi
2. US (Drugs), MOHFW, NB, New Delhi