

File No. 4-01/2015-DC (Misc. 63)
Directorate General of Health Services
Office of Drugs Controller General (India)
FDC Division

FDA Bhawan, Kotla Road
New Delhi-110002

Dated: 01 JAN 2016

To,

All State Licensing Authorities,

Subject: Manufacturing and Marketing of Unapproved Drug, Vitamin K2-7-
Regarding.

Sir,

Please refer to this office letter no. 12-50/12-DC dated: 04.06.2015 regarding manufacturing and marketing of unapproved drug, Vitamin K2-7 whereby it was informed that Vitamin K2-7 is not approved for marketing in the country. In this regard, it may be informed that based on the recommendations of Expert Committee, this office has approved various formulations containing Vitamin K2-7. Therefore, Vitamin K2-7 bulk drug (API) can be considered as deemed to be approved for the purpose and the aforesaid letter dated: 04.06.2015 issued by this office may be dealt accordingly.

This is for information and necessary action.

Yours faithfully,



(Dr. G. N. Singh)
Drugs Controller General (India)

Copy to:

All zonal, Sub Zonal offices of CDSCO