F. No. DCG (I)/MISC/2017 (II)
Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare
Office of DCG(I)

FDA Bhavan, Kotla Road,
New Delhi -110002

20 MAR 2017

Notice

Subject: Regulatory approvals relating to combination products for HIV (ANTIRETROVIRAL), Hepatitis B & C, which are recommended for concomitant use by WHO-Regarding.

The issue of regulatory approval relating to combination products for HIV (ANTIRETROVIRAL), Hepatitis B & C was discussed in 33rd meeting of the Apex Committee held on 21.02.2017 under the chairmanship of Secretary, Ministry of Health & Family Welfare. The committee agreed with the following course of action to be followed with a view to fast track regulatory approval relating to combination products for HIV (ARV) and Hepatitis B & Hepatitis C in the public interest:

- The manufacturer shall apply for BE NOC and New Drug Application simultaneously to ensure early availability of these important combination products for Indian population.
- Many of these combination products, recommended in WHO guidelines for concomitant use, may not have been approved internationally in combination but may have been approved individually. However, given the risk-benefit and recommendations by WHO the requirement of generated data may be waived based on the fact that the product has been recommended for concomitant use by WHO.
- Application for BE NOC for export of such products shall be initially made for pilot studies on batches manufactured at pilot scale and followed by pivotal studies on batches manufactured at pivotal scale. Manufacturer shall follow the international regulatory standards for manufacture of pilot and pivotal scale batches mandating its equivalence.
- The manufacturer will ensure adequate clinical and quality oversight on the conduct of these bioequivalence studies.
- The New Drug Application may be accepted with abbreviated data at pre-screening stage with firm commitment/Undertaking regarding submission of complete data prior to grant of approval. The scrutiny shall be applicable to New Drugs application only.
- Clinical Trial waiver for such products recommended by WHO for concomitant use may be given, as being falling under the category of extreme urgency and under the provisions of the Drugs and Cosmetics Rules .
- This regulatory policy applies to products recommended by WHO guidelines and Expression of Interest (Eol) for rational combination of products used for HIV and Hepatitis B & C. For approval of drugs for Hepatitis B & C in the Indian market, the combination products should be relevant to Indian population sub types.

This is for information and necessary action.

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

To
1. All officers of CDSCO (HQ)/Zonal/Subzonal/Port Offices of CDSCO.
2. All Stakeholders through website of CDSCO

Copy to:
1. PPS to Secretary, Ministry of Health and Family Welfare.
2. PPS to DGHS, Ministry of Health and Family Welfare.
3. PPS to Addl. Secretary (F&D), Ministry of Health and Family Welfare.
4. PS to JS(Regulation), Ministry of Health and Family Welfare.