INDIAN DRUG MANUFACTURERS' ASSOCIATION

102-B, POONAM CHAMBERS, 'A-WING', DR. A.B. ROAD, WORLI, MUMBAI-400 018, INDIA

Phone : 91- 22 - 24974308
91- 22 - 24944624
Fax : 91- 22 - 24950723

E-mail : idma@vsnl.com
idma1@idmaindia.com
Website : www.idma-assn.org

8 October 2013 **PARTNERS IN GLOBAL HEALTHCARE**

Dr. V.G Somani,
Joint Drugs Controller (I),
C D S C O, West Zone,
4th Floor, Zonal FDA Bhawan,
GMSD Compound, Bellasis Road,
Mumbai Central, Mumbai – 400 008.

Sub: Permission for import of Dual Purpose APIs with Retest dates

Dear Dr Somani,

We thank you for your initiatives and continued support to the Pharma industry in discussing and resolving issues.

As you will be aware, the issues related to the import of Dual Purpose APIs have been vexing all of us for some time. Guidelines were drafted, list of dual purpose APIs prepared along with the stakeholders in 2011 and some issues resolved. A major issue that has not been resolved is the insistence by the Port authorities that shelf life of even a dual purpose API should be more than 60% and that the expiry date should be provided on the label of the container.

We agree that Rule 31 under Drugs and Cosmetics Rules, 1945 lays down that *'the licensing authority shall not allow the import of any drug having less than sixty per cent residual shelf-life period as on the date of import'*. You will appreciate that this Rule is laid down to ensure that the formulation to be manufactured from the bulk drug has sufficient shelf-life to be beneficial to the consumer.

However, since dual purpose APIs are not intended for medicinal use of

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drugs and are used to manufacture other APIs, the proviso for providing 'expiry date' may be replaced with 're-test date' for this category of APIs, as allowed by all major regulatory authorities..

Rule 31 as above also has a proviso to allow import of drugs with lesser shelf-life period in exceptional cases. We suggest that such dual purpose APIs, even with lesser shelf-life period may be allowed to be imported with re-test date, as the importer intends only to manufacture another API and is not intending to make any formulation for medicinal use. Insisting on a label/ COA with expiry date instead of retest date may leave the importers with no option but to import such dual purpose drugs as intermediates to manufacture other APIs. This will allow the importers to import such chemicals without having to file Form 10, effectively taking away the regulatory control on import of such APIs.

Hence, we request you to consider our plea and allow import of dual purpose APIs with re-test date on the label/COA, even those with lesser shelf-life period, as they are not intended for medicinal use.
We look forward to your indulgence in resolving this practical issue at the earliest.

Thanking you,

M U Doshi
President

CC: Dr G N Singh, DCG (I), Delhi.