STATEMENT REGARDING
THE INDIAN RECOMMENDATION ON THE USE OF GELATINE AS INGREDIENT FOR CAPSULE MANUFACTURING

GME, the Gelatine Manufacturers of Europe, represents the European gelatine manufacturers.

GME monitored closely the evaluation done by a governmental Indian scientific Expert Committee concerning Gelatine and HPMC as ingredients for the manufacturing of pharmaceutical capsule shells.

The scientific Expert Committee submitted its evaluation report to the Indian Ministry of Health and Family Welfare on November 23rd, 2017.

In the executive summary, it is stated that *"compulsory and mandatory replacement of gelatin capsules with cellulose based capsules is not recommended due to the following reasons:*

a. *The contents of the capsules may also contain drugs which are not of vegetarian origin*
b. *The manufacturers will be again required to conduct stability, as well as, bioequivalence studies for complying with regulatory requirements. Further, the use of HPMC capsules may require change in dosage due to possibility of differences in dissolution pattern and onset of action, which is not desirable.*
c. *The HPMC capsules are significantly costlier than gelatin capsules.*
d. *The safety of gelatin capsules is already established, and these capsules are used worldwide for encapsulating the drug components.*
e. *As per the technology available worldwide, soft gelatin capsules cannot be manufactured by using cellulose based material.*
f. *Drugs belonging to the narrow therapeutic index would require more vigorous bridging studies to ensure safety and efficacy.*
g. *There is a problem of machinability and availability of technology in the country for manufacturing of cellulose based capsules in such a huge volume.*
h. *It will affect the export markets as enumerated by the representative of the Ministry of Commerce as it will require re-registration of their cellulose capsule based products in exporting countries, which might take considerable time of few years.*
i. *There will be a huge dependency on other countries for importing the raw material (HPMC) for manufacturing of cellulose based capsules as presently, all raw material is being imported mainly from China."*

To read detailed report: **Click-here**

GME welcomes the position made confirming that gelatine is the ingredient of choice for capsules.

GME believes that this recommendation reflects perfectly the need for globally available medication in a safe and affordable format for people all around the world and not only in India. Gelatine is a natural ingredient that has proven its safety and benefits for decades and has with continuous innovations helped to improve capsule manufacturing and medication release formats.

Validation period: until 31 December 2018.

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