AmCham-AdvaMed Comments on GSR 449 (E)

General Comments

1. It is requested to clarify the applicability of this Gazette notification on Medical Devices.
2. If a company is already following UDI code which includes GTIN code, it is requested to clarify whether it will be acceptable and if not what is required to be done.
3. Cost of uploading data / meeting Barcode specifications to be taken into account.
4. Database update is manufacturer's responsibility so in case of further supply channels (sale to distributor and Hospitals), the traceability up to end user and database updates will not be a feasible task.
5. Details / Specification to be uploaded on central portal are not clear.
6. The requirements in India for primary label are so extensive that there is no scope for further details.
7. Manufacturer is responsible for reporting supply chain partners which is not a feasible model in case of importers / foreign manufacturers.

S. No	Clause reference	Comments/ Remarks
1	1 (2)- They shall come into force after the expiry of 180 days from the date of the publication of the final rules in the Gazette of India.	**First and foremost, we recommend that medical devices should be exempted from this notification.** For track and trace, we recommend having a phased implementation in alignment to USFDA UDI (Unique Device Identifier), which is to be implemented in phases as per the risk based classification of the medical device. For this to happen it is imperative to have device classification at first place which can come only through specific medical device regulations so we urge for Amendment Bill to pass through first and then apply the track and trace mechanisms for medical devices. After the medical device specific regulations are set right, including risk based classification of all medical devices then a phased implementation over a period in alignment to USFDA UDI (Unique Device Identifier) and IMDRF's UDI Guidance Unique Device Identification (UDI) of Medical Devices can be assumed. Even after years of effort the U.S. does not plan to implement UDI till FY2018 and a five year phased implementation was provided. For India and in interest of SSU / MSU, it should be a voluntary exercise.
2	2) In the Drugs and Cosmetics Rules, 1945, in rule 96, in sub-rule (1), after clause (xii)	Rule 96 pertains to the Manner of Labeling of Drugs other than Homeopathic medicines. **We believe that Rule 96 of Drugs and**

	the following clause shall be inserted, namely	**Cosmetics Rules is no longer applicable to Notified Medical Devices.** As per Gazette Notification GSR 690 (E), dated 24 September 2014, Labelling of Medical Devices is as per Rule 109-A, as notified in Official Gazette. Thus, It is requested to clarify that medical devices are exempt from this notification.
3	2 (xiii) (a)- at primary level packaging of two dimensional barcode encoding unique and universal global product identification code in the 14 digits Global Trade Item Number format along with batch number, expiry date and a unique serial number of the primary pack	All medical devices do not have batch number unlike pharmaceuticals where it is more relevant. Also, Barcode at Primary pack is not feasible in case of medical devices. We suggest that there should be voluntary choice between one/two dimensional barcode encoding. The IMDRF standard and FDA regulation for UDI is technology neutral allowing for the manufacturer to determine the best type of barcode to meet patient and customer needs. There is a risk to manufacturers if individual countries begin to specify the barcoding requirements as these could then begin to differ from one country to the next defeating harmonization. US practice: The primary level (sterile barrier) does not always have 2D barcode. As per USFDA requirement, there are not many products that have a unique serial number on them at any package level. Those that do have serial numbers are likely to not have this information on the sterile barrier, but rather on the outer package (secondary level). Not all products have an expiry date (e.g. capital equipment) they have a date of manufacture. Batch does not apply to all products (those with serial numbers). The data required in 14 digits Global Trade Item Number must be mentioned. For example – Manufacturer name/ address/email, brand name of the device, version or model no. of the device.
4	2 (B)-The manufacturer of drug formulation shall maintain the data in the parent-child relationship for all three level of packaging and their movement in its supply chain	This requirement is extremely difficult to comply with for most high-risk medical devices. Parent – Child relationship as described in the gazette notification does not apply to medical devices such as orthopaedic implants where each implant is a single unit pack and the tertiary packaging is a mix of various types of implants and this mix is different for every consignment received in India. It will be difficult for the manufacture to be responsible for this information if using a third party distributor. For example, orthopaedic Implants are not imported in individual Secondary packs. Each implant is a unit pack and is sold as such to the hospitals. Unlike Pharmaceuticals, there are no bulk packs. Each secondary packing (carton) contains a mix of several implants and this mix varies for each consignment. It is impossible to affix

		barcodes as specified for secondary level to packaging of orthopaedic implants. Further, there is no bulk sale of a single type of orthopaedic implant to a hospital. A mix of implants of several different sizes is supplied. Hence, It is requested to clarify applicability to importers. If yes, will it be feasible for foreign manufacturer to maintain data? **Recommendation**: This should be consistent with GS1 to allow for different types. This needs to be more flexible to account for various product types.
5	2 (C) - The data referred to in sub-clause (B) shall be uploaded on the central portal of the Central Government by the manufacturer or its designated agency before release of the drugs for sale or distribution.	Sale and distribution model for medical devices is not similar to Pharmaceuticals. The devices are sent to hospital at the time of Operation Theatre (OT) in varied sizes. At the time of OT the Medical Practitioner decides the Size. In such case it will not be feasible to upload batch/serial number data prior to release. Ultimately it may result in Patient suffering in all these elongated requirements. The intent appears to have Batch/Serial Number data uploaded prior to the sale of individual devices – OR – would this be similar to the data that is uploaded for UDI in the United States? If it is intended to include the Batch/Serial Number data – we currently have no mechanism to do this. Would require excessive burden on the manufacturers.
6	2 (D)- Provided that the provision of this sub-rule shall not be applicable to such drug formulation which is manufactured for export purpose and where the Government of the importing country has mandated a specific requirement and the exporter intends to avail the option of printing the bar codes in the format specified by the importing country with the permission of licensing authority appointed under rule 21:	In the same manner, the importer should be allowed to have barcode as specified in Country of origin.