July 17, 2015

Mr. K L Sharma
Joint Secretary
Ministry of Health & Family Welfare
Government of India
Nirman Bhawan, New Delhi

Dear Mr. Sharma,

Subject: Industry feedback on Draft Gazette Notification 449(E)

Kindly refer to the draft gazette notification 449(E) uploaded on the CDCSO website which mandates barcoding on Primary, Secondary and Tertiary packaging of drug formulations. On detailed analysis of the draft gazette notification, we would like to bring to your kind notice that the requirements mentioned in the draft notification are NOT aligned with the standardized global requirement which is being implemented by most of the companies as part of UDI implementation and we recommend that it should NOT apply to medical devices.

UDI accomplishes many (if not all) the goals of the current MoHFW draft rule objectives but leverages the extensive work of the international community in developing a harmonized identification system. We urge that India harmonize with international standards and practices and not serve as duplicative barriers to local access.

In particular, the following variations are observed in the draft notification from the global requirements:

i. Globally UDI implementation is technology neutral embracing the standards of the internationally harmonized issuing agent. To meet patient and customer needs manufacturers are adopting one or two dimensional barcoding as appropriate for the product whereas in the present proposed requirement barcoding is prescriptive two dimensional with 14-digit for primary pack and uni/two dimensional with 14-digit for secondary pack and unidimensional for tertiary packaging. The proposed requirement requires serialization for each and every primary, secondary and tertiary package with manufacturer having to load the details of parent child relationship of primary and secondary packing as well as secondary and tertiary packing. This serialization requirement is not applicable to medical devices globally in any other country.

Further, while we understand that the medical devices traceability is important to Ministry of Health and Family Welfare, it is important that critical requirements are placed right in first place. Globally, UDI

has become the standard for device identification, is already requirement in the US, and is rapidly being adopted by other jurisdictions globally.

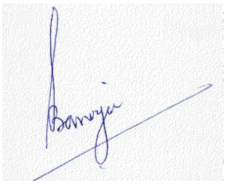
We would like emphasize the significant burden compliance with the proposed labeling/barcoding requirement will place on the medical device industry. In the United States a five year phased implementation period was provided in recognition of the significant logistical requirements associated with the process. Considerable cost is involved which is borne in part by regulatory authority, barcode issuing agency and the manufacturer. Aiming towards a harmonized track and trace mechanism, adopting USFDA UDI/ IMDRF UDI can significantly reduce the associated costs.

The draft notification without considering the above outlined facts, if implemented, would have a significant adverse impact on the medical device industry in India, potentially resulting in unavailability of product to patients in India. In view of the above, it is requested that medical devices should be kept out of the ambit of this notification and the industry, if forced to implement this policy, could lead to disruption of supply of life saving technologies to the patients in India. Further, we had extensively reviewed the draft notification and after numerous rounds of detailed discussions with our members, please find enclosed our initial comments on the draft notification for your kind consideration.

Finally, we would like to bring to your attention the fact that AdvaMed plans to develop a White Paper outlining (1) the positive elements of the FDA's UDI rule; and (2) implementation issues our industry has seen to date. The purpose of this effort is to provide a resource to other economies looking to align their UDI efforts with those of the US. We would be happy to provide a copy of this White Paper upon its completion later this year.

We would welcome the opportunity to meet and discuss our comments in a meeting on a date and time of your convenience on this most important topic.

Sincerely,



Sanjay Banerjee
Chair – India Working Group
AdvaMed

Prabal Chakraborty
Chair-Medical Devices Committee
AmCham

Enclosure: AmCham-AdvaMed comments on GSR 449(E)