



April 1, 2010

Shri V. Venkatachalam  
Addl. Secretary (Health)  
Ministry of Health and Family Welfare  
Nirman Bhawan  
New Delhi 110108

Dear Secretary Venkatachalam:

We write to you expressing urgent concern regarding the process, timing and application of a requirement by the Ministry of Health and Family Welfare to require bar codes on all medical technology procured by the Government of India after April 1, 2010. It is also our understanding that after April 1, 2010, only one standard, GS1, will be allowed. There are therefore two separate but related issues, the timing of the introduction of the requirement (April 1, 2010 with no transition period) and the mandate of use of a specific barcode standard (GS1).

We urge that the Government of India allow a reasonable transition period (e.g. three years) for companies to comply with the requirements, and also that GS1 as well as HIBCC and equivalent standards be permitted.

For many companies, the current timeline for implementation of GS1 standard bar coding will be impossible to meet. India's notice for a GS1 bar coding requirement was issued in late October 2009, with no notice and comment period provided. The industry was thus provided with no formal opportunity for its concerns to be heard. The "manual" for this requirement, an essential step for implementation of the policy, was only just issued on March 11, 2010. We are concerned that this aggressive implementation schedule will leave many manufacturers in a situation where they are not able to meet the labeling requirements, thus disrupting severely healthcare facilities' supply chains, and causing difficulties in patients obtaining access to our members' innovative and lifesaving medical technologies. We would like to bring to your attention to the fact that GHTF is currently developing Unique Device Identification (UDI) System guidelines in which both GS1 and HIBCC are identified as potential systems. Currently the U.S. and European authorities allow flexibility with regard to the use of bar code standards. On the other hand, acceptance of only one standard will add significantly to costs while distorting the competitive dynamics of the Indian market.

Finally, we would like to highlight the opportunity for India as a member of the Asian Harmonization Working Party (AHWP) to play a positive role in helping to define a globally harmonized approach to UDI in cooperation with all members of the GHTF.



We stand ready to work with you and assist you in whatever way we can to implement our proposed changes. Thank you very much for your time and attention to this vitally important matter.

Sincerely,

Anne-Marie Wolters  
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