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Harmonization of Regulations in India – Benefits and Challenges

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Healthcare Scenario In India

- India spends 5% of its GDP on Healthcare. Indian government spending is only 1%.
- 80% of healthcare spend takes place in the private sector which is amongst the highest private/ government ratios in the world.
- Paradigm Shift

- The 2007 – 2008 GOI's expenditure on healthcare increased to almost 25% from previous year's base.
- India's robust CAGR (Compounded Annual Growth Rate) of16% is expected to boost the healthcare market to US $ 50.2 billion by 2011 and US $ 78.6 by 2016.

Medical Devices – Promising Growth In India

- India Market expected to touch US$ 1.7 billion by 2010
- The demand for hi-tech medical devices in India growing between 12 - 15% annually
- Hi-tech product constitutes close to 80% of overall market
- Higher involvement of foreign players in hi-tech devices, which account for US$ 770 million

Current Indian Medical Device Regulations

- 10 category of medical devices notified as drugs in October 2005.
- Medical devices have been a misfit into the Drugs ambit of regulations.
- Regulating Medical Devices under the ambit of drugs is a major challenge in terms of:
  - Standards of Manufacturing facility
  - Inspection of Manufacturing facility
  - Testing of medical devices
  - Adverse Event Reporting

- Hitherto all Regulations have been retrospective rather than prospective.

Gathering Thoughts

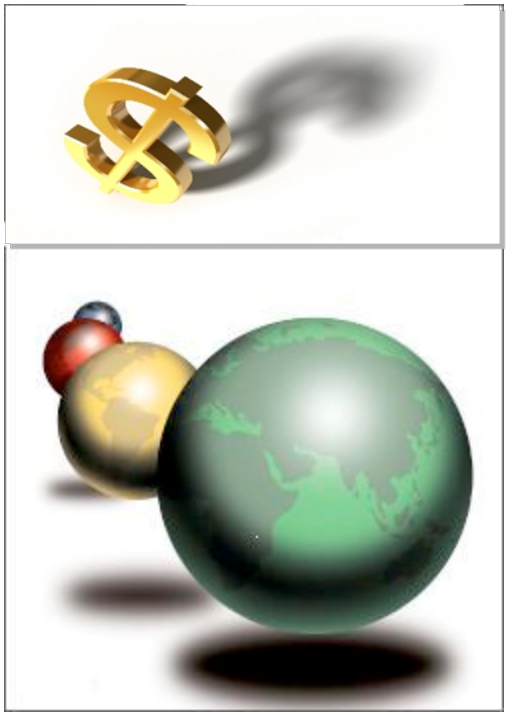
- Challenge for Indian Regulatory System – Framing comprehensive Medical Device Regulations
- Entry to the Harmonization Mosaic.
- Intent not to reinvent the wheel
- Taking Lessons from Pre Existing Regulations practiced worldwide
- The hallmark regulatory models:
  - USFDA: Robust Regulatory Mechanism since 1976
  - MDD: since 1993
  - TGA: since 2002

Need For Harmonization

- International boundaries are no longer obstacles - Global Village.
- Global community is enmeshed in complex regulations.
- Convergence of regulatory practices for uniformity of International regulatory environment.
- Lead to novel medical devices and enhance the assurance of device safety.

Why India Should Adopt Harmonization

- Challenges of complying with disparate international regulatory systems and requirements regardless of the fact where the manufacturing hub is located.
- Expending resources to deploy local infrastructure to access international markets.
- Identify and comply with different sets of regulations for each targeted country.
- Transparent and unified international regulatory systems translates in to reduce time to market – seamless access .



Harmonization Benefits and Obstacles

- Benefits include:
  - ➢ Potential cost and time savings when device manufactures expand to international markets.
  - ➢ A higher level of safety assurance for consumers, regardless of where products are manufactured.
  - ➢ Broader and quicker consumers access to innovative technologies developed around the world.

- Obstacles include:

  Harmonization can significantly be impeded by
  - ➢ Long lead times to draft and promulgate guidance documents.
  - ➢ The difficulty for stakeholders to reach consensus on harmonization efforts and agreements.
  - ➢ Delays inherent in transposition of agreements into laws and regulations.
  - ➢ Cultural differences can also present barriers to adoption of harmonized practices.

CDSCO's Approach towards Harmonization

- Facilitate the availability of safe and effective products
- CDSCO input in to adopting international regulations setting activities would be open to public scrutiny and would also provide the opportunity for the consideration of views of all concerned stake holders.
- CDSCO is open to accept, where legally permissible, the equivalent standards, compliance activities and enforcement programs of other countries, provided it is satisfied that such standards, activities and programs meet its level of public health protection in India.
- Scientific and regulatory information and knowledge would be exchanged with foreign government officials, to the extent possible within legal constraints, to expedite the approval of products.
- Minimize or eliminate inconsistent standards internationally ---- Not to reinvent the wheel

Recent CDSCO's Harmonization Efforts

- CDSCO'S International Cooperation Agreements:
  - Indo-EU Cooperation

    The EU has invited India to form a technical group under the Joint Working Group on Medical Devices. This will help the regulators to understand the EU regulatory system.
  - India-US High technology cooperation group (HTCG)

    6th Summit of India-US HTCG was held in Feb 28th and 29th 2008. Issues pertaining to Global Harmonization of medical device regulations and medical device manufacturing and FDI were discussed.

- With the cooperation of WHO, trainings of regulators and manufacturers will be carried out in the country.
- US FDA has also taken initiatives to train Indian regulators on the regulatory system being followed in the USA.
- CDSCO synergizing with the trade forums like FICCI and CII(Confederation of Indian Industries) has also motivated the industry to bring about awareness amongst different stakeholders both from indigenous manufacturers and regulators .

Stepping Stones – Core Group Formation

- Medical Device Core Group was formed in Feb 2008 between Industry and regulators.

- Objectives of medical device core group:
  - Framing medical device regulations
  - Leading towards harmonization
  - Adopting GHTF guidelines
  - Removing trade barriers for indigenous exporters

- To frame the Medical Device Regulatory guidelines and amend Schedule MIII of Drugs and Cosmetics Act.

GHTF Guidelines Proposed To Be Adopted By India

- The proposed Guidance document would be in coherence with GHTF Guidelines with regards to the following:
  - Definition
  - Classification
  - Conformity assessment procedures and Notified Bodies
  - Standards to be used and applied
  - Clinical Investigations
  - Post Market Surveillance

Definition

- Drugs & Cosmetics Act, 1940 has a holistic definition to “Drugs” mentioning Medical Devices under section 7 (iv).

- It is impossible to cover the different array of medical devices to be covered under the ambit of “Drugs” Definition as stated in Drugs & Cosmetics Act, 1940.

- Consequently it is proposed to define medical devices in accordance with the GHTF definition.

- Proposed Draft of Schedule MIII elaborates the definition in alignment to the GHTF definition.

Proposed Risk Based Classification

- Medical Devices are proposed to be classified as per their risk and use in proposed Schedule M III:

CLASS	RISK LEVEL
A	Low Risk
B	Low-moderate Risk
C	Moderate-high Risk
D	High Risk

Proposed Regulation Degree Per Risk Based Classification

- Class A Medical Device
  - Conformity Assessment carried out by the manufacturer
  - Manufacturing license not required from Central Licensing Authority (CLA)
  - However the manufacturer needs to be registered with the CLA.

- Class B Medical Devices
  - The Quality management system (QMS) to be certified by a Notified Body
  - Based on the assessment by Notified body CLA shall issue NOC (No Objection Certificate) to manufacturer for such device (s) to be marketed in the country.

Proposed Regulation Degree Per Risk Based Classification

- **Class C Medical Device**
  - Certification by a notified body is required with regard to the design and manufacture of the device.
  - The manufacturers are required to apply for a license with supportive documents for safety and effectiveness of these devises
  - Based on the certification of notified body and supportive documents manufacturing license shall be issued by the CLA

- **Class D Medical Device**
  - Certification by a notified body is required for design and manufacture of the devices
  - The manufacturers are required to apply for the license with the supportive documents in respect of safety and effectiveness of these devises to CLA
  - Inspection - by CLA and State Licensing Authority
  - Based on Recommendations of joint inspection's report and the certification by the Notified body, the manufacturing license will be issued by CLA.

Conformity Assessment Procedures

- Conformity Assessment Procedures as per SG1-N40:2006 of GHTF Guidelines have been recommended:

  – Quality Management System- Declaration of conformity would be issued on satisfactory assessment of QMS procedures.

  – Class based conformity assessment procedures have been laid down with varying Design and Development verification procedures.

  – Class A exempted from Design and development procedures.

Notified Bodies

- Designer, manufacturer, supplier, installer or user of the device shall not be a member of notified body.
- Notified body to share all required information with the CLA.
- Guaranteed Impartiality & Professional Secrecy of Notified Bodies will be maintained.
- Notified body must take out civil liability insurance.
- Manufacturer shall notify the CLA of the Accredited Notified Bodies which they have designated for carrying out conformity assessment.

Standards

- Bureau of Indian Standards (BIS) has already issued IS 15579:2005 in 2005 which is in alignment with ISO 13485:2003.

- Although the Quality Element Standards are in place since 2005 as proposed by BIS; they are not yet mandated in regulations.

- ISO and IEC standards are proposed to be followed in the proposed Sch MIII where in there are not specific standards yet defined.

- It is also proposed to follow established Pharmacopeial Standards wherever applicable.

Labeling Standards

- Stringent Guidelines are defined under Drugs & Cosmetics Rules 1945, Rule 97-101 for Drugs Labeling which cannot be applied for the Medical Devices.

- In lieu of undoubted non applicability of these set of rules clarification was issued and it was mandated that GHTF Labeling requirements are acceptable as mentioned under SG1-N43: 2005 .

- However following need still to be incorporated

  Date of Manufacturing

  Date of Expiry
  Name of the Product
  Name of the manufacturer
  India Toll Free Number
  Date of Import of Medical Device (Applicable to Imported devices)

Clinical Investigation

CURRENT SCENARIO	PROPOSED SCENARIO
• Presently Schedule Y Guidelines which are in alignment with the ICH/GCP Guidelines are followed for Medical Devices . • CLA Approval for conducting Clinical trial is mandated	• Intensive comparison carried out by the core group between ISO 14155, Schedule Y Regulations, Directive 2001/20/EC, and Directive 2005/28/EC • Consequently ISO 14155 as proposed by GHTF Guidelines are projected to be followed.

Post-Marketing Surveillance
Adverse Event (Vigilance) Reporting

CURRENT SCENARIO	PROPOSED SCENARIO
– No Device specific Adverse Event Reporting Forms is in place. – Medical device Adverse Events are reported as per the time Sch Y requirements specified in the Drugs and Cosmetics Act.	– GHTF Guidelines are proposed to be followed.

Road Ahead

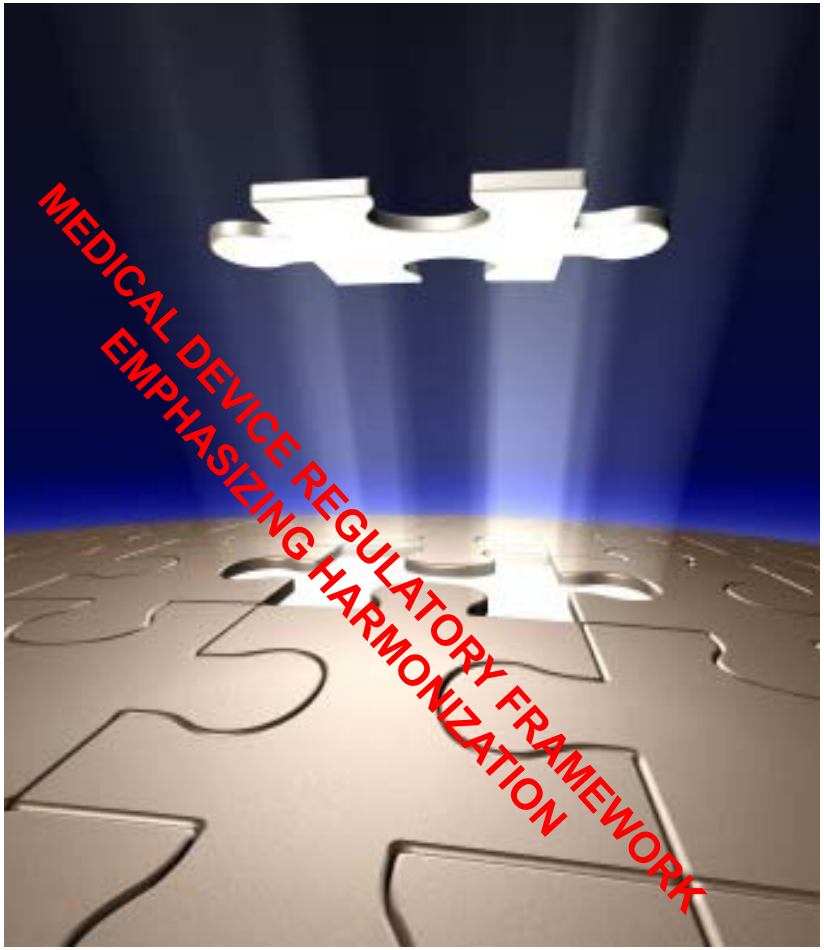
December 2008: Draft MIII to be placed before the Drugs Consultative Committee (DCC)

January 2009: To be placed in the Drug Technical Advisory Board

March 2009: Publication of Draft Notification for Comments

June 2009: Final Notification

FUTURE OF MEDICAL DEVICES IN INDIA



Adoption of GHTF guidance principles as best applicable in the Indian scenario

Classification of device recommended to be 4 level and risk based (similar to GHTF)

ISO 13485 already adopted by Bureau of Indian Standards, a standard body for quality systems; however not yet mandatory

PROVIDING BETTER BUSINESS OPPORTUNITIES


Three Rules of Work
Out of CLUTTER find SIMPLICITY
From DISCORD find HARMONY
In the middle of DIFFICULTIES lies OPPORTUNITY
Thank You