

U.S. Department of Commerce Medical Devices and Pharmaceuticals Roundtable (9/30/2003)

The International Trade Administration and Technology Administration hosted the Medical Devices and Pharmaceuticals Roundtable on September 30, 2003. Benjamin Wu, Deputy Under Secretary for Technology Administration, opened the Roundtable by describing Secretary Evans's Eight-Point Standards Initiative. Mr. Wu stressed the importance of bringing all DOC and other Federal Government resources together to focus on standards. He added that the health care industry is unique because of global regulations, which make standards even more important.

Following Mr. Wu's comments, NIST Director Arden Bement, Jr. stated that he was pleased that NIST and ITA are working together on the DOC Standards Initiative. He noted that NIST is actively involved in MRAs with the European Union and that NIST is working with the National Institutes of Health and the Centers for Disease Control on measurement and metrology activities. Mr. Bement added that NIST is particularly interested in nanotechnology and gene research, and that health care and biotech issues have emerged as NIST priorities.

Linda Conlin, Assistant Secretary for Trade Development, continued by outlining Trade Development's efforts on standards issues. Assistant Secretary Conlin also introduced ITA's new Standards Coordinator Heidi Hijikata.

Following introductory remarks, the roundtable moderator, Jeffrey Gren, called on each of the industry representatives for comments. Below is a summary of their remarks.

A. Medical Device Industry Associations

AdvaMed (The Advanced Medical Technology Association) - Presenter - Carolyn D. Jones; Associate Vice President, Technology and Regulatory Affairs

AdvaMed's stated mission is to advocate for a legal, regulatory and economic climate that enhances global health care by assuring patient access to the benefits of medical technology. AdvaMed represents more than 1,100 innovators and manufacturers of medical devices, diagnostic products and medical information systems. The association states that its members manufacture 90 percent of the \$75 billion of health care technology purchased annually in the United States and more than 50 percent of the \$175 billion purchased around the world.

· AdvaMed's top priority issues:

- o International Electrotechnical Committee (IEC) standards.
- o Safety standards.
- o Quality systems standards.
- o Biological evaluation standards.
- o In Vitro Diagnostic (IVD) standards.
- o Standards for blood-processing equipment.

· Standards concerns:

- o Although the current standards are adequate to address the needs of the medical device industry, problems result from the application of standards by regulatory bodies in the United

States, Japan, and China.

- o Problems also result when standards are developed before a medical technology is ready for standardization.

- Goals for the national and international standards-setting process:

- o Participation by trade association staff and member companies in national and international standards development activities.

- o Establishment of working groups to provide input to government and medical device industry representatives.

- o Access to clinical expertise when standards are developed.

- Desired government assistance:

- o AdvaMed would like support in developing standards from the Centers for Disease Control, the National Institute for Standards and Technology, and the Food and Drug Administration.

- Future Activities

- o AdvaMed is willing to participate in future roundtables to address the use of standards in developing markets, particularly in Asia and South America.

- o AdvaMed views the medical device Global Harmonization Task Force as a mechanism for global standards improvement.

- o AdvaMed will establish relationships with medical device trade associations outside the United States so that the global industry speaks with one voice.

- o Support for medical device regulatory training program for regulators from countries and economies developing medical device regulatory systems.

National Electrical Manufacturers Association (NEMA) - Presenter - Larry A. Kroger, Ph.D.;
Senior Regulatory Programs Manager, GE Medical Systems

NEMA reports that it represents over 400 member companies that manufacture products used in the generation, transmission and distribution, control and end-use of electricity. NEMA promotes safety in the manufacture and use of electrical products, including diagnostic imaging, provides information to the media and the public, and represents industry interests in new and developing technologies. The medical devices group of NEMA made the presentation on behalf of the association.

- Top priority issues:

- o Conflicts in country-specific versus international standards.

- o Universal acceptance of international standards.

- o Universal interpretation of standards.

- o In certain countries, inspectors do not always accept results of Nationally Recognized Testing Laboratories (NRTLs).

- Specific regions of concern:

- o Asia. Issue: interpretation and test methods.

- o South America. Issue: limited acceptance of NRTL reports, insistence on local testing.

- Technical requirements in standards vs. technical regulations that adopt standards:
 - o Some standards (for example, regarding diagnostic ultrasound) have inadequate industry input.
 - o Requirements must be reasonable and achievable.
 - o Requests for additional information delay installations.

- Assessment of compliance with technical requirements:
 - o Assessment has been an issue, particularly regarding IEC 60601-1 (humidity requirements).

- Approach to national and international standards:
 - o Continued industry participation in IEC working groups.
 - o Participation in the medical devices Global Harmonization Task Force, which uses international standards to promote global uniformity in medical device regulations.
 - o Since there is more reliance on international standards, country-specific standards are becoming less of a concern.

- Experiences in which the federal government has been effective in resolving standards problems:
 - o FDA's recognition of national and international consensus standards helps streamline the preparation of product approval applications and reduces review times
 - o FDA should continue to expand and update the list of recognized medical devices standards.

- Actions recommended to the Department:
 - o Organize international conferences for regulators to promote recognition of international standards.
 - o Support global acceptance of NRTL test results.
 - o Support efforts to harmonize and simplify standards.
 - o Continue to support the medical device Global Harmonization Task Force.

The Medical Device Manufacturers Association (MDMA) - Presenter - Edward M. Rozynski; President, Rozynski & Associates

MDMA represents the innovative and entrepreneurial sector of the medical device industry, claiming credit for a number of policy achievements. MDMA focuses its efforts on reimbursement issues and on developing technology assessment processes and standards. MDMA reportedly represents more than 160 independent manufacturers of medical devices, diagnostic products and health care information systems.

- Top priority issues:
 - o In certain countries, national standards are major barriers to trade and limit patient access to new medical innovations and solutions.
 - o Standards create barriers to trade in several ways. A lack of standards may create an outright ban on medical technology; national standards can inhibit trade; and there may be a lack of transparency in developing standards or in the methods to show compliance.
 - o Although countries have the right to regulate medical products, regulations could serve as barriers to advanced medical technologies, keeping medical solutions from citizens in need of health care.
 - o A better definition of the "health emergency" exception clauses in trade agreements is

necessary to ensure that such clauses are indeed used to protect the public's well-being and not used as trade barriers or to protect local manufacturers.

- General approach to standards:

- o Health and well-being must be the priority when devising standards and regulations.
- o The use of international standards, as opposed to country-specific standards, facilitates international trade.
- o The United States should show leadership to define and limit the use of standards as a protectionist tool.

- Problem Countries

- o Japan, France, China, Australia, Brazil, and India.

B. Pharmaceutical Industry Associations

Pharmaceutical Research and Manufacturers of America (PhRMA) - Presenter - Caroline J. Leow, Ph.D.; Deputy Vice President for Scientific and Regulatory Affairs

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. The industry invested more than \$30 billion in 2001 in discovering and developing new medicines.

- General Approach to Standards:

- o The pharmaceutical sector is one of the most heavily regulated industries in the world.
- o The International Conference on the Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a thirteen year old initiative aimed at harmonizing standards for the development and registration of innovative pharmaceutical products.
- o ICH is a tripartite initiative involving regulatory agency and the research-based pharmaceutical industry representatives from the US, EU and Japan. Canada, the European Free Trade Area and the World Health Organization are Observers to the process.
- o The regulatory agencies involved in ICH are bound by the process to nationally implement any standards that result from the process. The standards are developed by a consensus and are based on the latest scientific data and best practices.

- Specific Issues of Concern:

- o Standards those are not science-based.
- o Standards relating to data confidentiality and their implementation.
- o Transparency in the development and implementation of standards.
- o Technical requirements for clinical trials.
- o Requirements for product quality testing.
- o Method of implementation.

- Desired Government Assistance:

- o Coordinated actions by USG and industry.

- o Regular communication between USG and industry.
- o Help in codifying and implementing agreements reached.
- o Addressing issues in trade context using coordinated interagency approach as appropriate.

U.S. Pharmacopeia - Presenter - Roger L. Williams, M.D.; Executive Vice President and Chief Executive Officer

U. S. Pharmacopeia (USP) helps to ensure that consumers receive quality medicines by establishing state-of-the art standards that pharmaceutical manufacturers must meet. USP disseminates authoritative standards and information developed by its volunteer member companies for medicines, other health care technologies, and related practices. USP provides standards for more than 3,800 medicines, dietary supplements, and other health care products.

· General Approach to Standards:

- o A bottom up, dispersed system.
- o The government that governs least governs best.
- o USP standards recognized in 1906 in the Pure Food & Drugs Act.
- o USP standards enforceable by FDA.

· Specific Issues of Concern:

- o Multiple regulatory agencies and pharmacopeias.
- o Duplicate testing and certification.
- o How to regulate the quality of dietary supplements and food additives.

· Desired Government Assistance:

- o Work closer with foreign governments in setting standards.

Generics Pharmaceutical Association (GPhA) - Presenter - Gordon Johnston; Vice President, Regulatory Affairs

GPhA represents manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. The Generic Pharmaceutical Association represents 98 percent of the generic drug manufacturers whose drugs are dispensed in the United States. GPhA members' products are used in more than one billion prescriptions every year.

· General approach to standards:

- o Generics industry is just beginning to explore international markets; new to exporting as a whole.
- o Prefer market driven, transparent, standards-setting process.
- o Would like to see the adoption of international standards and the elimination of redundant testing.

· Specific issues of concern:

- o Raw materials come from foreign countries; import issues and traceability of materials

important.

- o Would like observer status, not active participant status, in the International Conference for Harmonization (ICH), as generics are not a part of ICH.
- o Generics are subject to increasing import fees.
- o Local manufacturing requirements make it impossible for U.S. companies to enter new markets.

· Desired government assistance:

- o Would like the DOC to assist U.S. manufacturers of generics to explore international market possibilities.

Consumer Healthcare Products Association (CHPA) - Presenter - David C. Spangler, Esq.; Vice President - International, and Assistant General Counsel

The Consumer Healthcare Products Association (CHPA) serves the manufacturers in non-prescription, over-the-counter (OTC) medicines and dietary supplement products. CHPA has over 60 member companies, which produce and distribute an array of products that address a variety of self-care concerns. The association works closely with the U.S. Food and Drug Administration (FDA) and other government officials at both the federal and state level.

· General approach to standards:

- o OTCs are regulated like other drugs and have similar technical requirements.
- o Prefer market driven, transparent, standards-setting process.
- o Would like to see the adoption of international standards and the elimination of redundant testing.

· Specific issues of concern:

- o OTCs in Japan are re-tested before they are approved. Would like to see Japan use existing western data for OTCs.
- o OTCs are sold only in pharmacies in Japan and cannot be advertised. Would like OTCs to be able to be sold at non-pharmacy outlets.
- o The Japanese Government is making reforms, but distribution restrictions favor the status quo and impede entry of competing products and there is growing resistance for change.

· Desired government assistance:

- o Collaboration to continue to make changes with regard to good manufacturing practices (GMPs), transparency, categories versus case-by-case basis, and need for amendment mechanism.
- o Follow the issue of re-testing or use of western data closely and remind U.S. embassies of their commitment to help in this regard.

C. Roundtable Discussion

Following the medical device presentations, Deputy Undersecretary Benjamin Wu asked the presenters to list their top priorities for joint work with the DOC. Medical device industry presenters outlined the following priorities:

- A major concern is emerging countries developing new medical device regulatory systems "reinventing the wheel" and developing control-based systems. Industry would like the Department to continue to support participation of countries developing new regulatory systems in the medical devices Global Harmonization Task Force.
- Focus on bi-lateral activities with key markets, such as China and Japan.
- Promote third-party conformity assessment bodies (CABs) as a global vehicle for product reviews and plant audits. If countries developing new regulatory systems could buy into a third-party review model, redundant reviews may be eliminated.
- Elimination of medical devices "type testing" in which sample products are tested. Type testing is considered obsolete and has been replaced with Quality Systems audits.
- Some countries require information from firms for regulatory reviews or in determining price levels, which is considered proprietary.

Pharmaceutical industry associations praised the Department for the strong support provided with Japan issues.

Overall the seminar was viewed as a success. Industry representatives provided important feedback to ITA.