

# Public Policy Position

## Counterfeiting of Medical Products

- The production, distribution, marketing and/or sale of counterfeit medical products is a serious criminal offense and a major public health risk around the globe. Available data suggest that the problem is more pronounced in developing countries; however, large scale incidents involving organized crime also occur in developed parts of the world. Merck is committed to cooperating with relevant government agencies, other pharmaceutical manufacturers, wholesalers, distributors, health professionals, consumer groups and key related organizations in the fight against the counterfeiting of pharmaceutical products.
- Consistent with its longstanding commitment to provide high quality, safe and effective medicines and vaccines to patients who need them, Merck maintains a comprehensive product integrity program. Merck carefully manages its supply chain through strict policies and procedures that are designed to help keep the drug distribution system safe and secure. In the United States, for example, Merck has implemented terms and conditions of sale for our medicines and vaccines to reduce the potential for counterfeit products to enter the supply chain by requiring that customers purchase Merck products directly from Merck or a Merck authorized distributor. Other practices used by Merck to deter counterfeiting include publishing the names of authorized distributors on Merck's website and auditing of distributors.
- Merck urges governments and world leaders to provide strong political will and leadership to counteract counterfeiting. We support increased enforcement of existing laws against counterfeiting and the infringement of intellectual property rights (IPR). Merck also encourages the adoption of new public policies that are needed to strengthen existing laws and enforcement programs, including the EU proposal to negotiate a new anti-counterfeiting trade agreement (ACTA) with its major trading partners that will raise the standard of global IPR protection through better communication and the establishment of common standards and enforcement practices. As recommended by the WHO International Medical Product Anti-Counterfeit Taskforce (IMPACT), Merck believes that drug regulatory authorities should "ensure that the manufacture, importation, exportation, distribution, supply and sale of drugs are carried out under specific licences/authorisation in licensed approved premises under the supervision of qualified persons."
- Along with our industry counterparts, Merck works with governments, law enforcement agencies, industry groups and other stakeholders to support robust policies and programs to prevent counterfeit medicines and vaccines from reaching consumers. For example, Merck is working to increase proactive cooperation with law enforcement agencies – notably Customs authorities – to act against the increasing importation of counterfeit medicines which are widely advertised in many markets and made available via the internet. In addition, Merck has strong corporate procedures in place to promptly investigate and report suspected instances of counterfeit Merck products around the world.

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- Recognizing that this global problem can be more effectively addressed through a coordinated, multi-pronged, technology-based response, Merck supports regulatory harmonization and cooperation to accelerate the adoption and implementation of technical solutions. We also support the development of a standardized, risk-based system to uniquely identify or code medical products in order to create a more secure supply chain.
- To be effective, Merck believes a reasonable timeframe is needed to develop regulations and/or standards for the implementation of serialization technologies. We believe these standards should be developed at the national or multinational level, rather than by states, provinces or other political subdivisions. Furthermore, we believe a risk-based approach is necessary, and that serialization is only one layer of protection that will be most effective when it is a part of an overall program that includes increased criminal penalties for counterfeiting, stricter enforcement and better wholesaler licensing requirements. As they are adopted, Merck will work diligently to comply with legislative requirements, such as in the United States where Congress has required the Department of HHS to develop standardized numerical identifiers by 2010. We will also continue working with the European Federation of Pharmaceutical Industries and Associations (EFPIA) to promote the adoption of a standardized coding system for medicines in the EU.
- To advance the use of serialization technologies, Merck has initiated pilot projects at Merck/MSD facilities to demonstrate the use of radio-frequency identification (RFID) and two-dimensional (2D) data matrix bar code technology, both of which have the potential to help facilitate the detection of counterfeit medical products.
- Merck is committed to working with government agencies, industry groups, pharmacies, consumer organizations and other stakeholders to educate the public about the risks of counterfeit drugs and how to protect against them. This effort includes encouraging consumers to obtain prescription medicines from a reputable, licensed pharmacy, health care providers licensed to distribute medical products, or other authorized outlets.

**Approved: January 2008**

*Merck and Schering-Plough are now one company. We are working to update our public policy position statements to reflect our new global organization.*