



Electronic Labeling for the EU: Update

Based on a presentation by Thierry Chignon, PhD, PharmD, RAC Senior Consultant (Europe) for Quintiles Consulting to the RAPS West Coast Symposium, 2004.

Introduction

Labeling requirements for the EU impose a substantial overhead on medical technology companies every year. The cost of label printing, stocking, and fulfillment are substantial and the design challenges of incorporating 10-20 EU languages can be daunting.

One solution proposed by industry is electronic labeling—product labeling delivered via CD or the Internet. A presentation at the 2004 RAPS West Coast Symposium by Thierry Chignon offered an informed perspective on the current state of discussions.

Current Status of Electronic Labeling

- The medical industry's position has been officially provided to the Commission
- As yet, there is no regulatory decision
- While there is general support for electronic labeling from the EU Commission, there is also reluctance from several member states including Germany, Belgium, Greece, and The Netherlands
- There is also a general reluctance regarding delivery via the Internet
- The Commission has received general support *only* for devices that are destined for “professional use”—it is not anticipated that consumer products will avoid the current hardcopy labeling requirements

Electronic Labeling via CD ROM

- **Please Note:** The current version of the MDD specifies hardcopy documentation
- The current proposal is for a labeling CD ROM to be supplied with each device—the CD would replace the required hardcopy labeling
- **Please Note:** Even under the current proposed change, the manufacturer retains responsibility for delivery of the required information
- The current proposal calls for the hardcopy version of the labeling to be available upon request, free of charge

Electronic Labeling via Internet

- The text of the MDD is expected to change since the Commission has issues with the current wording that specifies “accompanied” and “leaflet”
- Labeling via the Internet would shift responsibility from *supply* of the IFU to making it available via a manufacturer's website
- The manufacturer's website address would appear on the product label
- Several member states have questioned accessibility via the Internet
- Medtronic has established a Pilot study to demonstrate feasibility and user advantages

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