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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Enforcement Committee Meeting and Work Group on E-Pedigree

Minutes of the June 20, 2007 Meeting

Red Lion Hotel
1401 Arden Way
Sacramento, CA 95815

9:30 a.m. -- 1:30 p.m.

Present: Stan Goldenberg, RPh, Chair
Bill Powers, Board President
Ruth Conroy, PharmD, Board Members
Tim Dazé, Esq., Board Member
Rob Swart, PharmD, Board Member

Virginia Herold, Executive Officer
Karen Cates, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Anne Sodergren, Legislative Coordinator
Joshua Room, Liaison and Deputy Attorney General
Spencer Walker, Staff Counsel

Chairperson Goldenberg called the meeting to order at 9:30 a.m.

Chairperson Goldenberg asked each individual present to introduce him or herself. He referred individuals to meeting materials that were available online in advance of the meeting.

Workgroup on E-Pedigree

Amgen:

Lew Kontnik of Amgen spoke about counterfeit drugs in worldwide markets. Mr. Kontnik stated modern pharmaceutical discoveries and patient health are being threatened and compromised by counterfeit drugs, which in some countries is running at 30 percent.

He stated there is a need for a pedigree system like California's to ward against the introduction of counterfeit medicine.

EPCglobal:

Mike Rose, TriChair-EPCglobal, provided an overview of the status of where EPCglobal is with respect to the development for standards for electronic pedigrees. He also walked through the adoption process of standards. A copy of his PowerPoint presentation is appended to these minutes (Attachment 1).

The Pedigree Messaging Standard was ratified in January 2007. There are three companies currently certified:

- Axway
- rfxcel
- SupplyScape

Item Level Tagging Standard: the purpose of this standard is for tagging pharmaceuticals at the item level. This will include requirements for manufacturing lines, distribution environments, transportation and retail environments. Current high frequency (HF) and ultra high frequency initiatives are underway to provide uniform air interface protocol at the item level. The ratification of the standard is expected in October 2007.

Serialization Standard: will define requirements for the EPC identified to be encoded on an RFID tag, and is nearing completion of prototype testing of the proposed specification.

Supply Chain Integrity: will define requirements and/or guidelines for authenticating and decommissioning tags. This component is still under development. An EPCglobal seminar is scheduled for July 2007.

Track and Trace Standard: to define supply chain use cases, processes and information needs for sharing EPC information related for sales and returns. This component is under development.

Tag Data Standards: focuses on defining additional user memory requirements for tags (lot number, expiration date). This is still under development.

The industry adoption task force is working to define a starting set of guidance for industry trade associations. They are working on two options to provide a pedigree: drug pedigree messaging standard (available now) or track and trace (under development).

EPCglobal is working to deal with other specific issues, like what is the manufacturer's smallest saleable unit, and how will repackagers forward the pedigree? Other issues

include receipt of partial shipments, drop shipments, resale of saleable drugs returned to manufacturer, intracompany transfers, voided pedigrees, and inference.

The Industry Adoption Task Force has a meeting every Wednesday morning. Interested entities may contact Bob Celeste of EPCglobal about attending a Web Seminar. Mr. Celeste can be reached at rceleste@epcglobalna.org.

Pfizer

Next, Peggy Staver of Pfizer provided information about Pfizer's experience in electronically tagging Viagra. A copy of this presentation is provided in Attachment 2.

Ms. Staver indicated that Pfizer used a multifaceted approach to ward against counterfeiting of Viagra. They restricted sales so that Viagra can only be purchased from the manufacturer or from an authorized distributor. Pfizer also used technology, such as color shifting ink on the labels, RFID tags and 2-D bar codes.

In Pfizer's experience, the one-time costs of implementing serialization are about the same regardless of what type of tagging is used. The majority of the costs lie in the provision and commissioning of the serialized number and applying the tag.

Although she noted that the implementation costs for Viagra were $5 million, future costs for tagging Celebrex will be $4 million.

Pfizer also has tagged Celebrex and Lipitor, and Pfizer has learned that each implementation is unique.

Currently underway at Pfizer in 2007 are e-pedigree testing, RFID tagging of Celebrex, and work on an industry pilot.

Pfizer indicated that they have 65 product lines at 21 manufacturing sites worldwide producing drugs for the US market. They estimate $95 - $100 million in costs to implement serialization throughout the system, and this does not include ongoing costs.

Pfizer estimates that it will take five to seven years to implement serialization on all product lines and recommends a risk-based implementation for serialization, where the highest risk drugs are serialized first.

Walgreens

Sue Thoss, Walgreens Divisional Vice President, Logistics and Planning, provided a PowerPoint regarding Walgreens plans for item-level serialization. A copy of this presentation is attached to these minutes.

Ms. Thoss asked several questions, including in January 2009, what will happen to drugs in existence in the supply chain that are not tagged and serialized – will they be grandfathered in?

Ms. Thoss stated that item level serialization, starting at the manufacturer, would rely upon a manufacturer-applied RFID tag as well as an item level 2-D bar code as a back up to the RFID tag. They expect to use tunnel and handheld readers for item-level barcode reading and an RFID tunnel for case reading. They expect item-level inference and validation. They also will do audit sampling.

Walgreens believes there will be one-time costs at its distribution center of $700,000 to $1 million, and ongoing costs of $500,000 to $1 million annually.

They expect to be fully integrated one year after the standards are in place, and expect it will take six months to "bleed out" the untagged inventory.

If inference is not allowed, the implementation costs will double to $1 million to $1.5 million, and ongoing costs of $2.5 - $3 million.

Walgreens also provided information on costs of implementation if other processes are used, which would not comply with California law (e.g., the wholesaler applies the serialization tags).

Walgreens suggested a phased-in implementation with certain drugs being tagged initially, and all drugs becoming tagged over a period of time. They suggested that controlled drugs and list 1 products be the first to be required to be RFID tagged.

Walgreens stated that they wanted the tagging on all drug products to be RFID tagged.

PhRMA

Marjorie from PhRMA provided comments regarding California's electronic pedigree requirements. She encouraged the board to work with the end users of the pedigree systems as well as the manufacturers who are at the front end. She suggested that serialization should be first implemented for those drugs that have the greatest likelihood of being counterfeited, although PhRMA does not have a list of such drugs. Moreover, PhRMA states that the costs to serialize all item level packaging are significant with unproven safety benefits. She also spoke about some of the non-electronic techniques used by some manufacturers to prevent counterfeiting, like color shifting inks on labels and threads through labels.

She stated the PhRMA supports phased-in use of serialization, although serialization will only protect packaging, not the medicine inside. PhRMA suggests case level serialization with use of lot number control as a much better method.

She spoke about the complexities required throughout the supply chain to use serialization. She noted the pilot projects underway with tagging of one product from the manufacturer through the wholesaler. She stated it would take several years after all standards are in place for the tracking technology to be manufactured and put in use.

PhRMA suggests that the board initiate discussions to implement a nonserialized e-pedigree standard and consider legislation to make this possible.

HDMA

Liz Gallenag of HDMA stated that this association supports the use of RFID tags on products to achieve serialization from pedigrees started by the manufacturers tagging the product. She noted that the costs projected by Walgreens are not necessarily those of other wholesalers.

The HDMA seeks a track and trace system. They are not in favor of tracking by lot number, in part because of the burden placed on pharmacy for such systems, and principally because it is not possible to link transactions this way.

Other Discussion:

Following these presentations, several hospitals asked questions about how electronic pedigrees will be tracked into hospital pharmacies. Some of the questions included issues related to unit of use tracking versus unit of sale tracking.

The board will consider how to engage hospitals at a stronger level in the future.

Enforcement Committee

1. *Proposal to Develop an Ethics Course for Pharmacists*

Board Member Ravnan and Ms. Herold provided a brief update on where this project is currently headed. An ethicist met with Dr. Ravnan, Dr. Swart, Ms. Sodergren and Ms. Herold to discuss services he provides the Medical Board and Dental Board. A future meeting will be held with the course provider for the Medical Board's 22-hour course in the late summer. A full report will be provided at the October 2007 Board Meeting.

2. *Proposed Amendments and Restructuring of the Disciplinary Guidelines*

Chairperson Goldenberg referred the committee to the draft version of the *Disciplinary Guidelines* contained in the packet. He noted that comments from Ron Marks have been received.

Mr. Room noted that staff has been updating the guidelines for several years. Staff have picked up terms used by other boards and is suggesting a slightly different format.

After some discussion, Mr. Goldenberg requested that the guidelines be brought back to the next Enforcement Committee Meeting for a longer, more detailed discussion. Specific items for future discussion noted are:

- Posting a notice when on probation
- Requirements for the notice employers must sign
- Whether revocation based on nonpayment of cost recovery fees should be pursued.

3. Disposal of Drugs from Assisted Living Facilities

Ms. Herold stated that at the last meeting, a question was raised about how patients can dispose of drugs from patients in assisted living facilities, where sometimes bag-loads of drugs are no longer needed and need to be disposed of. This year, SB 966 would establish take back drug programs in large retailers and supermarkets. However, the bill will not resolve the problems of assisted living facilities.

4. 2007 Pharmacy Self Assessment Process

Ms. Herold noted that the 2007 hospital and community self-assessment forms have been completed and are available online. However, the 2007 version of the self-assessment forms cannot be required until regulation section 1715 is amended to reference the 2007 forms. While this regulation is being updated through a section 100 filing (rulemaking without regulatory effect), current regulation section 1715 requires the 2005 forms to be completed. As such the board is advising pharmacies that a self-assessment must be performed by the PIC every odd-numbered year or within 30 days of a change in PIC. If either the 2005 or 2007 form is on file, the pharmacy is in compliance. The board will encourage completion of the 2007 form. If neither version of the self-assessment forms has been completed, the pharmacy is in violation of this regulation section and may be subject to citation and/or fine.

5. Enforcement Statistics

Chairperson Goldenberg referred the committee to the Enforcement Statistics provided in the packet.

Adjournment

There being no additional business, Chairperson Goldenberg adjourned the meeting at 1:30 p.m.