PHARMACEUTICAL COMMERCE
Business Strategies for Pharma/Bio Success

After the California Pedigree Postponement—What?

The delay gives industry—and government regulators—needed time

REACTING TO PHARMACEUTICAL INDUSTRY concerns over implementation costs and challenges and a cited lack of guidance and standardization, the California Board of Pharmacy (CBOP) recently voted to delay the enforcement of ePedigree legislation (for the second time) from January 1, 2009 to January 1, 2011. While this move is applauded by the pharmaceutical industry as a whole, how it actually plays out depends on three groups or influencers—FDA, CBOP, and the wholesalers themselves.

The first influencer, FDA, has recently requested input regarding the development of national standards for the "identification, validation, authentication, and tracking and tracing of prescription drugs." FDA will use the comments to develop recommendations (or actual requirements) for serializing drug packages and operating a track-and-trace system. FDA posted this request on March 20 and it solicited input from "interested parties" by May 19, 2008. While it is encouraging that FDA is asking for this necessary input, they actually have until March, 2010 to evaluate it, according to The Food & Drug Administration Amendments Act of 2007 (sec. 913). The Act gives the agency 30 months to make its recommendation and while it doesn't have to take the full time allotment, if it does, the industry could potentially receive FDA recommendations a mere nine months before the new CBOP deadline takes effect.

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The next influencer is CBOP itself. As stated in its January 23 Q&A document, many process areas have not been fully addressed such as inference, grandfathering, returns, etc. and core business aspects such as Contract Manufacturing Outsourcer (CMO) and Third Party Logistics (3PL).

With the industry's best interest at stake, the CBOP subcommittee on ePedigree & Serialization needs to make this a top priority. It should identify every aspect within the law's interpretation that the Board has jurisdiction over, determine which are the "policy" areas, and then direct the industry to act on those specific areas. In the March 25th CBOP meeting, several Board members reiterated a fear that the industry would come back to them in late 2009 or early 2010 pleading for another reprieve. A proactive part by the CBOP in eliminating these gray areas would be a huge step toward ensuring that this won't happen.

If you are a manufacturer, the third influencer is your wholesaler/distributor trading partner. Within the past 7 months, all of the Big Three distributors—McKesson, AmerisourceBergen and Cardinal Health—issued letters detailing what they expect from their suppliers. They must reissue those with the new timeline in mind to reset their expectations. While this can naturally be done more expeditiously if FDA and CBOP respond accordingly and do their part, there are still areas where the wholesalers can indicate what they do know (and expect) now, following up at a later date.

Our conclusions, then, are the following:

- Companies should be lobbying to have FDA expedite their time line on reviewing standards input
- They should also be lobbying CBOP to prioritize its agenda by defining the "gray areas"
- Wholesalers provide their perspectives as soon as they can (even if it is done in phases).

While it remains unclear whether or not the responsible parties will do their part, we encourage you to seize the opportunity now. Collaborate with your trading partners, do additional diligence on serialization technologies, set up pilot programs and give your packaging engineers time to resolve the impact of serialization on their lines. Those who decide to wait to see what guidance is provided will not only miss valuable opportunities for ROI and process improvements, but they may very well be the ones in 2011 who are trying to explain to CBOP why they will not be ready in time. **PC**

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