

5 major policy developments of 2012

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The Year 2012 has seen crucial policy changes in the bioscience industry around the world. These changes that have taken place in 2012 hope to have an impact on the businesses of pharma, biotech and medtech companies. Here are the top five important policy changes that happened in 2012.

1) US FDA extends generic drug approval timeline

The US Food and Drug Administration (FDA) has decided to extend the timeline for granting tentative approval to generic drug applications. The timelines of applications filed under Paragraph IV have been increased from 30 months to 40 months for those whose 30-month stay expires between July 9, 2012, and September 30, 2015, and 30 months to 36 months for those whose 30-month stay expires between October 1, 2015, and September 30, 2016.

2) NZ's choking clinical trials sector gets a boost

New Zealand's Health Committee submitted a 62-page report to New Zealand's Parliament making necessary recommendations to improve the existing clinical trials industry. The committee made 54 recommendations, comprising eight key recommendations and 46 detailed recommendations.

3) India announces new biosimilar regulatory guidelines

India has announced the much-awaited new and simple regulatory guidelines for similar biologics which have been approved and marketed in USA or Europe for more than four years.

4) Singapore tweaks rules to fast-track product access

Health Sciences Authority (HSA) of Singapore enhanced its regulatory framework for low-risk Class A and B medical devices to ensure lower regulatory fees for these products and facilitate quicker access in market. The enhanced regulatory framework seeks to better address the concerns of the medical device industry while ensuring patient safety. Enhancements are also being planned for high-risk Class C and D devices.

5) Taiwan identifies focus areas for medical devices industry

Taiwan has pinpointed five focus areas to boost its medical devices industry. The industry, which generated nearly \$3.4 billion (NT\$100 billion) in 2011, is expected to expand seven percent in 2012 and despite weak global economic growth