

# Global Regulatory News

### International ANZTPA's Possible Joint Regulatory Scheme for Therapeutic Products<sup>1</sup>

In June 2011, the Australian and New Zealand Governments have agreed to proceed with a joint scheme for regulation of therapeutic products (that is, medicines, medical devices, biological and others) to be administered by the Australia New Zealand Therapeutic Products Agency (ANZTPA). The Heads of the current regulatory agencies in Australia and New Zealand, TGA and Medsafe are inviting participants to discuss high level aspects of a possible framework for regulation I of therapeutic products under the joint agency. The possible framework has been developed against the background of the Trans-Tasman Mutual Recognition Arrangement that aims to develop a more integrated trans-Tasman economy by removing regulatory impediments between Australia and New Zealand and to enable goods to be traded freely between them. It is also based on the Treaty, an Agreement between the Government of Australia and the Government of New Zealand for the establishment of a joint scheme for the regulation of therapeutic goods, signed by both countries in 2003. The objective is to develop a responsive and cost-effective regime for regulating therapeutic products that is consistent with international best practice.

### ICH E2C(R2) Guideline Reaches Step 4 of the ICH Process<sup>2</sup>

The ICH E2C(R2) Guideline on Periodic Benefit-Risk Evaluation Report reached Step 4 of the ICH Process in November 2012 and now enters the implementation period (Step 5). The purpose of this revised guidance is to ensure that the periodic safety update reports for marketed drugs have the role of being periodic benefit-risk evaluation reports by covering: Safety evaluation, evaluation of all relevant available information accessible to Marketing Authorization Holders (MAHs) and benefit-risk evaluation. The final Guideline is now available for download under the ICH Efficacy Guideline page at <http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html>.

### ICH S10 Guideline Reaches Step 2 of the ICH Process<sup>3</sup>

The ICH S10 Guideline on Photosafety Evaluation of Pharmaceuticals reached Step 2 of the ICH Process in November 2012 and now enters the consultation period (Step 3). This new Guideline on photosafety testing will be a valuable adjunct to the guidance provided in the M3(R2) Guideline. The draft Guideline is now available for download under the ICH Safety Guideline page at <http://www.ich.org/products/guidelines/safety/article/safety-guidelines.html>.

### ICH Steering Committee Revises the S1 Strategy<sup>4</sup>

In November 2012, the Steering Committee endorsed the revision of both the S1 Concept Paper and Business Plan to provide clarification concerning how the prospective data gathering period should be integrated in the normal ICH Step process. The revised S1 Concept Paper and Business Plan now describe the S1 strategy which consists of first preparing a draft "Regulatory Notice for Public Input" to be issued by each ICH regulatory health authority to solicit comments from the public to the proposal, the procedure, and the specific weight-of-evidence criteria. A final "Regulatory Notice" is planned to be published in June 2014 and will mark the beginning of the prospective data collection period. After collecting and incorporating results from the prospective analyses, a Step 2 document is planned to be published in November 2016, and a Step 4 document finalized in November 2017.

### U.S. and Canada Working Together to Provide Access to Needed Veterinary Drugs<sup>5</sup>

The first simultaneous review and approval of a veterinary drug by the United States and Canada marks a successful start to a collaboration aimed at providing quicker access to needed veterinary medicines. The collaboration is also intended to remove trade barriers and reduce costs for consumers, regulators, and manufacturers.

### Chinese SFDA Commissioner and Deputy Commissioner Met with Assistant Deputy Minister of Health Canada<sup>6</sup>

On 10 December 10, 2012, SFDA Commissioner Yin Li and Deputy Commissioner Bian Zhenjia respectively met with the delegation led by Mr. Paul Alfred Maurice Glover, Assistant Deputy Minister of Health Canada Health Products and Food

Branch. Both sides reviewed the cooperation in the field of drug supervision and exchanged opinions on implementation of GMP, monitoring of adverse reactions, experience on joining PIC/S, supervision on traditional Chinese medicines, and supervision system of international drug regulatory agencies. Main directors of SFDA's Department of International Cooperation, Department of Drug Safety and Inspection, and relevant directors of Center for Drug Certification of SFDA attended the meeting.

### European Union and Russia Partner for Modernization<sup>7</sup>

Cooperation on medicinal products is specifically considered in the Sub-Group on Pharmaceuticals of the Health dialogue. The current activities of this subgroup are focused on important issues such as:

- Legislation relevant to medicinal products
- Clinical trials
- Pharmacovigilance
- Orphan products and biosimilars
- GMP and details of registration procedures

### Asia/Pacific Rim

#### China

#### Chinese SFDA Cracks Down on Illegal Internet Pharmacy Sales<sup>8</sup>

In order to ensure drug safety for the public, from February 2012, the State Food and Drug Administration (SFDA) carried out the special operation on strengthening the supervision of drug information service and drug selling over the Internet, stringently cracking down on releasing false drug information and selling drugs illegally over the Internet. Throughout the past year, local drug regulatory authorities carried out the SFDA's overall deployment and worked actively. The special operation has achieved notable results.

#### Chinese Government Agencies Jointly Promoting the Implementation of Newly Revised GMP<sup>9</sup>

A notice on accelerating the implementation of newly revised GMP and promoting pharmaceutical industry upgrading was recently jointly issued by the State Food and Drug Administration, National Development and Reform Commission, Ministry of Industry and Information Technology and Ministry of Health. Under the original standard and schedule, the four government agencies advanced incentives in merger and reorganization, certification and inspection, examination and approval, contract manufacturing, price adjustment, bid procurement, and technical improvement to encourage and guide drug manufacturing enterprises to meet the requirements of the newly revised GMP.

#### India

#### Order Issued Ensuring Rights/Safety of Clinical Trial Subjects in India<sup>10</sup>

The Directorate of Health Services issued an order that the Ethics Committee review and accord approval to clinical trial protocol in order to ensure that trials are conducted according to GCP guidelines and other guidelines published by CDSCO as well as applicable regulations to safeguard the rights, safety, and well-being of all trial subjects.

#### India's National Vaccine Regulatory Authority Declared Functional Against WHO Assessment Indicators<sup>11</sup>

As a result of an assessment, WHO assures that the regulatory oversight of National Vaccine Regulatory Authority for vaccines meets international standards.

#### India Publishes Guidelines for Good Distribution Practices for Pharmaceutical Products<sup>12</sup>

The objective of these guidelines is to ensure the quality and identity of pharmaceutical products during all aspects of the distribution process. These aspects include, but are not limited to procurement, purchasing, storage, distribution, transportation, documentation, and record-keeping practices.

These guidelines are intended to be applicable to all persons and outlets involved in any aspect of the storage and distribution of guidelines on good distribution practices for pharmaceutical products from the premises of the manufacturer of the product to the person dispensing or providing pharmaceutical products directly to a patient or his or her agent. This includes all parties involved in trade and distribution of pharmaceutical, including the manufacturers of bulk, finished products, wholesalers, as well as others such as suppliers, distributors, government institutions, international procurement organization, donor agencies and certifying bodies, logistics providers, traders, transport companies, and forwarding agents and their employees as well as health workers. It also covers biological products in general.

#### Malaysia

#### Malaysia Enacts New Drug Registration Guideline<sup>13</sup>

This guideline, which went into effect 1 January 2013, can be downloaded at <http://portal.bpfk.gov.my/newsmaster.cfm?&menuid=52&action=view&retrieveid=213>.

#### Europe

#### European Union

#### European Medicines Agency Reviews its Operations and Prepares for Reorganization in 2013<sup>14</sup>

The European Medicines Agency has begun a review of its operations and

processes, focused on increasing the efficiency of its scientific activities and information- and communication-technology operations. As part of this process, it will focus on the support provided to the Agency's scientific committees to help them deliver high-quality, consistent opinions. The Agency expects this process to result in a significant reorganisation of its staff during 2013.

### European Medicines Agency's Management Board Endorses Work Program 2013<sup>15</sup>

The European Medicines Agency's Management Board, at its meeting on 13 December 2012, adopted the Agency's work program and budget for 2013. The Agency's priorities will be to continue to ensure that assessment activities are conducted to the highest scientific levels, to increase efficiency in its activities, and to develop initiatives for greater transparency and communication with stakeholders. Further specific drivers include the continued implementation of the pharmacovigilance legislation and the new falsified-medicines legislation, and the planned revision of the veterinary medicines legislation.

In 2013, the Agency expects a stable total number of applications for human medicines with 100 applications in 2013. These include some 54 applications for new medicinal products (excluding designated orphan medicines), 20 new orphan medicines, and 20 generic applications (2012: 52, 13 and 39 respectively). Some 10 applications for new veterinary medicines are expected, with three generic applications (2012: nine and three respectively). The work program is accompanied by a budget of €231.6 million (\$309 million), an increase of 4.1% over 2012, which includes fee revenue of €179.8 million (\$239.9 million) (3.8% increase compared with 2012, this increase is mainly due to inflation) and a European Union (EU) contribution of €39.2 million (\$52.3 million).

### Public Consultation on the Revision of EU Commission Guidelines on Good Manufacturing Practice Medicinal Products<sup>16</sup>

The EU launched a public consultation of the following revised guidelines on good manufacturing practice: Chapter 3 - Premises and Equipment; Chapter 5 - Production; Chapter 6 - Quality Control; and Chapter 8 - Complaints, Quality Defects, and Product Recalls. Comments are due by 18 July 2013.

### Denmark

#### Danish Health and Medicines Authority Publishes New Guideline: Renewal of Marketing Authorization for Nationally Authorized Medicinal Products<sup>17</sup>

Pursuant to section 27 of the Danish Medicines Act, a marketing authorization must be renewed after five years. The marketing authorization holder must submit a renewal application not later than nine months (human medicinal products) or six months (veterinary medicinal products) before expiry. Once an authorization has been renewed, it is valid for an unlimited period of time. However, if the benefit/risk ratio so dictates, the Danish Health and Medicines Authority may decide that an additional 5-year renewal is required. For more information, see <http://laegemiddelstyrelsen.dk/en/topics/authorisation-and-supervision/licensing-of-medicines/renewal-of-marketing-authorisation/guideline-on-application-for-renewal-of-authorisation.aspx>.

#### Danish Health and Medicines Authority Publishes Annual Report on Human Tissues and Cells 2011<sup>18</sup>

The annual report for human tissues and cells for 2011 has been prepared pursuant to the Danish Tissue Act and is based on reports submitted by tissue establishments and gynaecology clinics in Denmark in the period Janu-

ary to December 2011. The full report can be found at <http://laegemiddelstyrelsen.dk/~media/3753F2FF5378466387D731260AD3F4E1.ashx>.

### Great Britain British MHRA Publishes Medicines Reclassification Guidance<sup>19</sup>

Following the announcement in the Chancellor's Autumn Statement, the Medicines and Healthcare products Regulatory Agency (MHRA) has a new, streamlined procedure to speed the process of moving medicines from prescription-only to over-the-counter medicines.

The new procedure is underpinned by a new guideline on "How to change the legal classification of a medicine in the UK" published on the MHRA website. The new process outlined in the guideline could cut the time from application to decision by three months or more.

### North America/South America Canada

#### Health Canada Publishes Summary Report of Drug GMP Inspection Program<sup>20</sup>

In this report, Health Canada provides data on the drug GMP Inspection program. Over a five year time frame, the examples of the most common observations cited during GMP inspections include:

- Process validation for critical production processes not conducted or incomplete
- Incomplete manufacturing procedures/batch documents; failure to follow manufacturing procedures
- Incomplete packaging documents or procedures
- Inadequate/lack of quality agreements
- Inadequate/lack of recall system/procedure

- Absence of/ inadequate self inspection program
- Inappropriate procedures for handling storage and shipment of drug products with respect to temperature requirements
- Laboratory operations issues

### Summary Report of Inspections of Cells, Tissues, and Organs Establishments Conducted from August 2009 to June 2012<sup>21</sup>

This summary report provides the result and analysis of Cells, Tissues, and Organs (CTO) program inspections conducted by Health Canada from August 2009 to June 2012. This is the first summary report issued since the inspection program was launched in August 2009. The objective of sharing inspection results, anonymously, is to increase awareness of compliance with Canadian regulatory requirements within the CTO community, while maintaining the confidentiality and privacy of those involved in the inspections. The document can be found at [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/cell/report-rapport\\_2009-2012\\_CTO-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/cell/report-rapport_2009-2012_CTO-eng.php).

### United States US Publishes Strategies for More Successful Drug Trials<sup>22</sup>

In recent months, drug developers have succeeded in bringing important drugs to market for cystic fibrosis, cancer, and other conditions by employing strategies for achieving greater clinical trial success. FDA issued a draft guidance that spells out how drug developers can use such strategies, known as clinical trial enrichment, to greatly increase the likelihood that data collected during a clinical trial will demonstrate that an effective drug is effective. These are potentially powerful strategies for the pharmaceutical industry because appropriate use of enrichment could result in smaller studies, shortened

drug development times, and lower development costs.

### U.S. Court Voids Drug Rep's Conviction, Cites Free Speech<sup>23</sup>

A divided federal appeals court threw out the conviction of a sales representative for promoting off-label use of a prescription drug, a ruling that could make it harder for the government to police how drugs are marketed and sold. The 2nd U.S. Circuit Court of Appeals in New York found that the sales representative's free speech rights under the First Amendment had been violated.

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