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Brazil's ANVISA joins WHO's adverse effects alert system VigiMed

ANVISA

Brazil's National Health Surveillance Agency (ANVISA) has signed a contract with the Uppsala Monitoring Centre (UMC), which collaborates with the World Health Organization (WHO), to use its VigiMed system to notify adverse events caused by medicines and vaccines. The tool is a variant of VigiFlow, a system used by the WHO to receive adverse event notifications.

The new platform, which will help ANVISA better handle the flow of pharmacovigilance reports, is set to replace the current Health Surveillance Notification System (NOTIVISA) in the drug and vaccine areas. The transition is planned to be gradually introduced and conclude by the end of this year. More details can be referred from following weblink:

http://portal.anvisa.gov.br/noticias?p_p_id=101_INSTANCE_FXrpx9qY7FbU&p_p_c

MedDRA Releases Best Practices Document – Recommendations for Implementation and use of MedDRA

The purpose of this MedDRA Best Practices document is to provide the recommendations of the MedDRA Maintenance and Support Services Organization (MSSO) for the implementation and use of MedDRA.
Its objective is to promote the accurate and consistent use of MedDRA by users worldwide.
The document provides best practice considerations on several topics pertaining to the use of MedDRA. It does not specify regulatory requirements, nor does it address database issues.
Organizations are encouraged to document their own best practices in organization-specific guidelines which should be consistent with this MedDRA Best Practices document.
This MedDRA Best Practices document has five sections:

- Primary System Organ Class (SOC) Allocation in MedDRA
- Single Case Reporting Using Semi-annual Version Control
- MedDRA Implementation and Versioning for Clinical Trials
- Versioning Methodology
- Recommendations for the Implementation of MedDRA Supplemental Terms

More details can be referred from following weblink:

https://www.meddra.org/sites/default/files/guidance/file/000026_meddra_best_practices_2018.pdf

TGA Creates Guide to Adverse Event Management System for Sponsors

Australia's Therapeutic Goods Administration (TGA) has published a guide to help sponsors use its adverse event management system (AEMS). The guide walks sponsors through how to create accounts and use the AEMS reporting dashboard.
TGA used to collect reports of side effects through the adverse drug reaction system, but has now decommissioned that system in favor of AEMS. To help sponsors adapt to the new system, TGA has released a step-by-step guide to many of the common processes users will need to work through, such as the completion of adverse event reporting forms.
The agency released the guide alongside a separate document aimed at healthcare professionals.
Guideline can be assessed through following link:

https://www.tga.gov.au/aems-guidance-sponsors

Sultanate of Oman – Notice regarding online submission to Department of Pharmacovigilance & Drug Information (DPV&DI) via the MOH's e-portal

Sultanate of Oman has issued notice to all pharmaceutical manufacturers and marketing authorization holders (MAHs) of all pharmaceutical establishment regarding online submission of reports to department of pharmacovigilance & drug information via the MOH e-portal.

Sultanate of Oman
Ministry of Transport & Communications

Circular can be accessed via following link:

https://www.moh.gov.om/documents/16539/0/cir+75.pdf/329e592e-e9ee-ddb0-0a4f-981266f40a95

European Commission Revises Q&A on Safety Features for Medicinal Products

The European Commission released a revised question and answer document regarding the implementation of the rules on the safety features for medicinal products for human use.

Revisions in the document are related to two questions and answers, including one on if a pack bearing safety features is lawfully opened by, for instance, parallel traders or manufacturers replacing the leaflet, can the pack be resealed? The answer notes that in certain circumstances it can occur, based on the assessment of the national competent authority in the member state.

The other revised question is on whether it's acceptable to use stickers to place the unique identifier on the outer/immediate packaging.

Further details can be accessed via below link:

https://ec.europa.eu/health/sites/health/files/files/falsified_medicines/qa_safetyfeature_en.pdf

TGA Australia issues guidance on Boxed Warning

The TGA, along with other international medicine regulators, has in place Boxed Warnings as a risk mitigation measure to highlight special warning statements in the PI and CMI to the prescriber and the public. Boxed warnings represent one of the most serious types of warnings that can be mandated by a regulatory agency. More than 30 products on the Australian Register of Therapeutic Goods currently have a boxed warning that has been overseen by the TGA. The boxed warning is a risk mitigation measure that may be proposed by the sponsor or required by the TGA.

International regulatory agencies have taken varying approaches to the use of boxed warnings and they are not used consistently across jurisdictions. In Australia, these warnings are intended to highlight a potential for major impact on public health due to serious adverse events.

The purpose of this guidance is to:

- Outline the objectives for introducing a boxed warning to a Product Information (PI) or Consumer Medicine Information document (CMI)
- Provide guidance on how and when to use a Boxed Warning

The guidance is intended to assist sponsors to understand their obligations and prescribers to understand the rationale for the warning and the magnitude of risk.

Further details can be accessed via:

https://www.tga.gov.au/publication/boxed-warning-guidance

UK MHRA Pharmacovigilance Inspection Metrics Report from April 2017 to March 2018

The MHRA GPvP inspectorate recently published their latest inspection metrics for the period from April 2017 to March 2018.

The report is informative and useful for considering compliance and improvements within work or organization.

Full report is available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/761289/GPvP_Metrics_2017-18_.pdf

ABPI revises guidance for Pharmacovigilance in Market Research

The Association of the British Pharmaceutical Industry (ABPI) and the British Healthcare Business Intelligence Association (BHBIA) have produced a revised version of their guidance on collecting adverse events, product complaints and special situation reports during market research programmes (MRPs). The guidance document was first issued in October 2009, and is now version 4, which took effect from the beginning of October 2018.

Changes include the collection of contact details when information is collected directly from patients/consumers in order to enable the appropriate follow-up of adverse events by the marketing authorisation holder, and changes related to personal data protection.

The guidance document contains informative annexes, including suggested wording for the contract with the Market Research Agencies, templates for data collection and reconciliation forms, and interview scripts covering a range of scenarios.

The ABPI and BHBIA have worked on the guidance to ensure the scope of the guidance is clear in terms of market research types, market research methodologies, project types and mediums, and to make the remit of the researcher and the data collection process clear.

Further details are available on:

https://www.abpi.org.uk/media-centre/blog/2018/september/new-guidance-notes-on-collecting-adverse-events-product-complaints-and-special-reporting-situations-during-market-research/

EMA revises guideline on environmental risk assessment of human medicines

The updated European Medicines Agency (EMA) draft guideline on environmental risk assessment (ERA) now contains a decision tree which clarifies when ERA studies are required, and provides greater detail on technical guidance to help increase the consistency of the assessments. Performing an ERA is mandatory for any pharmaceutical company submitting a marketing authorisation application for a medicine.

The revision of the ERA guideline is based on a 2014 concept paper, and the work of a group of experts led by the Safety Working Party of EMA's Committee for Medicinal Products for Human Use (CHMP).

One of the major changes that has been introduces in the proposed revision is the introduction of the term 'endocrine active substances', to include all compounds that affect development or reproduction. Furthermore, guidance is given for the estimation of the exposure of predators to pharmaceuticals through the food chain, plus directly through the environment.

ERAs are designed to assess the possible effects of pharmaceuticals on the environment and ensure that adequate precautions are taken in case specific risks are identified. The ERA is based on the use of the product and the physico-chemical, ecotoxicological, and degradation and persistence of its active substance.

Stakeholders are invited to send their comments on the revised guideline by 30th June 2019.

For more details, follow:

https://www.ema.europa.eu/documents/scientific-guideline/draft-guideline-environmental-risk-assessment-medicinal-products-human-use-revision-1_en.pdf

EMA releases Guidance on the format of the risk management plan (RMP) in the EU – in integrated format (Rev.2.0.1)

This guidance should be read in conjunction with GVP module V. According to GVP module V, the aim of a risk management plan (RMP) is to document the risk management system considered necessary to identify, characterize and minimize the important risks of a medicinal product. To this end, the RMP contains:

- The identification or characterization of the safety profile of the medicinal product, with emphasis on important identified and important potential risks and missing information, and also on which safety concerns need to be managed proactively or further studied (the 'safety specification');
- The planning of pharmacovigilance activities to characterize and quantify clinically relevant Risks and to identify new adverse reactions (the 'pharmacovigilance plan');
- The planning and implementation of risk minimization measures, including the evaluation of the effectiveness of these activities (the 'risk minimization plan').

To go through entire document:

https://www.ema.europa.eu/documents/regulatory-procedural-guideline/guidance-format-risk-management-plan-rmp-eu-integrated-format-rev-201_en.pdf

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The launch of the new EudraVigilance System: Questions and answers (Q&A) from stakeholders - Version 1.7

This document addresses questions received from stakeholders as a part of the launch of the new EudraVigilance System, which went live on 22 November 2017. The document summarizes questions received through the Agency's service desk and as part of the EudraVigilance technical and pharmacovigilance support webinars organized by the EMA. The document is regularly updated and should be consulted as a first reference before contacting the Agency 's service desk.

Full document is available at :

https://www.ema.europa.eu/documents/other/launch-new-eudravigilance-system-questions-answers-stakeholders_en.pdf

EMA Updation of two work instructions

Validation of signals from the review of individual cases & Key activities when screening the electronic Reaction Monitoring Reports (eRMRs) for new signals

In December 2017, EMA has updated two work instructions related to signal detection activity. It will help MAHs to screen the resources for signal detection activity. Full work instructions can be accessed through following resources:

https://www.ema.europa.eu/documents/win/work-instructions-validation-signals-review-individual-cases_en.pdf

https://www.ema.europa.eu/documents/win/work-instructions-key-activities-when-screening-electronic-reaction-monitoring-reports-ermrs-new_en.pdf

Medical Device Safety Action Plan: FDA Sets Measure of Success Amid Funding Issues

The US Food and Drug Administration (FDA) updated its medical device safety action plan with "an important and ambitious new goal" and explained the path forward for its planned nationwide device surveillance system.

The new goal to propel the safety action plan—released in April—is centered around ensuring that the agency is "consistently first among the world's regulatory agencies to identify and act upon safety signals related to medical devices," FDA Commissioner Scott Gottlieb and Center for Devices and Radiological Health (CDRH) Director Jeff Shuren said in the statement.

The agency prioritized regulatory reforms to shift away from a passive approach toward an active surveillance system as it has come under increasing pressure to reform its postmarket oversight approach. A contentious debate emerged over the course of this journey about whether additional FDA authority is needed. The areas for which new oversight is needed remain unclear, but the updates indicate FDA is seeking to impose additional postmarket safety requirements on devices cleared via 510(k) submissions.

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm626286.htm

Materiovigilance Programme of India (MvPI) releases Medical Devices Adverse Event Reporting Tools

Indian Pharmacopoeia Commission as National Coordination Centre (NCC) for Materiovigilance Programme of India (MvPI) has developed the following tools for better medical devices adverse event reporting and management in consultation of CDSCO and NHSRC.

- Medical Device Adverse Event Reporting form version 1.1 (Please click) (Annexure I)
- Field Safety Corrective Action Form (Please click). (Annexure II)
- Registered Medical Devices Information Sharing Portal (Please click). (Annexure III)

Now these tools are available for comment/suggestions for stakeholders. Stakeholders are requested to offer their comments if any on or before 31st December 2018

http://www.ipc.gov.in/mandates/pvpi/materiovigilance-programme-of-india-mvpi.html?id=597:medical-devices-adverse-event-reporting-tools&catid=2

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