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TGA Australia's Pharmacovigilance Inspection Program (PVIP)

TGA
Health Safety Regulation

Following a successful pilot program conducted in 2015-16, the TGA's Pharmacovigilance Inspection Program (PVIP) has been implemented as an initiative to help sponsors of medicines to meet their pharmacovigilance obligations. The launch of the program in September 2017 was preceded by substantial stakeholder engagement and consultation, particularly with medicine sponsors. The rollout was supported by a series of information sessions held around the country. Between July 2017 and June 2018, 10 inspections were scheduled; and total 5 inspections were commenced. Inspection findings included 0 critical, 25 major and 12 minor observations. More details can be referred from following weblink:

https://www.tga.gov.au/sites/default/files/presentation-update-post-market-regulatory-requirements.pdf

UAE MOH guidelines in Good Vigilance Practice 2018

وزارة الصحة
MINISTRY OF HEALTH

Ministry of Health and Prevention UAE has released UAE MOH Guidelines in Good Vigilance Practice (GVP) For Marketing Authorization Holders / Pharmaceutical Manufacturers In UAE last month. This guideline was prepared as a result of the discussions and recommendations of the National Pharmacovigilance committee of the Ministry of Health and Prevention and other Local Health Authorities in UAE. All pharmaceutical companies/ Marketing Authorization Holder (MAH) whose products are registered and marketed in UAE must have a system in place for documenting following Objectives:

- Pharmacovigilance systems and their quality systems
- Pharmacovigilance System Master File (PSMF)
- Pharmacovigilance Inspections
- Pharmacovigilance audits
- Risk management systems
- Management and reporting adverse reactions to medicinal
- Products Periodic safety update reports (PSURs)
- Post authorization safety studies
- Signal management
- Safety communication
- Risk minimization measures

More details can be referred from following weblink:

http://www.mohap.gov.ae/Files/MOH_OpenData/1404/UAE%20MOH%20GVP%20Guidlines%202018-c.pdf

Central Drugs Standard Control Organization, India - Guidance (DRAFT) on Risk Based Programme for Pharmacovigilance Inspections of Market Authorization Holders (MAHs) for Human Medicinal Products

The Central Drugs Standard Control Organization (CDSCO) is seeking feedback a proposed risk-based pharmacovigilance inspection model. CDSCO plans to adopt a four-year cycle for pharmacovigilance inspections and prioritize the assessment of companies that introduce new drugs to the market.

Indian legislation tasks companies with setting up post-marketing surveillance programs that collect and process adverse event data for forwarding on to the licensing authority. CDSCO published a guide to help marketing authorization holders comply with these requirements around the start of the year, but has said less publicly about how it will enforce the rules. That began to change last month when the regulatory agency met with industry groups to discuss the draft guidelines it was developing.

Having presented the guidelines to those groups, CDSCO has now shared the document publicly. The strategy proposed by CDSCO has two components. CDSCO will conduct routine inspections of drug companies every four years. The exact time between inspections will depend on CDSCO's perception of the risk posed by a company. In parallel, CDSCO will conduct "triggered" inspections of companies it has reason to think may not be complying with the pharmacovigilance requirements.

The draft guidelines set out how CDSCO will prioritize routine inspections. Companies with new drugs on the market will move toward the top of the queue. CDSCO will also factor in the company's inspection history, whether it outsources some or all of its pharmacovigilance activities and its sales volumes. Finally, CDSCO will pay particular attention to companies that make a lot of post-approval changes or are the subject of complaints by government bodies and procurement agencies.

CDSCO is accepting feedback on the draft until the end of October.

Draft Guideline can be assessed through following link:

http://www.cdsco.nic.in/writereaddata/dps.pdf

Revised USFDA expectations for Postmarketing Adverse Drug Experience (PADE) Reporting Inspections

Postmarketing safety data collection and adverse event reporting is a critical element of the Agency's Postmarketing safety surveillance program for United States Food and Drug Administration (USFDA) regulated drug products. The USFDA has several obligations for Pharmaceutical companies to ensure that patient safety is considered as priority along with Good Pharmacovigilance Practices. There is a consistent increase in efforts from USFDA inspectors to ensure that companies comply with all regulations, which is most important in terms of human interest. In cases of noncompliance, various enforcement actions can be considered by USFDA which can result in withdrawal of marketing authorization of products or other serious outcomes. In September 2018, USFDA has updated PADE reporting inspection guidelines as part of their BIMO compliance program. More details can be accessed via following link:

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/UCM332013.pdf

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 1-4 October 2018

PRAC recommends restrictions on use of fluoroquinolone and quinolone antibiotics - Following a review of disabling and potentially long-lasting but very rare side effects reported with fluoroquinolone and quinolone antibiotics, the PRAC has recommended that they should only be used to treat infections when an antibiotic is essential and other antibiotics cannot be used. PRAC confirms precautionary advice on HIV medicine dolutegravir - The PRAC confirmed its precautionary advice issued earlier this year on the use of dolutegravir in pregnant women and women who can become pregnant. Women who can become pregnant should use effective contraception while taking dolutegravir. In addition, women should undergo pregnancy testing before starting treatment and the medicine should not be used during the first trimester of pregnancy unless there is no alternative. Further details can be accessed via below link:

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-1-4-october-2018

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