Saudi Vigilance Requirements

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Pharamacovigilance in Saudi Arabia: Rules and Requirements
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Public health Safety

30 Years of Essential Medicines

Safety comes first

La seguridad es lo primero

La sécurité d’abord
Pre-test

- ADRs
- PSURs
- SUSAR
- SFDA
- CIOMS
- E2B
- ADR1
- PQ-1
- MedDRA
- GPvP
Pharmacovigilance (PV)

• The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem*

• Pharmacovigilance database**
  – A collection of safety information stored on a computer in a defined and structured form
  – Allowing adding new information and retrieval of older information in different formats and reports

*World Health Organization

**Practical drug safety from A to Z
• Pharmacovigilance Plan
  – Development of methodology to study and track adverse events and other safety issues associated with drugs (new drug)
  – Should have a specific series of steps or actions that will track, record, and analyze safety issues that arise in the use of a drug
ROLES
Centro de Servicios Empresariales

RESPONSIBILITY
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Marketing Authorization Holders (MAHs)

• To ensure that
  – It has an appropriate system of pharmacovigilance and risk management in place
  – To assure responsibility and liability for its products on the market
  – To ensure that appropriate action can be taken, when necessary
MAH

• Ensure that all information relevant to the risk-benefit balance of a medicinal product is reported to the Saudi Food and Drug Authority (SFDA) fully and promptly in accordance with the legislation.

• Documentations!!!!
Roles and Responsibilities

• Establish and maintain a system to collect, collate, and evaluate pharmacovigilance data

• Meet legal obligations for reporting of suspected adverse reactions

• Meet legal obligations regarding the preparation and the submission of Periodic Safety Update Reports (PSURs)
Roles and Responsibilities

• Respond fully to requests from SFDA for additional information necessary for the evaluation of the benefits and risks of a medicinal product

• Ensure the marketing authorization is maintained and reflects the latest information

• In case of absence of the QPPV, all responsibilities should be undertaken by an adequately qualified person
Roles and Responsibilities

• Each company (i.e. Applicant/MAH or group of MAHs)
  – Should appoint one Qualified Person Responsible for Pharmacovigilance (QPPV)
  – Responsible for overall pharmacovigilance for all medicinal products for which the company holds marketing authorizations within Saudi Arabia
  – QPPV should be placed in Saudi Arabia
Roles and Responsibilities

• The QPPV should be qualified, with documented experiences and training in all aspects of pharmacovigilance

• The name and 24-hour contact details of the QPPV and back-up procedures
Qualified Person Responsible for Pharmacovigilance (QPPV) (QP)

- Individual, usually an employee of a pharmaceutical company, who is personally responsible for the safety of the human pharmaceutical products marketed by that company in “Saudi Arabia”
Role and Responsibilities

• Establishing and maintaining/managing the MAH’s Pharmacovigilance system
  • Adverse drug reactions/medication errors
  • Drug quality/Risk Management Plans
  • Health care professional and consumers
  • Periodic Safety Update Reports (PSURs)

• Having an overview of the safety profiles and any emerging safety concerns in relation to the medicinal products for which the MAH holds authorizations
Role and Responsibilities

• Conducting continuous pharmacovigilance evaluation

• Response to any request from the SFDA

• Provide the SFDA any other information relevant to the evaluation of the benefits and risks of a medicinal product

• Acting as a single contact point for the SFDA on a 24-hour basis
• Follow-up of reports for missing information and for information on the progress and outcome of the case(s)
• Detection of duplicate reports
• Expedited reporting
• PSURs
Qualifications

• QPPV should have at minimum:
  – Bachelor degree in Pharmaceutical Sciences; or,
  – Bachelor Degree in Medicine
  – Training in Pharmacovigilance and drug safety
Pharmacovigilance System

• QP contact details
  – All information (Name, degree, training, CV…etc)

• Organization structure
  – Company information (e.g. therapeutic areas/world-wide presence, how the pharmacovigilance is managed within the organization)
Pharmacovigilance System

• Pharmacovigilance system
  – Provide summary of the pharmacovigilance activities
  – How the company ensures the Saudi legislative requirements are met; (examples)
    • The activities of the QPPV and the back-up procedure to apply in their absence
    • The collection, processing (including data entry and data management), quality control, coding, classification, medical review and reporting of ICSRs
    • Process for PSUR preparation and submission to SFDA
    • Processes for signal detection and labeling change/update
    • Risk Management Plans
Pharmacovigilance System

• Computerized system and database
  – Provides details of the computerized system(s) & database(s) used to collect, collate and evaluate information about suspected adverse reactions

• Training
  – Training for all QPs and other staff who involved in drug safety issues

• Documentation
  – Provides a brief description of archiving activities for pharmacovigilance documents
Pharmacovigilance System

• Regulatory Reporting Compliance Statistics
  – For the last two years, a breakdown per month to include:
    • Total number of ADR reports (non-serious and serious) received by company (on a global basis)
    • Total number of ADR reports submitted
    • Total number of PSUR submitted

• Quality Management System
Quality Management System

- Quality control and assurance procedures
- Standard Operating Procedures (SOPs)
- Database operations
- Compliance data
  - Quality and completeness of reports
  - Timeliness for expedited reporting and submission of Periodic Safety Update Reports
- Audit reports and training of personnel in pharmacovigilance
Inspection

• To ensure that MAHs comply with pharmacovigilance regulatory obligations

• Routine Vs targeted
  – Targeted inspections may arise when one or more of the following arise:
    • No safety concern
      – The MAH has not previously been inspected;
      – The MAH has placed their first product on the Saudi market;
      – The MAH has recently been or is involved in a merger or takeover process
Inspection

• Routine Vs targeted
  – Targeted inspections may arise when one or more of the following arise:
    • Safety concern
      – Delays in expedited or periodic reporting;
      – Incomplete reporting;
      – Submission of poor quality or incomplete PSURs;
      – Inconsistencies between reports and other information sources;

• Pharmacovigilance System Inspections
  – Review the systems, personnel, facilities in place
Inspection

• Product-Specific Inspections
  • Focus specifically on a given product
  • Usually targeted as a result of triggers that have been identified

• Inspections of Contractors and Licensing Partners
  • Any party carrying out pharmacovigilance activities in whole or in part on behalf of, or in conjunction with, the MAH
  • To confirm their capability to support the MAH’s compliance with pharmacovigilance obligations
Inspection

- Inspections outside Saudi Arabia
  - Routine or targeted

- Unannounced Inspections
  - The majority of inspections will be announced.
  - However, on occasions, it may be appropriate to conduct unannounced inspections or to announce an inspection at short notice
Inspection

• Inspection Reports
  • Each inspection will result in an inspection report
  • A copy will be available to the SFDA and MAH

• Follow-up of Inspection Findings
  • Non-compliance
  • MAH will be required to prepare a remedial action plan to correct the non-compliances and avoid their recurrence
  • Re-inspection
Inspection

• Type of inspection findings
  – Critical
    • A finding that impacts the validity or usability of data,
    • Has a significant subject protection or safety impact,
    • Has a significant and immediate regulatory impact
    • This category includes the findings of fraud, as well as repeated or deliberate actions such as non-reporting of reportable ADRs, misrepresenting or hiding data, etc
  – Major
    • A violation of a requirement, which individually would not directly impact data usability or validity or patient safety and regulatory compliance
Inspection

• Type of inspection findings
  – Minor
    • Findings other than critical or major ones such as non-adherence to internal SOPs or requirements
Inspection

• Regulatory Action
  • Education and Facilitation
    – MAHs may be informed of non-compliance and advised on how this can be remedied

• Inspection
  – Non-compliant MAHs may be inspected to determine the extent of non-compliance and then re-inspected to ensure compliance is achieved

• Warning
  – SFDA may issue a formal warning reminding MAHs of their pharmacovigilance regulatory obligations
Inspection

• Regulatory Action
  • Naming non-compliant MAHs
    – SFDA will consider a policy of making public a list of MAHs found to be seriously or persistently non-compliant

• Variation of the Marketing Authorization
• Suspension of the Marketing Authorization
• Revocation of the Marketing Authorization
SOPs

• Each pharmacovigilance office at each MAH should have a detailed written SOPs for each process (for examples):
  – Submitting ADRs
  – Expedited reporting procedures
  – Submitting PSURs
  – Work flow
  – Information confidentiality
Pharmacovigilance Software

• Each MAH should have a database or software that include all data related to pharmacovigilance
  – ADRs
  – PSURs
Sales and leaflet information

• MAH should provide the SFDA with the updated leaflet on each product that marketed in Saudi Arabia

• The leaflet should include the last updated one (i.e. updated indication/safety profile)

• Provide information on product sales
Training

• QPPVs must take training in Pharmacovigilance and drug safety from a well known organization

• Training courses, workshops, forum
  – Saudi Food and Drug Authority (SFDA)
  – Each MAH
  – www.diahome.org
  – www.who.int
  – www.isoponline.org
11105 5th European Forum for Qualified Person for Pharmacovigilance (QPPV)

Overview:
Title: 5th European Forum for Qualified Person for Pharmacovigilance (QPPV)
Date(s) And Time(s): May 10 2011 1:00PM - May 12 2011 5:30PM
Location: Novotel London St Pancras 100 - 110 Euston Road London NW1 2AU United Kingdom

Interest Area(s): Outsourcing, Clinical Safety/Pharmacovigilance, Pharmacology, Regulatory Affairs

Overview:
This is the 5th European Forum for Qualified Person for Pharmacovigilance (QPPV). The role of the QPPV continues to be an important one and it is vital to remain abreast of any areas likely to impact on this role. Changes may

11542 Training Course on How to Prepare for Pharmacovigilance Audits and Inspections

Overview:
Title: Training Course on How to Prepare for Pharmacovigilance Audits and Inspections
Date(s) And Time(s): May 10 2011 1:30PM - May 11 2011 3:30PM
Location: Hotel Mercure Amsterdam Aan De Amstel Joan Muyskenweg 10 1096 CJ Amsterdam Netherlands

Interest Area(s): Clinical Research, Clinical Safety/Pharmacovigilance, Project Management, Quality Assurance/Quality Control, Regulatory Affairs, R

Overview:
Every pharmacovigilance function will, at some point or another, undergo governmental or health authority inspections as well as audit partners, internal auditors and others. The course will teach you how to prepare for an audit / inspection from the time of the receipt
Some Pharmacovigilance Resources

Saudi Pharmacovigilance Guideline of Registered Medicines for Human Use  
www.sfda.gov.sa

An Introduction to Pharmacovigilance by Patrick Waller  
www.ema.europa.eu  
www.mhra.gov.uk  
www.fda.gov

Manual of Drug Safety And Pharmacovigilance by Barton Cobert
Thank you