Generic Industry Postmarket Surveillance Practice

Presentation to Workshop on Substitutability of Generic Drugs: Perceptions and Reality

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Applicable US Post-marketing Safety Reporting Requirements

Regulation or Law	Product
21 CFR § 310.305	Prescription drugs marketed for human use without approved new drug applications
21 CFR § 314.80	Drugs with approved new drug applications (NDAs)
21 CFR § 314.98	Drugs with approved abbreviated new drug applications (ANDAs)
21 CFR § 600.80	Biologics with approved biologics license applications (BLAs)
21 CFR § 1271.350	Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)
Section 760 of the FDCA	Nonprescription human drug products marketed without an approved application

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Perspective of a Global Generic

-Global approach

-Processes designed to be in Global compliance

-Presentation focused on FDA's post-marketing surveillance requirements, noting additional factors

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ICSRs Case Processing

Adverse drug experiences, Special Situations (abuse, off-label use, misuse, pregnancy)

-Serious and Non-serious adverse experiences evaluated

-Case cycle closed to be in compliance with expedited reporting

-Expedited reporting done

-Mandatory electronic post-marketing safety reporting

-Periodic reports submitted as per CFR

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Lack of Efficacy, Literature Search & Regulator Database

-Lack of efficacy reports and product complaints evaluated

-Global literature search conducted weekly for all drugs to inform the safety profile and to identify case reports

-Regulator Safety database monitoring

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Periodic Adverse Drug Experience Reports

Timetable based on requirements

-At quarterly intervals for the first 3 years from date of approval, and then at annual intervals thereafter

-Quarterly reports submitted within 30 days of close of the quarter

-Annual reports submitted within 60 days of anniversary date of approval

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REMS

As an ANDA holder, participate in the common REMS programs for approved drugs and development of REMS for drugs awaiting approval

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Post-marketing Safety Studies

Participate in surveillance studies e.g.

- Anti-Retroviral Pregnancy Registry
- Anti-Epileptic Registry

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Other activities(1)

- Safety Signal Management
- Active Drug Safety Committee reviewing all necessary information and agree on actions/communications to stakeholders
- PVAs/SDEAs with Business Partners for specific PV responsibilities incl.
  - Post-marketing ADRs collection/reporting
  - Ongoing reconciliation of ADE/ADR reports
  - Scientific Literature search(global/local)
  - PADERs
  - Validated Drug Safety Database

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Other Activities(2)

-Integrated PV throughout product lifecycle, incorporating data from e.g. Sales & Marketing, Medical Information, Regulatory Affairs

-QA audit of entire Global PV system, incl affiliates, CROs, other 3rd parties to ensure suitable processes followed to a high standard

-Same Agency inspection process/expectations, as per Chapter 53 (Post marketing Surveillance & Epidemiology: Human Drug & Therapeutic Biological Products) FDA Compliance Program Guidance Manual

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Standardized Operating Procedures

Entire PV System/Processes – Written Procedures

-Data collection, Source Data extraction, Follow-up information, 15-Day Alerts

-Case Processing up to Regulatory submission

-PADER/PSUR/PBRER

-Safety Signalling

-Drug Safety Database Management

-REMS/RMP

-PVAs & SDEAs

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Conclusion

-Generic post-marketing surveillance is held to the same standard as innovator-NDA holders

-Absolutely no difference in regulatory requirements

-There is no difference in generic industry post-marketing surveillance practices

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References

-21 CFR

-CIOMS V, Current Challenges in Pharmacovigilance: Pragmatic Approaches, 2001

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