Periodic Safety Update Report

Module 9 Topic 5

PSUR?

- Its a formal, structured update of the worldwide safety experience for a registered medicinal product (per ICH E2C standards), prepared for submission to regulatory authorities at defined times post-authorisation.

Why?

- report all the relevant new safety information from appropriate sources;
- relate these data to patient exposure;
- summarise the market authorisation status in different countries and any significant variations related to safety;
- create periodically the opportunity for an overall safety re-evaluation;
- indicate whether changes should be made to product information in order to optimise the use of the product.

New drug and CT rules say…..

- The PSURs shall be submitted every six months for the first two years after approval of the drug is granted to the applicant.
- For subsequent two years – the PSURs need to be submitted annually.
- Licensing authority may extend the total duration of submission of PSURs if it is considered necessary in the interest of public health.
- PSURs due for a period must be submitted within 30 calendar days of the last day of the reporting period.

ICH region says….

- The US regulations require quarterly reports during the first 3 years, then annual reports.
- In the EU, Council Directive 93/39/EEC and Council Regulation 2309/93 require reports with a periodicity of 6 months for two years, annually for the three following years and then every five years, at time of renewal of registration.
- In Japan, the authorities require a survey on a cohort of a few thousand patients established by a certain number of identified institutions during the 6 years following authorisation. Systematic information on this cohort, taking into account a precise denominator, must be reported annually.

Glossary Of Special Terms

- **Company Core Data Sheet (CCDS)** – A document prepared by the MAH containing, in addition to safety information, material relating to indications, dosing, pharmacology and other information concerning the product.
- **Company Core Safety Information (CCSI)** – All relevant safety information contained in the Company Core Data Sheet prepared by the MAH and which the MAH requires to be listed in all countries where the company markets the medicinal product, except when the local regulatory authority specifically requires a modification. It is the reference information by which **listed** and **unlisted** are determined for the purpose of periodic reporting for marketed products, but not by which expected and unexpected are determined for expedited reporting.

Glossary Of Special Terms

- **Data Lock-Point (Data Cut-off Date)** – The date designated as the cut-off date for data to be included in a PSUR. It is based on the International Birth Date (IBD) and should usually be in six-monthly increments.
- **International Birth Date (IBD)** – The date of the first marketing authorisation for a new medicinal product granted to any company in any country in the world.
- **Listed Adverse Drug Reaction** - An ADR whose nature, severity, specificity, and outcome are consistent with the information in the CCSI.
- **Spontaneous Report** or **Spontaneous Notification** – An unsolicited communication to a company, regulatory authority or other organisation that describes an adverse drug reaction in a patient given one or more medicinal products and which does not derive from a study or any organised data collection scheme

Model For A Periodic Safety Update Report

SAMPLE TITLE PAGE

PERIODIC SAFETY UPDATE REPORT FOR: *(PRODUCT)*

MAH's NAME AND ADDRESS *(Corporate headquarters or other company entity responsible for report preparation)*

PERIOD COVERED BY THIS REPORT: *(dates)*

INTERNATIONAL BIRTH DATE: Date *(Country of IBD)*

DATE OF REPORT

(Other identifying information at the option of MAH, such as report number)

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