Module-7:

**European Good pharmacovigilance modules:**

Good Pharmacovigilance practices came in to existence on 2012.

The guidelines on GVP modules are described in two categories:

* Modules covering major Pharmacovigilance process.
* Product or population specific considerations.

The Product or population specific considerations are available for vaccines, biological medicinal products and the pediatric population. EMA considers two more chapters:

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| --- | --- | --- |
| Chapter number | Preliminary chapter title | Date of release for public consultation |
| PIII | Pregnancy and breast-feeding | Q1/Q2 2019 |
| PV | Geriatric population | To be announced |

This information is freely available in EMA website.

Major Pharmacovigilance process includes GVP modules from I to XVI. Modules XI, XII, XIII, XIV are discussed in the guidance documents on the Agency website and as such not described in the module’s mode.

A small and brief explanation of each module:

**GVP Module I: Pharmacovigilance systems and their quality systems.**

It covers the

* Over all organizational structure
* The Pharmacovigilance system responsibilities
* Complete procedures of the system
* Process and Resources of the system
* Appropriate resource management of the system
* Compliance management
* Record management.

**GVP Module II: Pharmacovigilance system master file (PSMF).**

The PSMF is a legal requirement in Europe.

It contains information related to:

* Location of the PSMF and where is it registered.
* Complete contact details of QPPV.
* Organizational structure of marketing authorization holder.
* Various sources of safety data
* Details of database and computerized systems
* The complete Pharmacovigilance processes
* Quality management system.

**GVP Module III: Pharmacovigilance inspections.**

Pharmacovigilance inspections can be

* Routine Inspections-which occurs as a routine follow up.
* For cause inspections-which occurs suspected non-compliance or potential risks that can impact public safety.
* System and product related inspections
* Pre-authorization and post authorization inspections.

**GVP module IV: Pharmacovigilance audits.**

Audits verifies the implementation and operations of the pharmacovigilance systems.

It can be:

* Strategic level audit planning
* Tactical level audit planning

**GVP module V: Risk management system:**

The main of the system is the appropriate risk management thorough out the life cycle of the product.

Risk management plan (RMP) is a dynamic document which will be updated through the life cycle of the product.

RMP explains the safety concerns:

* Important identified risk
* Important potential risk and
* missing information

If any change these safety concerns an update of RMP will be required.

Any important safety information for a product which requires additional risk minimization measures will be explained in the RMP.

**GVP module VI: Collection, management and submission of reports of suspected adverse reactions to medicinal products.**

This module completely explains the collection of Individual case safety reports (ICSRs) and the sources of the ICSRs, and the reporting timelines of the ICSRS.

This stays a basic document for the safety associates and physicians for the case processing.

**GVP module VII: Periodic safety update report (PSUR)**

Periodic safety reports are the reports which are updated on a regular basis estimating the benefits and risks of a medicinal product.

This is not the document to identify and inform the information which is crucial or which needs urgent attention, But the data provided through PSUR are evaluated for the safety information.

In Europe region, EURD (European reference dates) list is maintained online which gives the frequency of submission of PSURs.

**GVP module VIII: Post-authorization safety studies (PASS).**

PASS is a study conducted after the marketing authorization and it can be imposed by authority or conducted by MAH to further evaluate the data of the medicinal product.

These studied are conducted to identify the risks when used in patient population which are not studied in clinical trials, to evaluate the long-term use of the product or to assess the effectiveness of any risk minimization measures.

PASS will have a protocol design to conduct.

**GVP module IX: Signal management.**

Signal management is a process which identifies, validates, prioritizes and further assessment of a signal will be done.

Signal is defined as “Information arising from one or multiple sources, including observations and experiments, which suggests a new potentially causal association, or a new aspect of a known association between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action [IR Art 19(1)]”.

Any important urgent issue identified during the process will be notified in the form of “Emerging safety issue”.

**GVP module X: Additional monitoring**

Even though the drug is marketed, In order to identify the risks in specific targeted population or any risks which cannot be identified during the clinical trials will be monitored further by Additional monitoring.

European medical agency is maintaining a list of Additional monitoring drugs which should be reviewed in quarterly or six-monthly review.

This will be explained in the patient leaf let as inverted black triangle and informed that any adverse events to be reported.

**Module XV – Safety communication:**

This module explains, any safety information which is identified to be communicated in a clear accurate and consistent manner to reach the public and health care profession.

Safety communication can be by:

* Direct healthcare professional communication (DHPC)
* Documents in lay language to patients and the public
* Press communication
* Company website

**Module XVI – Risk minimization measures: selection of tools and effectiveness indicators.**

Safety concerns are usually addressed by routine risk minimization measures, for some products to evaluate the further safety information additional risk measures are required.

It helps in maintaining the risk benefit balance of the product.

This module explains development and implementation of the risk minimization measures.

The implementation can be:

* Educational tools for Health care professionals and public.
* Controlled access programmes
* Pregnancy prevention programme

Measuring the outcome also described in this module.

The status of the GVP modules:

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| --- | --- |
| GVP Module | Status |
| I PhV and Quality system | Published |
| II PSMF | Rev. 2 Published |
| III Pharmacovigilance Inspections | Published |
| IV Pharmacovigilance Audits | Rev. 1 Published |
| V Risk management system | Rev. 2 Published |
| VI ICSR | Rev. 2 Published including Addendum 1 |
| VII PSUR | Periodic Safety Update Reports (Rev. 2) draft is ongoing. |
| VIII PASS | Rev. 3 Published including Addendum 1 (Rev. 2) |
| IX Signals | Rev. 1 Published Addendum 1 |
| X Additional Monitoring | Published |
| XI Participation | Replaced by web information |
| XII Regulatory action | Replaced by other modules |
| XIV International | Replaced by web information |
| XV Safety Communication | Rev. 1 Published |
| XVI RMM | Rev. 2 Published including Addendum 1 |

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| Specific modules | |
| P.I Vaccines | Published |
| P.II Biologicals | Published |
| P.III Pregnancy and breast-feeding | Planned to be released for public consultation in Q1 2018 |
| P. V Geriatrics | Planned to be released for public consultation in Q1 2018 |
| Specific privacy statement | Published |
| Good practice guide on recording, coding, reporting and assessment of medication errors | Published |
| Good practice guide on risk minimisation and prevention of medication errors | Published |