FAQ: PRODUCT QUALITY MONITORING PROGRAMME

1. What is Post-Market Surveillance (PMS)?

Post-Market Surveillance (PMS) refers to monitoring activities carried out after a product has received market authorization. The scope of PMS includes maintenance of product registration status, including variations and renewals; regular inspections of manufacturers, wholesalers, distributors, and retailers; quality control testing; pharmacovigilance activities; promotion control; public reporting of substandard or poor-quality products; handling of market complaints; and removal and disposal of non-compliant products.

PMS is a core regulatory function that encompasses a comprehensive set of quality surveillance activities to ensure the ongoing monitoring and assurance of product quality in the market.

2. What is Product Quality Monitoring (PQM)?

PQM is a component of Post-Market Surveillance (PMS) that focuses on the ongoing monitoring of product quality in the market. It includes proactive and reactive activities such as product sampling, laboratory testing, document assessment, and monitoring of compliance and regulatory actions.

The activities under PQM include:

- Sampling of products
- Laboratory testing
- Assessment of quality control documentation provided by the company, where necessary.
- Monitoring of labelling compliance to ensure adherence to current regulatory requirements.
- Handling of product quality reports.
- Monitoring of regulatory actions taken for non-compliant products.
- Oversight of voluntary product recalls initiated by companies.
- Dissemination of risk communication related to identified product issues.

3. What is the purpose of the PQM program?

The NPRA conducts the PQM program to monitor the quality of registered products available in the market. The PQM programme aims to detect quality defect or non-compliant products in the market with regulatory standards and to take necessary regulatory actions and/or measures in a timely manner to address any potential risks.

4. Are all registered products sampled under the PQM program?

Not all registered products are sampled. NPRA selects products for sampling following a risk-based approach. This includes:

- Proactive sampling of products identified as having a higher risk.
- Reactive or ad-hoc sampling in response to specific triggers such as:
    - Findings from GMP/GDP inspections.
    - Product complaint reports.
    - A history of non-compliance.

Sampled products are sourced from various market channels, including product registration holders (PRHs), wholesalers, distributors, health facilities, pharmacies, and retail premises.

5. What types of quality parameters are tested in the laboratory?

The laboratory testing covers a range of critical quality parameters, including:

- Identification and content of active pharmaceutical ingredients.
- Testing for impurities.
- Dissolution profiles.
- Limits for heavy metals.
- Microbiological contamination.
- Adulterant screening.

6. What happens if a product fails laboratory testing or is found to be non-compliant with labelling requirements under the PQM program?

Regulatory actions will be initiated based on the severity and nature of the non-compliance. These may include issuance of warnings, product recall from the market, suspension, or cancellation of product registration. PRH is responsible for identifying the root cause of laboratory test failures/non-compliance with labelling requirements and taking appropriate corrective and/or preventive action. The NPRA will monitor the regulatory actions taken against the product or company.

7. How are consumers informed when a product is recalled due to quality or safety issues?

An official statement will be released on the NPRA's official website if a product recall could seriously impact consumer health. Consumers may also consult the list of recalled products on the NPRA website (insert link to recall information) for more information.

8. How can industry ensure compliance under the PQM program?

Companies are responsible to ensure the following:

- **Product Specifications and Labelling:** Marketed products adhere to approved specifications and use approved packaging, labels, and package inserts that comply with the latest labelling requirements.
- **Company and Product Information:** Company and product information, particularly test documentation and labelling, is kept up-to-date in the QUEST system.
- **Record Keeping**: Complete quality control and marketing records are maintained for products, in accordance with the principles of Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP).
- **Regulatory Cooperation:**
    - Fully cooperate by submitting product samples, documents, and other testing requirements within the specified timeframe when requested by the NPRA.
    - Providing feedback and supporting documents within the specified timeframe when requested by the NPRA.

Disclaimer: This FAQ is intended for general guidance only and does not replace the official guidelines and regulations issued by the National Pharmaceutical Regulatory Agency (NPRA) Malaysia. Always refer to the latest official documents and contact NPRA directly for specific advice or clarification.