FAQ: QUALITY PRODUCT REPORTING TO NPRA MALAYSIA

This FAQ provides guidance on reporting product quality issues for registered products to the National Pharmaceutical Regulatory Agency (NPRA) in Malaysia.

General Information

1. What is the NPRA?

The National Pharmaceutical Regulatory Agency (NPRA) is an agency under the Ministry of Health Malaysia responsible for ensuring the quality, efficacy, and safety of pharmaceutical products, traditional products, health supplements, and cosmetics in Malaysia.

2. What is "product quality reporting"?

Product quality reporting refers to the process of notifying the NPRA about any issues or defects related to the quality, efficacy, labelling, or packaging of a registered product. This is distinct from reporting Adverse Drug Reactions (ADRs) or Adverse Events Following Immunization (AEFIs), though some quality issues might lead to adverse events.

3. Why is it important to report product quality issues?

Reporting product quality issues is crucial for:

- Protecting public health and safety.
- Allowing NPRA to monitor the quality of products in the market.
- Facilitating investigations into defects and determining necessary market actions (e.g., recalls).
- Ensuring product registration holders (PRHs) and manufacturers maintain quality standards.

4. What kind of products fall under "registered products" for quality reporting?

"Registered products" generally refer to medicinal products (pharmaceutical products, traditional products, health supplements) that have been approved by the Drug Control Authority (DCA) for sale and use in Malaysia. Each registered product has a registration number starting with "MAL".

Who Should Report?

5. Who is responsible for reporting product quality defects to NPRA?

- **Product Registration Holders (PRHs):** The company or legal entity holding the

marketing authorization for the product is primarily responsible for notifying NPRA of any known product defect issues and providing a complete investigation report.

- **Licensed Manufacturers, Importers, and Wholesalers:** These parties also have a responsibility to report product defects, especially if they are aware of them. If there's a business arrangement, at least one party should report, keeping others informed.
- **Healthcare Professionals (Prescribers, Pharmacists, Nurses):** They are encouraged to report any product complaints they encounter, using the designated NPRA complaint form.
- **Consumers:** Members of the public can also report concerns about the quality of medicines they use.

What to Report

6. What constitutes a "product quality defect" or "issue" that should be reported?

A product quality defect (also known as a quality defect) refers to attributes of a medicinal product or component that may affect its quality, safety, and/or efficacy, or which deviates from its registered pharmaceutical properties. Examples include:

- Ineffective medicines.
- Contamination (e.g., foreign particles, microbial growth).
- Incorrect packaging or labelling (e.g., wrong expiry date, missing information).
- Physical defects (e.g., cracked tablets, discolored solutions).
- Stability issues (e.g., product degrading before expiry).
- Suspected counterfeit products.
- Any deviation from the approved specifications or manufacturing standards.

7. What is the difference between a "critical defect" and a "non-critical defect"?

- **Critical Defect:** A defect that can pose a serious threat to the intended users or public health in Malaysia. A serious threat may lead to death or serious injury.
- **Non-critical Defect:** Defects that do not meet the criteria of a "critical defect" but may still cause illness, affect the outcome of medical treatment, and/or affect the product's quality.

How to Report

8. How do I report a product quality issue to NPRA?

- **For Product Registration Holders (PRHs):** You should notify NPRA with a complete investigation report, including root cause analysis and corrective actions, if necessary. Refer to the "Guideline for Product Quality Reporting and Recall Procedures" (Appendix 34 of the DRGD) on the NPRA website for detailed instructions.
- **For Healthcare Professionals:** Use the NPRA complaint form (e.g., BPFK 419 / BPFK

418), ideally with a complaint sample if available.

- **For Consumers:** You can use the "Reporting Form for Medicine Complaint by Consumers" (BPFK 419) which can be downloaded from the NPRA website. This form can be mailed, faxed, or sometimes submitted online.

9. Where can I find the official forms and guidelines?

The relevant forms and guidelines, such as the "Guideline for Product Quality Reporting and Recall Procedures" and consumer complaint forms, are typically available on the official NPRA website (www.npra.gov.my) under sections like "Health Professionals," "Consumers," or "Compliance and Licencing." Look for "Quality Reporting of Registered Product Form [PDF]".

10. What information should I include in my report?

Provide as much detail as possible, including:

- Product name, brand, and registration number (MAL number).
- Batch number and expiry date.
- Name and contact details of the reporter (confidentiality is maintained).
- Detailed description of the defect or issue observed.
- Date and location where the product was obtained.
- Any adverse effects experienced (if applicable, though dedicated ADR reporting exists).
- Photos or samples (if requested or feasible).

After Reporting

11. What happens after I submit a report?

- NPRA will acknowledge receipt of your report.
- All complaints received will be investigated by NPRA and the relevant Product Registration Holder (PRH)/manufacturer.
- NPRA will assess the risk posed by the defect and determine appropriate market actions, including potential product recalls.
- The PRH/manufacturer is responsible for determining and implementing appropriate corrective and preventive actions (CAPA).
- You may be contacted if additional information is needed.

12. Can NPRA initiate a product recall?

Yes, NPRA (specifically the Director of Pharmaceutical Services Division) can direct a product recall if a defect poses an actual or potential risk to product users. Product Registration Holders are also responsible for conducting voluntary recalls in consultation with NPRA.

13. What are the consequences for non-compliance or serious defects?

NPRA may take punitive action against companies involved in serious quality issues, such as adulteration. This can include:

- Cancellation of product registration.
- Recall of all batches of the affected product.
- Revocation or suspension of manufacturer's, import, or wholesale licenses.
- Freezing of transactions for the involved PRH.

Contact Information

14. Who can I contact for general enquiries about product quality reporting?

You can contact the NPRA general line at +603-7883 5400 and ask for the Pharmacovigilance Section or the relevant Quality Reporting section. You can also use their online enquiry form available on the NPRA website.

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.