



NATIONAL PHARMACEUTICAL
REGULATORY AGENCY
(NPRA)

REGISTERED
PRODUCT
QUALITY
REPORTING
&
CONSUMERS
SIDE EFFECTS
REPORTING

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REGISTERED
PRODUCT
QUALITY REPORTING

What is a
Registered Product
Quality Reporting ?

Product Quality Reporting means any complaint involving the possible failure of a product to meet any of the specifications.

Complaint
Classifications

Quality
Efficacy
Labelling &
Packaging

Examples of quality reporting that can be reported:

- The **manufacturing info** is not stated on the label.
(e.g: batch number, expiry date)
- **Tablets changed colour** despite storing in the recommended condition.
- The **medicine is not effective** despite proper administration.

MEDICINE SIDE EFFECTS REPORTING

What to do if you experience a side effect?

Step 1: Talk to your doctor or pharmacist

Note down:

- The name of medicine and doses taken
- How long after taking the medicine did the side effect occur?
- The name of other medicines taken at the same time.

Step 2: Report to the NPRA

Please use Reporting Side Effect to Medicine (ConSERF) to report to the NPRA the side effects that you suspect may be due to the medicine.

WHY REPORT A SIDE EFFECT?

- It helps NPRA to detect new side effects for a medicine.
- Reporting of side effects which are already documented helps NPRA monitor the prevalence of these side effects.
- It helps with the implementation of preventive measures to strengthen the safe use of medicines for everyone.

What is a side effect?

A side effect (adverse drug reaction) is any unwanted effect of a medicine that occurs to a person taking the medication at a normal dose.

Examples of some commonly reported side effects are **itching, rash, swelling, vomiting, nausea and headache.**



EXAMPLES



tablets changed colour



incomplete manufacturing info on label



Visit our website at:
www.npra.gov.my
> Consumers > Reporting >
Quality Reporting on
Registered Product



Download and fill the
complaint form



Post to NPRA or email to:
qpr@npra.gov.my
*Post the complaint sample to NPRA
(if available)*

HOW TO

MAKE

A

PRODUCT

QUALITY

REPORTING?

