

PRODUCT QUALITY REPORTING & CONSUMERS

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REPORTING

SIDE EFFECTS

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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 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.

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.

HOW TO **MAKE** A **PRODUCT QUALITY** REPORTING?



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)

EXAMPLES



tablets changed colour



incomplete manufacturing info on label

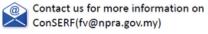
HOW TO REPORT MEDICINE SIDE EFFECTS?

Visit our website at:

www.npra.gov.my
> Pengguna> Pelaporan> Pelaporan
Kesan Sampingan Ubat-Ubatan
(ConSERF)

Report directly online through ConSERF webform

Download the form and fill it in, then email to fv@npra.gov.my



EXAMPLE

