SOP 18 Reporting Adverse Reactions and Quality Defects

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Approved by (Supervising Pharmacist)	
Pharmacy to which this SOP relates	
Date of Implementation in this Pharmacy	
Roles to which this SOP relates	Pharmacists Pharmacy Assistants Pharmacy Interns/APPEL Students Pharmacy Technicians and Trainee Pharmacy Technicians Dispensary Staff

Allcare Pharmacy

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1. Introduction

1.1 Context

Pharmacists have a duty of care to promote and protect public health, which includes responsibly reporting adverse reactions and quality defects.

Compliance with this SOP will ensure that mandatory procedures for reporting to the Health Products Regulatory Authority (HPRA) and the manufacturer will be adhered to.

The HPRA specifically asks for compliance from Healthcare Professionals in reporting the following:

- All suspected teratogenic reactions
- All suspected reactions to new medicines (i.e. those authorised in the last 5 years)
- All suspected reactions to vaccines
- Serious suspected reactions to established products
    - 'Serious' in defined by the HPRA as a reaction that results in death, is life--threatening, requires in-patient hospitalisation, results in disability or incapacity, or results in congenital anomaly/birth defect
- Any suspected increase in frequency of non-serious reactions

1.2 Purpose

Adherence to this policy will ensure that:

- All Adverse Reactions and Quality Defects are reported in line with HPRA guidelines and European pharmacovigilance legislation.
- Patient safety is maintained at all times.

This SOP must be used in conjunction with all relevant SOPs including:

- SOP22 Use of Patient Consultation Areas
- SOP 49 Data Protection
- SOP 52 Using Healthmail

1.3 Scope

- This SOP applies to all staff involved in the dispensing process in the pharmacy.
- It is the ultimate responsibility of the supervising pharmacist to ensure that all staff are appropriately trained, and the SOP is implemented.
- It is also the responsibility of the supervising pharmacist to ensure this SOP reflects the day-to-day practice in their pharmacy.
- All pharmacists are expected to exercise their professional judgement when needed.

2. Procedure

2.1 Patient Presentation

- A patient reporting a suspected adverse reaction to a medicine (human or veterinary) or a cosmetic or reporting a suspected defect should be referred to the pharmacist on duty.
- Pharmacists have a professional and regulatory obligation to report suspected adverse reactions or quality defects.
- The pharmacist should take a thorough patient medical and medication history to establish the relevant information.
- As some adverse reactions may not be apparent to the patient, pharmacists should be alert to the possibility of their occurrence. Clinical observations and initiative are vital in this respect, linking signs or symptoms to current or previous therapies.
- Pharmacists should be particularly alert to:
    - Abnormal clinical measurements (e.g. temperature, pulse, blood pressure, blood glucose, body weight)
    - Abnormal biochemical or haematological laboratory results
    - New drug therapies initiated which may be treating the symptoms of an adverse reaction to another medicine
    - The patient's own concerns regarding their drug therapy
- Patient suffering from adverse reactions or who have taken medicines suspected to be defective should be referred for medical examination.

2.2 What are Adverse Reactions and Quality Defects?

- An '**Adverse Reaction'** is defined by legislation as "a response to a medicinal product which is noxious and unintended".
    - Type A (Augmented) adverse reactions are the result of an exaggeration of a drug's normal actions.
    - Type B (Bizarre) reactions are idiosyncratic responses not expected from the known pharmacological actions of the drug.
    - Reactions can also be classified as Type C: Chronic (Dose-related and time-related), Type D: Delayed (Time-related), Type E: End of use (Withdrawal) and Type F: Failure (Unexpected failure of therapy)
- Adverse reactions following use of a medicine outside of the terms of it's marketing authorisation should still be reported to the HPRA. This includes incidents of overdose, misuse or error.
- A **'Quality Defect'** can be defined as an unplanned attribute of a medicinal product, an investigational medicinal product or a component of such (e.g. active pharmaceutical ingredient) which may affect the quality, safety and/or efficacy of a product and which is not in line with the approved marketing authorisation/product registration.

2.2 How to report an Adverse Reaction or Quality Defect

- Healthcare professionals and patients are strongly encouraged to report suspected adverse reactions to the HPRA.
- Patients have a legal right to report adverse reactions themselves directly to the HPRA. The Patient Information Leaflet enclosed with each medicine includes information for the patient on how to report suspected Adverse Reactions.

- Suspected Adverse Reactions or Quality Defects should be reported to the HPRA by one of the following methods:
    - Online using the HPRA website (www.hpra.ie)
        - Click on 'Report an issue'
        - Select the relevant online reporting form (e.g. human, veterinary, medicine quality issue/defect, medical device adverse incident)
    - Download a form from the HPRA website to fill out manually and return via email or post
    - Using the traditional 'Yellow Card' system. Cards can be obtained from the HPRA.
    - By telephone to the HPRA Pharmacovigilance Section on 01-6764971
- For convenience, pharmacists may wish to print out the relevant downloadable form to complete with the patient in the pharmacy consultation room for later uploading onto the HPRA website.
    - Please note that the online system does require reporter details and a contact email address in order to submit a report.
- For all Adverse Reaction reports, the following criteria must be provided:
    - A patient identifier (e.g. initials/age/sex/record number)
    - An identifiable medicinal product
    - An identifiable reporter
    - An identifiable reaction
- Further information such as relevant medical history, concomitant treatment(s), actions taken, patient outcome and any relevant in-use circumstances are also extremely helpful in the evaluation of a suspected Adverse Reaction. Obtaining as much information as possible initially will help to reduce the need for subsequent follow up of individual cases.
- When reporting a quality defect, it is important to provide as much information as possible including:
    - Exact name (brand), form and strength of product
    - Container type/size
    - Batch number and Expiry Date
    - Manufacturing Authorisation Number and Holder
    - Wholesaler Name
    - Manufacturer Name
    - Details of the defect and who noticed the defect
- Where possible, samples of defective medicines should be retained in the pharmacy for forwarding on to the HPRA if requested.
- Where the online system has been used for reporting, a hyperlink to a copy of the report will be generated and it will also be attached to the acknowledgement email. This report should be printed and placed in an 'Adverse Event' folder in the dispensary.
- The manufacturer should also be notified of the suspected adverse reaction or defect. Their contact details can be found in the product's Summary of Product Characteristics (SmPC) which is accessible via the HPRA website.

2.3 Additional Monitoring

- All medicinal products that receive a Marketing Authorisation (MA) or license, do so on the basis of a positive benefit-risk profile at the time of authorisation. This will be based on a relatively small number of patients who took part in clinical trials. After authorisation, a large number of patients may use the drug in less controlled circumstances and new, less

common Adverse Reactions may emerge. That is why it is important that the safety of all drugs is monitored throughout their period of usage in clinical practice.

- The additional monitoring status of a medicine is indicated by the presence of an inverted black triangle symbol "▼", accompanied by an explanatory statement encouraging the reporting of ADRs, in the Summary of Product Characteristics (SmPC) and the Package Leaflet. This status is always applied to new active substances, biological medicines, medicines with conditional approval or approved under exceptional circumstances or if the company marketing a medicine is required to carry out additional studies (e.g. on long term use or rare side-effects).
- Any medicine can be placed under additional monitored based on a decision by the European Medicines Agency (EMA)'s Pharmacovigilance Risk Assessment Committee (PRAC).
- The list of medicines under additional monitoring is updated monthly and published on the EMA's website.

2.4 Cosmetics

- Retailers of cosmetics have an obligation to inform suppliers and/or the HPRA if a customer experiences an undesirable effect (adverse reaction) after using a cosmetic product.
- In the event of a serious undesirable effect occurring, it must be reported, without delay, to the HPRA and the company at the European address on the product label. The following details should be reported:
    - The name of the relevant cosmetic product so it can be identified;
    - All serious undesirable effects that you are aware of related to this product;
    - Any corrective action taken. This might include stopping a product from being sold.
- Report forms are available from the HPRA.

2.5 Record-keeping

- A record of any suspected adverse reactions or quality defects reported by a patient and the date the HPRA was notified should be documented on the **Patient Medication Record (PMR)** on the MPS dispensing software.
- The prescriber should be notified and any outcomes from discussion with the prescriber documented. If the prescriber is not the GP, ensure that the patient's GP is made aware of any adverse events that have been reported to you.
- Adverse Drug Reactions should also be logged on **Pharmapod** website under the 'Incident' tab. Once completed a hard copy of this incident report can be printed off and kept in an 'Adverse Event' folder in the dispensary which should include all correspondence from the HPRA or manufacturer relating to adverse drug events.

3. Data Protection

- Patients should be reassured that the Adverse Reaction Report will only contain anonymised patient identifiers which will allow the reporter to identify the patient but not the HPRA.
- The HPRA operates the national system for recording and reporting details of suspected adverse reactions occurring in Ireland. These reports are submitted to the HPRA by healthcare professionals, patients and indirectly from pharmaceutical companies, through the European Medicines Agency's database, known as 'EudraVigilance'.

- Adverse reaction reports may comprise personal data such as age, sex and 'special categories' of personal data, in particular, health data, such as the condition being treated and the effects experienced.
- Contact details included on adverse reaction report forms are used solely for the purposes of interaction regarding the report submitted. The HPRA may seek further information from any healthcare professional(s) nominated by the patient for additional information, following provision of their contact details and an indication of consent to so.
- The HPRA is legally obliged to collect adverse reaction reports to human medicines and also to transmit details of adverse reaction reports received (excluding personal identifiers and contact details) to the EudraVigilance Database. This database is owned and administered by the European Medicines Agency (EMA), which is an agency of the European Union and is also subject to the laws of the European Union.

4. Useful References

- S.I. No. 272 of 2012 (Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2012)
- S.I. No. 273 of 2012 (Medicinal Products (Control of Manufacture) (Amendment) Regulations 2012)
- S.I. No. 274 of 2012 (Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2012)
- National Medicines Information Centre Bulletin Volume 25 Number 4, 2019 Adverse reactions to medicines.
- The Healthcare Products Regulatory Authority website – www.hpra.ie

5. SOP Amendments

- Version 2 – May 2015: Required review. Updated
    - To reflect changed of name from Irish Medicines Board (IMB) to Health Products Regulatory Authority (HPRA)
    - To include a link to a list of medicines which require additional monitoring
- Version 3 – March 2017: Required review. Updated to include PSI record keeping requirements
- Version 4 – October 2019: Required review: Reformatted
    - Section 1: Definition of Quality Defect moved to Section 2.2
    - Section 2 Rewritten
        - Section 2.1 Added – Patient presentation
        - Section 2.4 Added - Cosmetics
        - Modified Section 2.2 to 2.5 Record-keeping – added reference to Pharmapod
        - Section 2.6 Biological Traceability incorporated into additional monitoring section
        - Removed Section 2.7 New levels of transparency – no longer relevant
    - Added Section 3 Data Protection
    - Added Section 4: Useful References