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Repackaging: Guidelines for Healthcare Facilities (1998)

Canadian Society of Hospital Pharmacists
Société canadienne des pharmaciens d'hôpitaux

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Repackaging: Guidelines for Healthcare Facilities

PREFACE

This is the 1998 edition of the Canadian Society of Hospital Pharmacists (CSHP) Repackaging: Guidelines for Healthcare Facilities. Pharmacy departments often have to repackage drugs because the required quantities are not commercially available. These guidelines were developed to assist pharmacists working in health care facilities in assessing current repackaging practices and in developing appropriate procedures and controls for drug repackaging within their own facilities.

These guidelines were approved under the title of Guidelines for Repackaging Products in Health Care Facilities; the title was fine-tuned in 2009.

1. SCOPE

1.1

These guidelines establish minimum requirements for pharmacy departments which engage in the repackaging of drug products, and are intended to optimize the quality and safety of repackaged pharmaceuticals.

1.2

These guidelines are intended to augment but not to replace the department's existing policies and procedures relative to repackaging.

1.3

These guidelines are not intended to include intravenous admixtures prepared using commercially available Injectable products. In preparing intravenous admixtures, the pharmacist should refer to the Sterile Preparation of Medicines: Guidelines for Pharmacies.

1.4

The pharmacist may also refer to the Pharmacy Technicians: Guidelines on the Delegation of Functions to Pharmacy Technicians.

2. GLOSSARY OF TERMS, ABBREVIATIONS, AND SYMBOLS

The definitions given below apply to the terms used in these guidelines. They may have different meanings in other contexts.

Commercially available (product)	A pharmaceutical product authorized for use in Canada by the Health Protection Branch, Health Canada, i.e. notice of compliance received, a Drug Identification Number (DIN) assigned, and marketed in Canada.
Pharmacy control number	A unique number assigned to each batch of repackaged product. This number can be used to trace back to the repackaging record, lot number, and original expiry date. Where computerized packaging equipment does not allow a unique number, the manufacturer's number can be used.

3. PERSONNEL

All repackaging shall be conducted under the supervision of a pharmacist who possesses the knowledge, experience and ability deemed necessary by the director to assume the responsibility for same.

4. PREMISES

The area designated for repackaging shall:

a) be sanitary;
b) permit effective cleaning of all surfaces;
c) minimize the potential for contamination of the drug; and
d) be conducive to the orderly flow of work.

5. EQUIPMENT

The equipment used in repackaging shall:

a) permit the effective cleaning of its surfaces;
b) minimize the potential for contamination of the product;
c) be operated only for its intended use; and
d) be maintained under health care facility policies and procedures pertaining to health and safety.

6. REPACKAGING CONTROL

6.1 Procedures

Written procedures shall be in place for repackaging to ensure that the end product will meet the specifications for that product.

6.2 Repackaging Records

6.2.1

A separate repackaging record shall be kept for each batch repackaged. This may be manually produced or maintained in a computerized database.

6.2.2

The repackaging record shall include:

a) generic name of drug;
b) name of manufacturer;
c) dosage form;
d) strength;
e) pharmacy control number;
f) manufacturer's lot number;
g) date of repackaging;
h) number of units repackaged;
i) quantity in each unit repackaged;
j) expiry date of the original container;
k) expiry date of the repackaged container;
l) identification of the repackager and checker;
m) a sample of the label; and
n) a description of packaging materials and equipment used.

6.2.3

Records should be kept for an appropriate period of time.

Note: *The Good Manufacturing Practice (GMP) Guidelines, Therapeutic Products Program, Health Canada, suggest a period of one year after the expiration date on the original manufacturer's label.*

6.3 Pharmaceutical Product for Repackaging

6.3.1

The colour, odour, appearance and markings of the pharmaceutical product shall be inspected prior to use.

6.3.2

The manufacturer's container shall be examined for evidence of water damage, contamination or other deleterious effects.

6.3.3

The following characteristics of all packaging materials used shall be available:

a) composition;
b) light transmission;
c) size;
d) thickness;
e) moisture permeability;
f) sealing temperature; and
g) storage requirements.

Note: *Latex-free packaging materials should be considered in accordance with individual health care facility guidelines and practices.*

6.4 Packaging

6.4.1

The packaging of the finished product shall:

a) be appropriate for the dosage form;
b) protect the product from light and moisture as necessary; and
c) minimize the potential for interaction between the drug and the container.

Note: *In the absence of accurate stability information, drugs supplied by the manufacturer in plastic should be repackaged in plastic, and those drugs supplied by the manufacturer in glass should be repackaged in glass.*

6.4.2

Packaging material should be stored in accordance with the manufacturer's instructions.

6.4.3

Pharmaceuticals shall not be repackaged more than once. This is due to the lack of stability, information and the need to track each repackaged dose.

6.5 Labelling

6.5.1

A lot numbering system shall be devised to facilitate the identification of each batch.

6.5.2

The label of the finished product shall be permanent and shall contain descriptive information including:

a) generic name of product;
b) identification of manufacturer, i.e., name or code;
c) strength of product;
d) dosage form of product (if abbreviations are used, they should be approved by health care facility);
e) amount;
f) pharmacy control number;
g) storage conditions, when applicable;
h) auxiliary labels;
i) expiry date; and
j) Expiration periods shall be derived using any or all of the following references:
    i) manufacturers' recommendations;
    ii) pharmaceutical compendia;
    iii) professional literature; and/or
    iv) in-house stability and/or sterility studies.

6.6 Storing the Repackaged Product

All repackaged products shall be stored in a temperature and humidity controlled environment to minimize degradation by heat and moisture.

6.7 Reporting

Health care facilities shall comply with all Health Protection Branch reporting requirements.

6.8 Quality Control

6.8.1 Premises

Written procedures for cleaning the repackaging area shall include:

a) the cleaning interval;
b) cleaning agents and their concentrations; and
c) disposal of waste material and debris.

6.8.2 Equipment

Routine equipment maintenance, calibration, and certification shall be defined, documented, and carried out.

6.8.3 End Product Verification

6.8.3.1
Procedures for end product verification shall be established by the pharmacy department.

6.8.3.2
A final check of the end product shall be performed.

6.8.3.3
Appropriate training shall be provided for staff involved in the checking process.

6.8.3.4
Ultimate responsibility for all repackaging operations shall rest with the pharmacist.

Note: *Many health care facilities use automated packaging machinery as well as bar code/scanning technology. These may facilitate packaging and inventory maintenance processes and can be incorporated while adhering to practice parameters.*

7. BIBLIOGRAPHY

Good Manufacturing Practice (GMP) Guidelines, Therapeutic Programs Branch, Health Canada, 1998.

CSHP Guidelines for Preparation of Sterile Products in Pharmacies, Ottawa, Canada, 1996.

Note: ***I****n 2009 the title of this document was fine-tuned to Sterile Preparation of Medicines: Guidelines for Pharmacies.*

CSHP Guidelines for the Delegation of Functions to Pharmacy Technicians and Other Support Personnel, Ottawa, Canada, 1992.

Note: ***I****n 2009 the title of this document was fine-tuned to Pharmacy Technicians: Guidelines on the Delegation of Functions to Pharmacy Technicians.*