Acceptable Abbreviations

for Prescription Health Product Labels in Canada

Project Background

Abbreviations are commonly used in healthcare, in both manual and electronic systems, to efficiently convey clinical narrative and product information. An abbreviation can be an acronym (e.g., "CR" for "controlled release") or a shortened form of a word or phrase (e.g., "susp" for "suspension"). Many abbreviations are ambiguous, and the same abbreviation may be used for several different meanings (e.g., "ER" for "emergency room" or "extended release"). Abbreviations have also been developed in response to external constraints (e.g., the need to limit the number of characters in a data field). Abbreviations are useful only when users fully understand the intended meaning and there is minimal potential for misinterpretation.³

In an effort to minimize the risk of miscommunication, several patient safety organizations have published lists of "Do Not Use" abbreviations – those that should not be used in healthcare settings. The dangerous and error-prone abbreviations on these lists have been identified globally from medication incident reviews, with similar findings in Canada, the United States, and internationally. The creation of an abbreviation in the absence of structured guidelines is a recognized vulnerability in patient safety.

ISMP Canada, with support from Health Canada, undertook an initiative to create consistency in the use of select abbreviations on prescription health product labels in Canada, with the goal of increasing understanding while also minimizing misinterpretation of label information.

Project Rationale

The health product label communicates key information including ingredient identity and intended use. Therefore, if an abbreviation is used on a product label, it must be clear and unambiguous. The user must be able to understand the label information, without risk of misinterpretation, in order to identify, select, and administer a product safely.^{1,16}

A list of acceptable abbreviations for specific terms used on labels for prescription health products has been developed collaboratively, as described below, to provide consistency and direction for Canadian manufacturers.

Project Key Milestones

Environmental Scan

An environmental scan was undertaken to derive a list of abbreviations that have been used on the inner and/or outer labels of prescription health products. This scan included a literature search for English-language publications using the keyword "abbreviation" and a search for regulatory documents, guidelines, and other published works related to the general use of abbreviations in healthcare settings. It also included a search of labels readily available for viewing (e.g., photographs on the internet), to ascertain current practices.

The environmental scan generated 58 published resources that were used to inform this project: 27 relevant articles (of 176 identified) from the literature search and 31 documents (9 Canadian, 10 American, and 12 international) from the search of other published works.

Review of Medication Incidents

Medication incidents can offer insight into the unique safety concerns associated with abbreviation use. Accordingly, a review was conducted of medication incidents voluntarily reported to ISMP Canada databases (practitioner, community pharmacy, and consumer) and to the National System for Incident Reporting (NSIR) databaseⁱ. Reports from June 2006 to June 2016 with selected keywords were extracted, along with those identified by reporters as involving labelling and packaging.

In total, 1283 incidents were retrieved from the ISMP Canada databases, of which 225 met the inclusion criteria for the review of medication incidents related to use of abbreviations on prescription health product labels. Abbreviations associated with product names constituted about three-quarters of the medication incidents. Just over 90% of the name-associated abbreviations were formulation release modifiers (e.g., SR, ER, XR).

The search of the NSIR database yielded 13 incidents for review. The majority of these incidents related to the use of dangerous or error-prone abbreviations (e.g., "U" instead of "units"); the remainder were shortened forms of medication names and an abbreviated suffix.

External Consultation

Findings from the environmental scan and the review of reported medication incidents facilitated development of a preliminary list of acceptable abbreviations for use on prescription health product labels. The preliminary list was sent for review and feedback to multiple groups during an external consultation period (Figure 1).

At each step in the review process, input was requested on both the preliminary list of acceptable abbreviations and on the document outlining guiding principles for labelling prescription health products. These consultations sought to determine which abbreviations for the inner and/or outer labels of prescription health products were easily understood and considered "acceptable" by most stakeholders.

ⁱ The National System for Incident Reporting (NSIR) is a database provided by the Canadian Institute for Health Information and is a component of the Canadian Medication Incident Reporting and Prevention System (CMIRPS) program. More information about the NSIR is available from: http://www.cmirps-scdpim.ca/?p=12

Disclaimer: Although the analyses described in this bulletin were based on data provided by the Canadian Institute for Health Information, the opinions expressed are those of ISMP Canada only.

Canadian Expert
Advisory Panel
+ Health Canada

- Canada Health Infoway
- Canadian Institute for Health Information
- Canadian Patient Safety Institute
- Canadian Pharmacists Association
- Canadian Society of Hospital Pharmacists
- Health Insurance Reciprocal of Canada
- HealthPRO Procurement Services Inc.
- National Association of Pharmacy Regulatory Authorities

International Medication Safety Network

- Australia (Australian Commission on Safety and Quality in Health Care)
- Hong Kong (Hospital Authority)
- Ireland (Health Service Executive)
- United Kingdom (National Health Service)
- United States of America (Institute for Safe Medication Practices; United States Food and Drug Administration)

Stakeholders (open consultation)

- Healthcare providers (acute care, long-term care, correctional facilities)
- Healthcare organizations (regional health and individual facililities)
- Pharmaceutical manufacturers

Figure 1: External consultation process

Guiding Principles for Acceptable Abbreviations

ISMP Canada's development of the list of "Acceptable Abbreviations for Prescription Health Product Labels in Canada" (see page 6) was guided by the following principles:

General Approach to the Use of Abbreviations

- The use of abbreviations should be minimized on prescription health product labels and packages.
- The intended meaning of an abbreviation should be consistent and clear to users to minimize misinterpretation and errors.
- An abbreviation should not be ambiguous or otherwise have the potential to be misinterpreted by the user.¹³
- Abbreviations should provide information that is useful and easily identifiable to the users (i.e., healthcare providers, patients).¹³
- The use of error-prone abbreviations, symbols, and dose designations should be avoided. 4,6,8,9,10
- Stakeholders (e.g., manufacturers, healthcare providers, etc.) should be educated about the risk of misinterpretation and error with the use of abbreviations. This will be a key implementation strategy.
- User comprehension testing for any new abbreviation is highly recommended. User testing can help to determine whether the intended meaning of the abbreviation is clear and understood.
- Complaint and incident data should be reviewed to identify issues with the use of abbreviations early in the label design process and post-market. Gathering information throughout the product life cycle can assist with the identification of abbreviations that may be misinterpreted by users.
- Periodic review of the list of "Acceptable Abbreviations for Prescription Health Product Labels in Canada" will allow re-assessment of the acceptability of each abbreviation. For example, a previously acceptable abbreviation may become a source of medication error, or another abbreviation may be considered for addition to the list.
- It is essential that the use of abbreviations on prescription health product labels is consistent with regulatory requirements for manufacturers.

Use of Abbreviations for Key Information

- Where possible, express in full any key information⁸ in order to minimize the risk of misinterpretation and error.
- The common or proper drug name of a prescription health product should not be abbreviated.¹
- Use international or national standards for abbreviations (e.g., abbreviate "milliliters" as "mL").
- Express in full any uncommon route of administration (e.g., intrathecal), as it may be unfamiliar to users, and use of an abbreviation may result in confusion. Abbreviated routes of administration should be explained in full at least once (e.g., outer label) if used on the health product label. 1
- Abbreviations used on product dose delivery devices should be consistent with abbreviations used on the product labels and packaging, such as label directions, outer packaging (e.g., carton labelling), containers, and any accompanying written materials.¹

Use of Abbreviated Drug Name Suffixes (Abbreviated Modifiers)

• A description should be provided that clearly conveys the meaning of the abbreviated modifier to healthcare providers and patients. ¹⁴ For example, [Health Product Name]-CR should have 'Controlled Release' below the name.

- The abbreviated modifier should be clear, distinctive and not easily confused with other medical abbreviations (including acronyms, dosing intervals, etc.). 14
- The abbreviated modifier should have a single and unique meaning.¹⁴
- The abbreviated modifier should communicate important pharmacological and/or clinical information for the safe and effective use of the prescription health product. The abbreviated modifier should not be used solely as a marketing tool.
- Generic versions should contain the same abbreviated modifier to the brand name version or innovator product, where permissible with respect to copyright/trademark law.¹⁵ (e.g., diltiazem CD, Cardizem CD).¹⁶
- When considering the use of an abbreviated modifier on a prescription health product label, determine whether the proposed modifier is already in use in the marketplace.¹¹ Refer to ISMP Canada's list of "Acceptable Abbreviations for Prescription Health Product Labels in Canada". If an existing modifier with the same accepted meaning is available, with no incidence of misinterpretation and error, use the existing modifier.¹¹
- The use of abbreviated modifiers should be minimized, where possible; this is particularly important for novel modifiers. If a modifier is necessary for the safe and effective use of the prescription health product, however, the rationale/purpose and unique meaning must be provided to Health Canada for approval.

Conclusion

This initiative was undertaken to create consistency and common understanding in the use of abbreviations on labels for Canadian prescription health products and to minimize the risk of misinterpretation of label information. The list of "Acceptable Abbreviations for Prescription Health Product Labels in Canada" (see page 6) is intended to reduce misinterpretation of abbreviations and ultimately improve patient safety.¹⁷

Disclaimer

The utmost care has been taken to ensure the accuracy of information presented in this report. Nonetheless, any person seeking to apply or consult the report is expected to use independent judgement in the context of individual circumstances. ISMP Canada makes no representation or guarantee of any kind regarding the use or application of the report content.

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Abbreviation ACCEPTED MEANING

Acceptable Abbreviations

for Prescription Health Product Labels in Canada

The abbreviations listed are deemed acceptable for prescription health product labels in Canada. This list was developed using the Principles for the Use of Abbreviations on Prescription Health Product Labels in Canada and after careful consideration by internal and external stakeholders. Use of an abbreviation from this list on a product label does not imply that Health Canada has approved the product itself. Each prescription health product name, label, and package submission is always thoroughly reviewed within its unique context, by Health Canada, before approval for marketing is granted.

- * The meaning of any of these abbreviations should be explained in full at least once elsewhere in the labelling (e.g., side panel). By exception, and only if necessary because of space limitations, labels affixed to small containers (e.g., vials, ampoules) may use any of these abbreviations without definition, provided that the outer labelling (e.g., carton) spells out the term in full.
- † "Extended release" is preferably abbreviated as "XR" because of its lower risk of misinterpretation (relative to "ER" or "XL", which may be misinterpreted as "emergency response", or as "extra-large" pack size/ formulation, respectively).
- [‡] For labelling purposes, "microgram" should be abbreviated as "mcg" instead of the SI unit, "μg". The Greek letter "μ" may be difficult to see in some print and size formats and may be misread as the letter "m" (i.e., misread as "mg" meaning "milligrams", rather than the intended "μg" meaning "micrograms").
- The 2-letter abbreviations for months of the year are compatible with both English and French, which is a unique consideration in Canada. It is possible that "JN" will be mistakenly interpreted as "January" instead of "June"; however, this potential misinterpretation would result in a product being discarded prematurely, rather than being used beyond its expiry date, so carries no health risk. The same would apply if "MA" were interpreted as "March" rather than "May".

Available at https://www.ismp-canada.org/download/ AcceptableAbbreviations-ISMPCanada.pdf



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MEDICATION NAME*	CR EC LA SR XR	controlled release enteric coated long-acting slow or sustained release extended release [†]
ROUTE OF ADMINISTRATION	IM IV	intramuscular intravenous
DOSAGE STRENGTH	kg g mg mcg L mL mEq mg/kg mg/m² mol mmol	kilogram gram milligram microgram [‡] litre millilitre milliequivalent milligram(s) per kilogram milligram(s) per square metre mole millimole
DOSAGE FORM*	amp cap inj oint tab	ampoule capsule injection ointment tablet
CALENDAR MONTH ^s	JA FE MR AL MA JN JL AU SE OC NO DE	January February March April May June July August September October November December
DAY OF THE WEEK	Sun Mon Tue Wed Thu Fri Sat	Sunday Monday Tuesday Wednesday Thursday Friday Saturday
OTHER	BMI BSA DIN Exp Lot	body mass index body surface area drug identification number expiry date lot number

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