Addendum to the National guidelines for on-screen display of clinical medicines information, Sydney: Australian Commission on Safety and Quality in Health Care, 2016
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The National guidelines for on-screen display of consumer medicines information and the National guidelines for on-screen display of clinical medicines information are available on the Commission website at www.safetyandquality.gov.au.
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Summary

Medication errors in community settings contribute to patient harm and increase hospital admissions. Unclear, incomplete or confusing presentation of medicines information can increase the opportunity for consumers to make errors and cause themselves harm.

Consumers are increasingly able to access their medicines information on-screen through a number of resources (e.g. the Medicare website, the My Health Record system). Providing clear, standardised medicines information in these formats has the potential to improve patient safety and quality use of medicines.

The National guidelines for on-screen display of consumer medicines information (the Consumer Guidelines) are a companion to the National guidelines for on-screen display of clinical medicines information (the Clinical Guidelines). The Clinical Guidelines describe consistent, unambiguous terms and processes for on-screen display of medicines information to health professionals within clinical information systems, and include background, aims and scope that also apply to the Consumer Guidelines.

The Consumer Guidelines aim to describe consistent and unambiguous terms for the on-screen display of medicines information in information systems where consumers are interacting with this information.

These guidelines are intended for those developing, assessing, procuring and implementing systems for electronic medication management, prescribing and consumer health records to understand how presentation contributes to patient safety. It is expected that recommendations may be applied during software development and will assist evaluation of systems during procurement.

The majority of recommendations in the Clinical Guidelines also apply to consumer-facing medicines information. However, the Consumer Guidelines contain important exceptions and additions to the Clinical Guidelines to reflect the needs of consumers when accessing electronic information about their medicines.

These exceptions and additions are:

- changing the order of some information – for example, the route is described after the dose label (e.g. ‘oral’ becomes ‘by mouth’) to improve clarity for consumers
- replacing the ‘/’ symbol (e.g. 2 mg/5 mL) with ‘in’ or other appropriate descriptors (e.g. 2 mg in 5 mL) – using appropriate words such as ‘in’ improves clarity and prevents misreading or misunderstanding; the ‘/’ should be retained when this is consistent with other presentations of product information
- displaying time using the 12-hour clock and words (e.g. 10:00 in the morning, 9:00 at night) rather than the 24-hour clock (e.g. 10:00, 21:00) – the 12-hour clock is more readily understood by consumers, and descriptive words are more readily understood than ‘am’ or ‘pm’
- using common, everyday words instead of technical terms or jargon – this improves readability and comprehension for consumers, who are often not familiar with technical terms used by health professionals
- ensuring dosing instructions (such as frequency and timing) are explicit and standardised – studies show that consumers want clear and consistent instructions about how and when to take their medicines.
1. Introduction

The *National guidelines for on-screen display of consumer medicines information* (the Consumer Guidelines) are a companion to the *National guidelines for on-screen display of clinical medicines information* (the Clinical Guidelines).[1] The background, aims and scope of these guidelines are expanded in the Clinical Guidelines. Recommendations in the Clinical Guidelines that also apply to consumers are not repeated in the Consumer Guidelines. However, the Consumer Guidelines contain a few important exceptions and additions to the Clinical Guidelines.

Medication errors in community settings contribute to patient harm and hospital admissions.[2][3][4] Unclear, incomplete or confusing presentation of medicines information can increase the opportunity for consumers to make errors and cause themselves harm.

Consumers are increasingly able to access their medicines information on-screen through a number of resources (e.g. the Medicare website, the My Health Record system). Providing clear, standardised medicines information in these formats has the potential to improve patient safety and quality use of medicines.

For this reason the Commission has developed the Consumer Guidelines to reflect the needs of consumers when accessing electronic information about their medicines.

1.1 Consumer needs

A recent literature review identified studies on the information that consumers want or need about their medicines.[5] Studies show that consistency of information is critical – consumers want clear instructions from their doctor on exactly how to take their medicines, and for this information to be confirmed by their pharmacist.[6] Knowing when and how to use their medicines is an important need.[7]

Consumers also want information on adverse effects, risks, interactions and the condition for which the medicine was prescribed. These issues are outside the scope of these Consumer Guidelines.

The Consumers Health Forum of Australia held a consumer workshop in 2010 to discuss best practice for packaging and labelling of medicines.[8] Consumers made a range of recommendations, including the following:

- Positive statements should be used to avoid ambiguity of the message. Negative directions may be misleading.
- The active ingredient should be displayed in equal size and prominence as the brand name.
- Information relating to the quantity of active ingredient per dose or unit must be clearly displayed.

1.2 Best practice for medicines information to consumers

Evidence on best practice for provision of medicines information to consumers was summarised by Vitry and Roughead.[5] Evidence included research and guidelines on print or electronic media, including Consumer Medicines Information (CMI), medicine labels, medicine lists and electronic health records.
1. Introduction

1.2.1 Vocabulary and information design

Research has focused on the vocabulary used and the graphical display of information for consumers, with the main objective to improve comprehension and therefore improve appropriate medicines use and adherence.

There is general consensus on best practice in information design for medicines information for consumers. Main principles include use of:

- short, familiar words (e.g. blood pressure instead of hypertension)
- short sentences
- short headings that stand out from the text
- conversational tone of voice, addressing the reader as ‘you’
- large type size while retaining sufficient white space
- bullet points to organise lists
- unjustified text (ragged right)
- bold, lower-case text for emphasis.

1.2.2 Medicine labels

Guidance on labelling of dispensed medicines is outside the scope of these guidelines. However, some principles of best practice for medicine labelling apply to both pharmacy-dispensed medicine labelling and on-screen presentation of medicines information, particularly relating to dosing instructions.

Recommendations and studies undertaken in the USA may be helpful to inform the development of a standard template for consumer dosage instructions in Australia. The ‘Universal Medication Schedule’ (UMS) developed by the Institute of Medicine recommends provision of dosage instructions into four time periods (morning, noon, evening, bedtime), use of simplified language and formatting to promote understanding (e.g. ‘take 1 tablet in the morning and 1 tablet at bedtime’ instead of ‘take one tablet twice daily’) and use of numeric characters.

A number of studies have shown that adherence to these best practices improved prescription understanding, regimen dosing and medicines reconciliation.

In 2013, the Commission and the NSW Clinical Excellence Commission hosted a roundtable discussion on improving the safety and quality of pharmacy dispensing labels. Several recommendations from this roundtable are also relevant to on-screen medicines information for consumers, including the following:

- A standard template should be developed to present information to consumers in a consistent format.
- Dosing instructions should be explicit and standardised.
- Dose should be clearly separated from the interval, and the frequency of medicine dosage should be explicit.
- Sentence case should be used; that is, lower-case lettering capitalising the first word in the sentence.

1.2.3 Medicine lists

Medicine lists may be given to patients as part of an educational intervention in community pharmacies, at hospital discharge or downloaded from electronic health records or prescription records. The core elements of medicines information usually mirror information provided on the medicine prescription form itself – generic name, brand name, strength and form, dosage and sometimes treatment duration, with variations in the amount of additional information that may be included.

The Pharmaceutical Society of Australia’s (PSA) Guidelines and standards for pharmacists: medication profiling service, published in 2007, includes a table of the key elements that should be included by community pharmacists when they prepare a medicine list: brand and generic names, strength and form, a list of alternative brand names, coloured pictorial or written product
1. Introduction

description, dosage instructions including duration of treatment, and supplementary information (i.e. indication for use, route of administration if unclear to the consumer, special directions or cautions).

Electronic mobile apps, such as the NPS MedicineWise’s MedicineList+ or MedAdvisor, allow consumers to make their medicine lists themselves by accessing prescription records stored in community pharmacies, scanning medicines’ barcodes or selecting the medicine from a list. The apps may also set alarms for medicine doses and calendar alerts for refilling prescriptions. They do not typically include the indications for medicines unless manually entered by consumers. They provide links to more medicine or health information such as the CMI provided by the manufacturer. A small evaluation study showed that among app users, adherence to the PSA guidelines improved by 8–17%. That is, there was an increase in the percentage of compliant prescriptions, with the increase equivalent to one to two more dispensings per year in app users compared with nonusers for 10 common long-term prescription medications.[193]

1.3 Consumer testing

A range of examples of on-screen presentation of consumer medicines information was tested in a consumer focus group to determine information needs and preferences. These guidelines reflect these preferences. Further details of the focus group are provided in Appendix 1.

1.4 Guideline implementation and future work

Healthcare providers are encouraged to seek and procure software systems that work towards implementation of the standard formatting and terms set out in these guidelines. This is expected to be an evolving process, during which the Commission is responsible for maintaining these guidelines and reducing national barriers to implementation.

Feedback on these guidelines will be collated for review by a Commission-convened expert advisory group. The outcomes of decisions on these issues will be made available on the Commission website.

The consumer addendum differs minimally from recommendations for clinical display of medicines information. However, differences described in Section 2, including the order of information and use of plain language, for consumer-facing medicines information will require data to be transformed to take information from the clinical view to the consumer view. Machine readability of the information between the clinical and consumer views of medicines information must be maintained using strict mapping guidance to avoid introducing errors.
The following tables list the recommendations and rationales for the display of medicines information following the section numbering of the Clinical Guidelines. Exceptions and additions to the Clinical Guidelines for consumer-facing medicines information are indicated in shaded rows and are described in the following sections of these Consumer Guidelines.

### Medicine names

<table>
<thead>
<tr>
<th>Item</th>
<th>Recommendation</th>
<th>Rationale</th>
<th>Identical to Clinical Guidelines?</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.1.1</td>
<td>Display full medicine names</td>
<td>Avoid confusion arising from non-standard medicine names</td>
<td>Yes</td>
</tr>
<tr>
<td>6.1.2</td>
<td>Display medicines available as different salts</td>
<td>Avoid confusion caused by abbreviating or omitting salts</td>
<td>Yes</td>
</tr>
<tr>
<td>6.1.3</td>
<td>Display active ingredient name and brand name using consistent font styles for each</td>
<td>Avoid confusion between active ingredient and brand name</td>
<td>Yes</td>
</tr>
<tr>
<td>6.1.4</td>
<td>Use National Tall Man Lettering for medicine names known to cause confusion</td>
<td>Avoid confusion between ‘look-alike, sound-alike’ medicine names</td>
<td>Yes</td>
</tr>
</tbody>
</table>

### Text, abbreviations and symbols

<table>
<thead>
<tr>
<th>Item</th>
<th>Recommendation</th>
<th>Rationale</th>
<th>Identical to Clinical Guidelines?</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.2.1</td>
<td>Do not use abbreviations</td>
<td>Avoid confusion caused by abbreviations</td>
<td>Yes</td>
</tr>
</tbody>
</table>
| 6.2.2 | Display prescription details in full | Prevent misreading symbols as numbers or words | Exception – for consumer presentation, use ‘in’, ‘over’ or other descriptors instead of ‘/’. (Retain ‘/’ when this is consistent with other presentations of product information)  
Exception – spell out ‘morning’, ‘evening’ and other descriptors instead of using either the 24-hour clock, or ‘am’ and ‘pm’ |
| 6.2.3 | Use plain language | Improve readability and comprehension | Addition – use everyday words and avoid technical terms for consumer presentation |
| 6.2.4 | Ensure dosing instructions are explicit and standardised | Avoid misinterpretation of dosing caused by using short statements | Addition – expand instructions to improve clarity for consumer presentation |
### Numbers and units of measure

<table>
<thead>
<tr>
<th>Item</th>
<th>Recommendation</th>
<th>Rationale</th>
<th>Identical to Clinical Guidelines?</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.3.1</td>
<td>Use a consistent display format and order</td>
<td>Prevent misinterpretation caused by different numerical elements having similar formats and units of measure</td>
<td>Exception – order of information on route differs in consumer-facing information</td>
</tr>
<tr>
<td>6.3.2</td>
<td>Use standard approved units of measure, consistently formatted</td>
<td>Prevent misreading or misinterpreting units of measure</td>
<td>Yes</td>
</tr>
<tr>
<td>6.3.3</td>
<td>Use spacing and labels to differentiate display elements</td>
<td>Prevent misreading numbers due to close proximity of preceding words</td>
<td>Yes</td>
</tr>
<tr>
<td>6.3.4</td>
<td>Use a space between numbers and units of measure</td>
<td>Prevent misreading numbers due to close proximity of trailing units of measure</td>
<td>Yes</td>
</tr>
<tr>
<td>6.3.5</td>
<td>Do not use trailing zeros</td>
<td>Prevent misreading numbers</td>
<td>Yes</td>
</tr>
<tr>
<td>6.3.6</td>
<td>Display numbers without ambiguity</td>
<td>Prevent misreading numbers</td>
<td>Yes</td>
</tr>
<tr>
<td>6.3.7</td>
<td>Use a comma to separate groups of three digits for numbers 1,000 and above</td>
<td>Prevent misreading very large numbers</td>
<td>Yes</td>
</tr>
<tr>
<td>6.3.8</td>
<td>Use ‘million’ instead of ‘mega’</td>
<td>Avoid confusion of meaning of ‘m’ or ‘mega’</td>
<td>Yes</td>
</tr>
</tbody>
</table>
### General information display

<table>
<thead>
<tr>
<th>Item</th>
<th>Recommendation</th>
<th>Rationale</th>
<th>Identical to Clinical Guidelines?</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.4.1</td>
<td>Unambiguously position related elements and labels when using text wrapping</td>
<td>Avoid confusion caused by visual dissociation between related prescription elements</td>
<td>Yes</td>
</tr>
<tr>
<td>6.4.2</td>
<td>Never truncate any part of the prescription</td>
<td>Prevent misinterpretation caused by part of the prescription not being visible</td>
<td>Yes</td>
</tr>
<tr>
<td>6.4.3</td>
<td>Ensure the full details of multiple prescriptions in a selection list are accessible</td>
<td>Prevent misinterpretation caused by part of the prescription not being visible</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Examples to support the guidelines are used throughout the document, illustrating each recommendation in terms of appropriate display and differences between the clinical view and consumer view. They are schematic and contain fragments representing individual components of the Australian Medicines Terminology (AMT) rather than representing the design of a prescribing system with full AMT descriptors.

In addition, use of human factors design principles may assist in distinguishing prescription elements. These include highlighting techniques such as colour, bold, shading, underline, italics and uppercase to enhance usability. The examples in the guidelines do not use all of these elements. Rather, designers are encouraged to employ these techniques to their best potential within their own systems.
3. Exceptions to the Clinical Guidelines

This section details the items in the Clinical Guidelines that have been modified in the Consumer Guidelines.

**Item 6.2.2 Display prescription details in full**

_**Recommendation: use full English words in place of symbols**_

The Clinical Guidelines recommend using full English words to describe all text elements of a prescription, with the exceptions of '%', decimal points, ‘+’, ‘&’ and ‘/’.

Consumers preferred that the ‘/’ symbol be replaced with ‘in’ or other descriptors, as appropriate. For example:

- ‘2 mg/mL’ becomes ‘2 mg in 1 mL’
- ‘10 mg/hour’ becomes ‘10 mg over 1 hour’.

However, consistent information is also important, so where ‘/’ is part of an expression of strength and is used in other presentations of product information, such as the packaging and consumer medicines Information, the ‘/’ should be retained. The ‘/’ symbol is also retained when it is part of a brand name combination (e.g. Coversyl Plus 5 mg/1.25 mg).

---

**Clinical:**  
**6.2.2a**  
**6.2.2b**

**sodium valproate** 200 mg/5 mL – Epilim  
**Dose:** 200 mg – twice a day  
**Supply:** 400 mL

**sodium valproate** 200 mg in 5 mL – Epilim  
**Dose:** Give 5 mL by medicine measure by mouth in the morning and 5 mL at night  
**Supply:** 400 mL
Recommendation: display time using the 12-hour clock with descriptive words

The Clinical Guidelines recommend using the 24-hour clock to display time, with ‘am’ used to show times before midday (e.g. 10:00 am, 19:00).

For consumer-facing information, display time using the 12-hour clock, with ‘in the morning’ to show times before midday (e.g. 10:00 in the morning) and ‘in the afternoon’, ‘in the evening’ or ‘at night’ to show times after midday (e.g. 9:00 at night). Midnight should be displayed as ‘12:00 midnight’ and midday should be displayed as ‘12:00 midday’ (not 12:00 noon).

Rationale: improve clarity of information for consumers

 Consumers may not be familiar with the way the ‘/’ symbol is used by health professionals. Using everyday words such as ‘in’ or ‘over’ improves clarity and prevents misreading or misunderstanding. Consumer testing for these guidelines (see Appendix 1) suggested that ‘am’ or ‘pm’ to indicate time could be misread or missed altogether, and consumers preferred ‘in the morning’, ‘in the evening’, ‘at night’ and similar descriptors.
4. Additions to the Clinical Guidelines

This section details additional items to the Clinical Guidelines that are specific for consumer-facing information and appear only in the Consumer Guidelines.

Item 6.2.3 Use plain language

**Recommendation: use common, everyday words instead of technical terms or jargon**

Plain language includes:
- using the active voice (‘Take 1 tablet’, not ‘1 tablet should be taken’)
- using the imperative voice for instructions (‘do this’ or ‘do not do this’)
- using short sentences and short, simple words instead of technical terms.

See Appendix 10.2 of the Clinical Guidelines for acceptable terminology.

_Rationale: improve readability and comprehension_

Technical terms and jargon are not well understood by consumers. Using common, everyday words improves readability and comprehension by consumers. For example, use:
- ‘inside the cheek’ instead of ‘buccal’
- ‘under the tongue’ instead of ‘sublingual’
- ‘apply to the affected area’ as appropriate instead of ‘topical’.
4. Additions to the Clinical Guidelines

Item 6.2.4 Ensure dosing instructions are explicit and standardised

**Recommendation:** display full details of dosing instructions in a standardised format and order

**Frequency, timing and interval**

Dosing instructions (including frequency and timing) in consumer-facing medicines information should be explicit and standardised. For example, ‘Take two tablets twice daily’ should be displayed as ‘Take 2 tablets in the morning and 2 tablets in the evening’. Specify the dosing interval if doses need to be evenly spaced (e.g. for some medicines, ‘Take 1 tablet every 12 hours’ is preferable to ‘Take 1 tablet in the morning and 1 tablet at night’).

If doses should be taken with food, specify ‘with food’. If doses should be taken with meals, specify ‘with meals’.

**Use of verbs**

Verbs should be used in instructions (e.g. ‘2 tablets’ becomes ‘Take 2 tablets’, ‘Sparingly’ becomes ‘Apply sparingly’).
4. Additions to the Clinical Guidelines

**Alerts and warnings**

Alerts or warnings should be included (e.g. ‘Do not take more than 8 tablets in 24 hours’). Consumer testing indicated that maximum daily doses can be a source of confusion, especially for liquids. The minimum recommendation is to state the number of tablets or volume of liquid (e.g. ‘Do not take more than 8 tablets in 24 hours’, ‘Do not take more than 40 mL in 24 hours’). However, for liquids, doses may also be specified in brackets to aid consumers, if necessary (e.g. ‘Do not take more than 40 mL (4 doses) in 24 hours’).
4. Additions to the Clinical Guidelines

**Order of information**

The Clinical Guidelines recommend presenting information in a consistent order. This is also true for consumer-facing medicines information. However, the order of information is different in consumer-facing medicines information; the route of administration should be moved to become part of the dosing instructions to improve readability. For example:

- Consumer Guidelines: ‘paracetamol 500 mg – tablets – DOSE Take 2 tablets by mouth every 6 hours’.

**Rationale: avoid misinterpretation of instructions**

Consumers want clear and consistent instructions about how to take their medicines. For most consumers, the most important information is instructions on when and how to take their medicine.
5. Clinical scenarios

Case study 1: 74-year-old female with coronary heart disease and angina. Patient has hypertension and rheumatoid arthritis.

Case study 2: 60-year-old male with type 2 diabetes and dyslipidaemia.


To inform the development of these guidelines, the Commission engaged the Consumers Health Forum of Australia (CHF) to conduct a consumer focus group to elicit consumers’ preferences about on-screen display of medicines information. Participants were sought from consumer organisations, as well as individuals with an interest in medicines information.

A focus group of 10 consumers was held in April 2016. All the participants were experienced health consumer representatives and had high degrees of health literacy and understanding of quality use of medicines, but they were encouraged to reflect a cross-section of consumers’ views. Participants were given a workbook with options for displaying the information, which covered the following areas of the guidelines:

- presentation of the medicine name (using national Tall Man lettering or not)
- use of symbols (e.g. '/' or 'in')
- a range of ways to display time
- use of plain English
- use of words or numerals to display numbers
- a range of ways to describe when to take a medicine (e.g. ‘twice a day’ or ‘1 in the morning and 1 in the evening’)
- a range of ways to describe maximum daily dose
- order of information
- use of ‘food’ or ‘meals’.

Consumers broadly agreed on most issues, and these preferences are reflected in these guidelines. Issues of interest include the following.

### A1.1 Tall Man lettering
Consumers did not reach a complete consensus on whether national Tall Man lettering was preferred. Participants felt that Tall Man lettering helped to draw attention to the active ingredient and would be especially helpful for people whose first language is not English. Overall, participants felt that the purpose of Tall Man lettering is to reduce risks (which apply to both pharmacists and consumers), and that use of Tall Man lettering is unlikely to cause harm.

Some consumers felt Tall Man lettering may be confusing as it does not apply to all medicines, and that the on-screen presentation should be consistent with the presentation of the medicine name on the product pack.

In line with the World Health Organization initiative of Tall Man lettering, national Tall Man lettering is recommended for clinical on-screen display of medicines for medicines with look-alike, sound-alike names that are known to cause confusion. Consumer views did not reject national Tall Man lettering, and it is therefore retained in the consumer addendum for consistency across clinical and consumer views.

### A1.2 Time
Participants agreed that ‘am’ and ‘pm’ to indicate before and after midday can be easily missed or misunderstood, and preferred phrases such as ‘in the morning’ and ‘in the evening’.

### A1.3 Maximum daily doses
Participants suggested that maximum daily doses should be highlighted in bold or similar (e.g. ‘do not take more than 8 tablets in 24 hours’). Participants also felt that maximum daily doses for tablets and liquids could be presented differently for clarity (see Item 6.2.4 in these guidelines).

### A1.4 ‘Food’ or ‘meals’
Consumers preferred ‘food’, as this is more easily understood by people from culturally and linguistically diverse backgrounds.

### A1.5 MICROg
MICROg as a presentation of micrograms was not specifically tested.

The strong support for clinical presentation to reduce the display of microgram in full led to the term MICROg.\[^{16}\]

The presentation of microgram in full is consistent with consumer views relating to clarity and plain language. However, MICROg was retained to avoid inconsistency between clinical and consumer presentations.