New words for cautionary and advisory labels make them easily understood

A revised set of cautionary and advisory labels will be published in the new edition of the British National Formulary (March 2011). Emma Harris, staff editor, and Duncan Enright, publishing director, BNF Publications, explain how the changes came about.

Revision
The wording of the original cautionary and advisory labels was recommended by a working party of the Royal Pharmaceutical Society of Great Britain, and have been included in the BNF since 1985, with minor adjustments to the wording being made over time by the BNF’s Joint Formulary Committee.

Further improvements have now been sought through research carried out by Professor Raynor and the team at Luto Research, who have been engaged in user testing as a method of readability testing since the company was formed in 2005. Professor Raynor and his colleagues are leading authorities on the European legislative framework with respect to patient information for licensed medicines, and this strong research base has helped to enhance the clarity of information created for patients.

Readability testing
Luto undertook readability testing of the 32 cautionary and advisory labels for dispensed medicines (CALDM) from appendix 9 of the BNF. Most people see the CALDM on computer-generated printed labels, which are affixed to medicine packs. Depending on the medicines that they are taking, people often have to read multiple cautionary or advisory messages spread over several labels. Luto believes this could impact on a person’s ability to find and understand the information contained in these warnings and, therefore, selected a range of medicines to be represented in the testing in order to cover each one of the CALDM.

Participants in the research were all literate in English and covered a range of ages and educational abilities. They were asked to read and answer questions about medicines with several label wordings and medicines with single-label wordings. A group of paediatric medicines was also created and used for participants who were parents or carers of children. The questions were agreed by an expert panel consisting of pharmacists from Luto Research and the BNF.

Almost 200 lay participants were involved over three rounds of testing. The results from each round of testing were combined with...
good practice and research evidence to produce revised wordings that reflect current best practice in written medicines information for patients. Of the 32 labels, three existing wordings (labels 12, 17, and 29) worked well and are retained in the proposed revised wording for the new labels. The BNF now recommends improvements to the other 29 wordings and examples are given in the Panel.

Although the wording of individual labels may have changed, the intended instruction of each of the numbered labels remains largely the same. The proposed changes include terminology that is better understood by patients. For example, user testing showed that, in label 1, the word “drowsiness” is not always readily understood and has been improved by using the wording “This medicine may make you sleepy”.

The recommended changes (see Panel for examples), following user testing, also produce more precise instructions, which present little opportunity for different interpretations. Thus, in label 4, the wording “Avoid alcoholic drink” is replaced with “Do not drink alcohol while taking this medicine.”

Luto’s testing showed that label wordings that can be incorporated in an appropriate position in the directions for dosage or administration (labels 21 to 26) did not generally work well. Separating these wordings into a discrete instruction worked better and this format has been adopted in the proposed wordings.

Conventional label styles were used for the first two rounds of testing. This was when most of the wording improvements were made and tested. In the third round, where the wordings were mostly only refined, a designed label format recommended in the 2007 National Patient Safety Agency publication “Design for patient safety: a guide to the design of dispensed medicines” was used. This ensured that the revised wordings worked in this aspirational format, as well as in the conventional label style.

According to Nick Barber, professor of pharmacy practice at The School of Pharmacy, University of London: “When serious errors occur which cause harm to patients, it is often as a result of a series of minor failures at various stages. Therefore, in taking more care about the wording of detailed instructions, we can help improve the safety of medicines. With two million prescriptions being issued every day, a small percentage improvement through labels being more understandable could make a significant impact.”

It has never been easier to change labels on medicines given current computerised systems, and we therefore hope that the large pharmacy chains and independent pharmacies will adopt these recommendations, which appear in the new edition of the BNF (BNF 61, March 2011).

### BNF CAUTIONARY AND ADVISORY LABELS: EXAMPLES — BEFORE AND AFTER RECOMMENDED CHANGES

<table>
<thead>
<tr>
<th>Label</th>
<th>Before wording of original cautionary and advisory labels</th>
<th>After wording of revised cautionary and advisory labels (BNF 61)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Warning: May cause drowsiness</td>
<td>Warning: This medicine may make you sleepy</td>
</tr>
<tr>
<td>2</td>
<td>Warning: May cause drowsiness. If affected do not drive or operate machinery. Avoid alcoholic drink</td>
<td>Warning: This medicine may make you sleepy. If this happens, do not drive or use tools or machines. Do not drink alcohol</td>
</tr>
<tr>
<td>4</td>
<td>Warning: Avoid alcoholic drink</td>
<td>Warning: Do not drink alcohol while taking this medicine</td>
</tr>
<tr>
<td>5</td>
<td>Do not take indigestion remedies at the same time of day as this medicine</td>
<td>Do not take indigestion remedies 2 hours before or after you take this medicine</td>
</tr>
<tr>
<td>7</td>
<td>Do not take milk, indigestion remedies, or medicines containing iron or zinc at the same time of day as this medicine</td>
<td>Do not take milk, indigestion remedies, or medicines containing iron or zinc, 2 hours before or after you take this medicine</td>
</tr>
<tr>
<td>8</td>
<td>Do not stop taking this medicine except on your doctor’s advice</td>
<td>Warning: Do not stop taking this medicine unless your doctor tells you to stop</td>
</tr>
<tr>
<td>9</td>
<td>Take at regular intervals. Complete the prescribed course unless otherwise directed</td>
<td>Space the doses evenly throughout the day. Keep taking this medicine until the course is finished, unless you are told to stop</td>
</tr>
<tr>
<td>10</td>
<td>Warning: Follow the printed instructions you have been given with this medicine</td>
<td>Warning: Read the additional information given with this medicine</td>
</tr>
<tr>
<td>11</td>
<td>Avoid exposure of skin to direct sunlight or sun lamps</td>
<td>Protect your skin from sunlight — even on a bright but cloudy day. Do not use sunbeds</td>
</tr>
<tr>
<td>14</td>
<td>This medicine may colour the urine</td>
<td>This medicine may colour your urine. This is harmless</td>
</tr>
<tr>
<td>15</td>
<td>Caution flammable: keep away from fire or flames</td>
<td>Caution: flammable. Keep your body away from fire or flames after you have put on the medicine</td>
</tr>
<tr>
<td>16</td>
<td>Allow to dissolve under the tongue. Do not transfer from this container. Keep tightly closed. Discard eight weeks after opening</td>
<td>Dissolve the tablet under your tongue—do not swallow. Store the tablets in this bottle with the cap tightly closed. Get a new supply 8 weeks after opening</td>
</tr>
<tr>
<td>19</td>
<td>Warning. Causes drowsiness which may continue the next day. If affected do not drive or operate machinery. Avoid alcoholic drink</td>
<td>Warning: This medicine makes you sleepy. If you still feel sleepy the next day, do not drive or use tools or machines. Do not drink alcohol</td>
</tr>
<tr>
<td>21</td>
<td>. . . with or after food</td>
<td>Take with or just after food, or a meal</td>
</tr>
<tr>
<td>22</td>
<td>. . . half to one hour before food</td>
<td>Take 30 to 60 minutes before food</td>
</tr>
<tr>
<td>23</td>
<td>. . . an hour before food or on an empty stomach</td>
<td>Take this medicine when your stomach is empty. This means an hour before food or 2 hours after food</td>
</tr>
<tr>
<td>25</td>
<td>. . . swallowed whole, not chewed</td>
<td>Swallow this medicine whole. Do not chew or break</td>
</tr>
<tr>
<td>27</td>
<td>. . . with plenty of water</td>
<td>Take with a full glass of water</td>
</tr>
<tr>
<td>28</td>
<td>To be spread thinly . . .</td>
<td>Spread thinly on the affected skin only</td>
</tr>
<tr>
<td>30</td>
<td>Do not take with any other paracetamol products</td>
<td>Contains paracetamol. Do not take anything else containing paracetamol while taking this medicine</td>
</tr>
<tr>
<td>32</td>
<td>Contains aspirin</td>
<td>Contains aspirin. Do not take anything else containing aspirin while taking this medicine</td>
</tr>
</tbody>
</table>