

<b>Enclosure No.</b>	5/AWMSG/0216
<b>Agenda item No.</b>	9 – Welsh Cautionary and Advisory Labels in the British National Formulary for Prescription Medicines
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## 1.0 ACTION FOR AWMSG

The All Wales Medicines Strategy Group (AWMSG) is asked to consider the *Welsh Cautionary and Advisory Labels in the British National Formulary for Prescription Medicines* report, part of the *Welsh Lexicon* project.

## 2.0 PURPOSE

It was proposed that the All Wales Prescribing Advisory Group (AWPAG) develop a lexicon of Welsh medication labelling terminology, which could be adopted by pharmacy system suppliers and pharmacy contractors. The first stage of this project involves the translation of cautionary and advisory labels for prescription medicines from the British National Formulary (BNF).

### 2.1 Process

- March 2015 – Project discussed at AWPAG meeting.
- September 2015 – List of translated cautionary and advisory labels in the BNF for prescription medicines presented to AWPAG members.
- February 2016 – *Welsh Cautionary and Advisory Labels in the British National Formulary for Prescription Medicines* to AWMSG.
- Ongoing – Further translations to be carried out subject to funding.

### 2.2 Stakeholders

- Royal Pharmaceutical Society
- Community Pharmacy Wales
- Welsh Government
- Association of the British Pharmaceutical Industry

## 3.0 INTRODUCTION

The provision of Welsh language services within healthcare in Wales has been highly scrutinised. The Welsh Language Commissioner's inquiry found that a Welsh language or bilingual service is vital for the welfare of Welsh-speaking patients<sup>1</sup>. Specifically, a recommendation, later endorsed by the Chief Pharmaceutical Officer for Wales, was for bilingual labels on prescription medicines to be made available to patients.

Recognising that directions for use would extend to a few thousand instructions, priority was given for Welsh language versions of cautionary and advisory labels. These warn patients (e.g. not to drink alcohol) or remind patients of certain actions (e.g. to dissolve or mix with water before taking) and are a legal requirement to be included on the labels on all medication dispensed in the UK. These should be used without modification and should be legible on all medication containers.

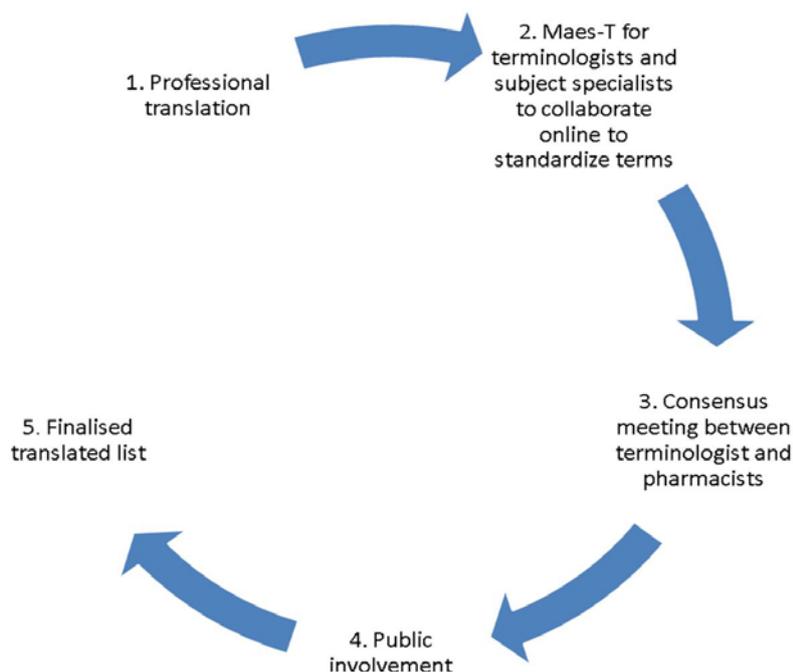
## DRAFT FOR AWMSG ENDORSEMENT

The aim of the present study, therefore, was to develop a Welsh language version of the 30 cautionary and advisory labels. The study is a collaboration between Betsi Cadwaladr University Health Board (BCUHB) and Bangor University; it is funded by the BNF, and reports to AWPAG (a subgroup of AWMSG).

### 4.0 METHODS

Cautionary and advisory labels were identified from Appendix A3 of the most recent version of the BNF<sup>2</sup>. A pharmacist provided initial translation, which was published on Maes-T (<http://maes-t.com>), an interface for the creation and development of online terminology resources aimed to facilitate collaboration between terminologists and subject specialists. Feedback was provided by hospital and academic pharmacists and a terminologist at the Language Technologies Unit at Bangor University, and a consensus meeting was held to agree a second draft. This was distributed to a small group of Welsh-speaking community pharmacists within BCUHB, to local members of Merched y Wawr (a national women's organisation) and to the BCUHB service users reader panel. Comments were collated and discussed within the team, and with the involvement of a second terminologist, to arrive at the final version.

**Figure 1. Iterative process of development of Welsh language versions of the labelling**



### 5.0 RESULTS

See *Appendix 1: Welsh Cautionary and Advisory Labels in the BNF* for the translated terms as they appear in the online BNF.

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### 6.0 DISCUSSION

Terminologists, pharmacists and members of the general public were in agreement on the wording for the Welsh versions of the majority of terms. However, some words and terms posed specific challenges, such as in relation to geography of use, as in *llaeth* or *llefrith* for milk (the latter being used in North Wales). The term *hydoddi* for dissolve is not used commonly, and stakeholders preferred *toddi*, which means melt, but is often used to mean dissolve. The colloquial term *dŵr* (meaning water) was preferred to *wrin* for urine.

The iterative approach to arrive at the final agreed list was inclusive of service users and subject specialists, and proved a robust approach to ensure generalisability across Wales.

### 7.0 CONCLUSION

The final version is now published in the online version of the BNF and will become available in the paper version.

There is a need, however, to also translate the 2,000+ directions to the Welsh language, following the same robust methods, but this will require a funding investment.

### 8.0 ACKNOWLEDGEMENTS

Siôn Llewelyn, Rowlands Pharmacy, Bala; participating members of Merched y Wawr; Gruffudd Prys, Language Technologies Unit, Canolfan Bedwyr, Bangor University; and members of the BCUHB service users reader panel.

### 9.0 FUNDING

We gratefully acknowledge funding from the BNF (Pharmaceutical Press).

### 10.0 PRESENTATIONS

The list of translated terms was presented at the 2015 North Wales Medicines Research Symposium, Bodelwyddan, 1 July 2015, and at the National Eisteddfod, Meifod, 3 August 2015.

### REFERENCES

- 1 Welsh Language Commissioner. My Language, My Health: The Welsh Language Commissioner's Inquiry into the Welsh Language in Primary Care. 2013. Available at: <http://www.comisiynyddygydraeg.cymru/English/Publications%20List/Health%20inquiry%20full%20report.pdf>. Accessed Aug 2015.
- 2 British Medical Association & Royal Pharmaceutical Society. British National Formulary. 2015. Available at: <https://www.medicinescomplete.com/mc/bnf/current/index.htm>. Accessed Aug 2015.

[Dashboard](#) > [BNF](#) > [Cautionary and advisory labels for dispensed medicines](#)

[◀ Previous page](#)

[Next page ▶](#)

## Labels

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1

Warning: This medicine may make you sleepy

Rhybudd: Gall y feddyginiaeth hon eich gwneud yn gysglyd

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To be used on *preparations for children* containing antihistamines, or other preparations given to children where the warnings of label 2 on driving or alcohol would not be appropriate.

2

Warning: This medicine may make you sleepy. If this happens, do not drive or use tools or machines. Do not drink alcohol

Rhybudd: Gall y feddyginiaeth hon eich gwneud yn gysglyd. Peidiwch â gyrru, defnyddio offer llaw neu beiriannau os yw hyn yn digwydd. Peidiwch ag yfed alcohol

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To be used on *preparations for adults that can cause drowsiness*, thereby affecting coordination and the ability to drive and operate hazardous machinery; label 1 is more appropriate for children. *It is an offence to drive while under the influence of drink or drugs.* Some of these preparations only cause drowsiness in the first few days of treatment and some only cause drowsiness in higher doses. In such cases the patient should be told that the advice applies until the effects have worn off. However many of these preparations can produce a slowing of reaction time and a loss of mental concentration that can have the same effects as drowsiness. Avoidance of alcoholic drink is recommended because the effects of CNS

depressants are enhanced by alcohol. Strict prohibition however could lead to some patients not taking the medicine. Pharmacists should therefore explain the risk and encourage compliance, particularly in patients who may think they already tolerate the effects of alcohol (see also label 3). Queries from patients with epilepsy regarding fitness to drive should be referred back to the patient's doctor. Side-effects unrelated to drowsiness that may affect a patient's ability to drive or operate machinery safely include *blurred vision, dizziness, or nausea*. In general, no label has been recommended to cover these cases, but the patient should be suitably counselled.

### 3

**Warning: This medicine may make you sleepy.  
If this happens, do not drive or use tools or  
machines**

**Rhybudd: Gall y feddyginiaeth hon eich gwneud  
yn gysglyd. Peidiwch â gyrru, defnyddio offer  
llaw neu beiriannau os yw hyn yn digwydd**

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To be used on *preparations containing monoamine-oxidase inhibitors*; the warning to avoid alcohol and dealcoholised (low alcohol) drink is covered by the patient information leaflet. Also to be used as for label 2 but where alcohol is not an issue.

### 4

**Warning: Do not drink alcohol**

**Rhybudd: Peidiwch ag yfed alcohol**

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To be used on *preparations where a reaction such as flushing may occur if alcohol is taken* (e.g. metronidazole). Alcohol may also enhance the hypoglycaemia produced by some oral antidiabetic drugs but routine application of a warning label is not considered necessary. Patients should be advised not to drink alcohol for as long as they are receiving/using a course of medication, and in some cases for a period of time after the course is finished.

### 5

**Do not take indigestion remedies 2 hours  
before or after you take this medicine**

## Peidiwch â chymryd meddyginiaethau camdreuliad 2 awr cyn neu ar ôl y feddyginiaeth hon

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To be used with label 25 on *preparations coated to resist gastric acid* (e.g. enteric-coated tablets). This is to avoid the possibility of premature dissolution of the coating in the presence of an alkaline pH. Label 5 also applies to drugs such as gabapentin *where the absorption is significantly affected by antacids*. Pharmacists will be aware (from a knowledge of physiology) that the usual time during which indigestion remedies should be avoided is at least 2 hours before and after the majority of medicines have been taken; when a manufacturer advises a different time period, this can be followed, and should be explained to the patient.

### 6

Do not take indigestion remedies, or medicines containing iron or zinc, 2 hours before or after you take this medicine

## Peidiwch â chymryd meddyginiaethau camdreuliad neu feddyginiaethau sy'n cynnwys haearn neu sinc, 2 awr cyn neu ar ôl y feddyginiaeth hon

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To be used on *preparations containing ofloxacin and some other quinolones, doxycycline, lymecycline, minocycline, and penicillamine*. These drugs chelate calcium, iron, and zinc and are less well absorbed when taken with calcium-containing antacids or preparations containing iron or zinc. Pharmacists will be aware (from a knowledge of physiology) that these incompatible preparations should be taken at least 2 hours apart for the majority of medicines; when a manufacturer advises a different time period, this can be followed, and should be explained to the patient.

### 7

Do not take milk, indigestion remedies, or medicines containing iron or zinc, 2 hours before or after you take this medicine

## Peidiwch â chymryd llaeth, meddyginiaethau camdreuliad, neu feddyginiaeth sy'n cynnwys

## haearn neu sinc, 2 awr cyn neu ar ôl cymryd y feddyginiaeth hon

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To be used on *preparations containing ciprofloxacin, norfloxacin, or tetracyclines that chelate calcium, iron, magnesium, and zinc*, and are thus less available for absorption. Pharmacists will be aware (from a knowledge of physiology) that these incompatible preparations should be taken at least 2 hours apart for the majority of medicines; when a manufacturer advises a different time period, this can be followed, and should be explained to the patient. Doxycycline, lymecycline, and minocycline are less liable to form chelates and therefore only require label 6 (see above).

## 8

**Warning: Do not stop taking this medicine unless your doctor tells you to stop**

**Rhybudd: Peidiwch â stopio cymryd y feddyginiaeth hon, oni bai fod eich meddyg yn dweud wrthy ch am stopio**

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To be used on *preparations that contain a drug which is required to be taken over long periods without the patient necessarily perceiving any benefit* (e.g. antituberculous drugs). Also to be used on *preparations that contain a drug whose withdrawal is likely to be a particular hazard* (e.g. clonidine for hypertension). Label 10 (see below) is more appropriate for corticosteroids.

## 9

**Space the doses evenly throughout the day. Keep taking this medicine until the course is finished, unless you are told to stop**

**Gadewch yr un faint o amser rhwng pob dôs yn ystod y dydd. Parhewch i gymryd y feddyginiaeth nes bod y cyfan wedi'i orffen, oni bai eich bod yn cael cyngor i stopio**

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To be used on *preparations where a course of treatment should be completed* to reduce the incidence of relapse or failure of treatment. The preparations are antimicrobial drugs given by mouth. Very occasionally, some may have severe side-effects (e.g. diarrhoea in patients receiving clindamycin) and in such cases the patient may need to be advised of reasons for

stopping treatment quickly and returning to the doctor.

10

Warning: Read the additional information given with this medicine

Rhybudd: Darllenwch y wybodaeth ychwanegol gyda'r feddyginiaeth hon

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To be used particularly on *preparations containing anticoagulants, lithium, and oral corticosteroids*. The appropriate treatment card should be given to the patient and any necessary explanations given. This label may also be used on other preparations to remind the patient of the instructions that have been given.

11

Protect your skin from sunlight—even on a bright but cloudy day. Do not use sunbeds

Diogelwch eich croen rhag golau'r haul, hyd yn oed ar ddiwrnod braf ond cymylog. Peidiwch â defnyddio gwely haul

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To be used on *preparations that may cause phototoxic or photoallergic reactions* if the patient is exposed to ultraviolet radiation. Many drugs other than those listed in Appendix 3 (e.g. phenothiazines and sulfonamides) may, on rare occasions, cause reactions in susceptible patients. Exposure to high intensity ultraviolet radiation from sunray lamps and sunbeds is particularly likely to cause reactions.

12

Do not take anything containing aspirin while taking this medicine

Peidiwch â chymryd unrhyw beth sy'n cynnwys aspirin gyda'r feddyginiaeth hon

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To be used on *preparations containing sulfinpyrazone* whose activity is reduced by aspirin. Label 12 should not be used for anticoagulants since label 10 is more appropriate.

13

Dissolve or mix with water before taking

Gadewch i doddi mewn dŵr cyn ei gymryd

---

To be used on *preparations that are intended to be dissolved in water* (e.g. soluble tablets) or *mixed with water* (e.g. powders, granules) before use. In a few cases other liquids such as fruit juice or milk may be used.

14

This medicine may colour your urine. This is harmless

Gall y feddyginiaeth hon liwio eich dŵr. Nid yw hyn yn arwydd o ddrwg

---

To be used on *preparations that may cause the patient's urine to turn an unusual colour*. These include triamterene (blue under some lights), levodopa (dark reddish), and rifampicin (red).

15

Caution: flammable. Keep your body away from fire or flames after you have put on the medicine

Rhybudd: Fflamadwy. Ar ôl rhoi'r feddyginiaeth ymlaen, cadwch yn glir o dân neu fflamau

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To be used on *preparations containing sufficient flammable solvent to render them flammable if exposed to a naked flame*.

16

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

Rhowch y dabled i doddi dan eich tafod - peidiwch â'i lyncu. Cadwch y tabledi yn y botel yma gyda'r caead wedi'i gau yn dynn. Gofynnwch am dabledi newydd 8 wythnos ar ôl ei hagor

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To be used on *glyceryl trinitrate tablets* to remind the patient not to transfer the tablets to plastic or less suitable containers.

17

Do not take more than . . . in 24 hours

Peidiwch â chymryd mwy na . . . mewn 24 awr

---

To be used on *preparations for the treatment of acute migraine* except those containing ergotamine, for which label 18 is used. The dose form should be specified, e.g. tablets or capsules. It may also be used on preparations for which no dose has been specified by the prescriber.

18

Do not take more than . . . in 24 hours. Also, do not take more than . . . in any one week

Peidiwch â chymryd mwy na . . . mewn 24 awr. Hefyd, peidiwch â chymryd mwy na . . . mewn wythnos

---

To be used on preparations containing ergotamine. The dose form should be specified, e.g. tablets or suppositories.

19

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

Rhybudd: Bydd y feddyginiaeth hon yn eich gwneud yn gysglyd. Os ydych yn dal i deimlo'n gysglyd drannoeth, peidiwch â gyrru, defnyddio offer llaw neu beiriannau. Peidiwch ag yfed alcohol

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To be used on *preparations containing hypnotics (or some other drugs with sedative effects) prescribed to be taken at night*. On the rare occasions when hypnotics are prescribed for daytime administration (e.g. nitrazepam in epilepsy), this label would clearly not be appropriate. Also to be used as an *alternative to the label 2 wording* (the choice being at the discretion of the pharmacist) *for anxiolytics prescribed to be taken at night*. It is hoped that this wording will convey adequately the problem of residual morning sedation after taking 'sleeping tablets'.

21

Take with or just after food, or a meal

Cymerwch gyda neu ar ôl bwyd

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To be used on *preparations that are liable to cause gastric irritation, or those that are better absorbed with food*. Patients should be advised that a *small amount of food is sufficient*.

22

Take 30 to 60 minutes before food

Cymerwch 30 i 60 munud cyn bwyd

---

To be used on some preparations *whose absorption is thereby improved*. Most oral

antibacterials require label 23 instead (see below).

23

Take this medicine when your stomach is empty. This means an hour before food or 2 hours after food

Cymerwch y feddyginiaeth hon ar stumog wag. Mae hyn yn golygu awr cyn, neu 2 awr ar ôl bwyd

---

To be used on *oral antibacterials whose absorption may be reduced by the presence of food and acid in the stomach.*

24

Suck or chew this medicine

Bydd angen cnoi neu sugno'r feddyginiaeth hon

---

To be used on *preparations that should be sucked or chewed.* The pharmacist should use discretion as to which of these words is appropriate.

25

Swallow this medicine whole. Do not chew or crush

Llyncwch yn gyfan. Peidiwch â chnoi neu falu'n fân

---

To be used on *preparations that are enteric-coated or designed for modified-release.* Also to be used on *preparations that taste very unpleasant or may damage the mouth* if not swallowed whole. Patients should be advised (where relevant) that some modified-release preparations can be broken in half, but that the halved tablet should still be swallowed whole, and not

chewed or crushed.

26

Dissolve this medicine under your tongue

Gadewch i'r feddyginiaeth hon doddi o dan y tafod

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To be used on *preparations designed for sublingual use*. Patients should be advised to hold under the tongue and avoid swallowing until dissolved. The buccal mucosa between the gum and cheek is occasionally specified by the prescriber.

27

Take with a full glass of water

Cymerwch gyda llond gwydr o ddŵr

---

To be used on *preparations that should be well diluted* (e.g. chloral hydrate), *where a high fluid intake is required* (e.g. sulfonamides), or *where water is required to aid the action* (e.g. methylcellulose). The patient should be advised that 'a full glass' means at least 150 mL. In most cases fruit juice, tea, or coffee may be used.

28

Spread thinly on the affected skin only

Taenwch yn denau ar y croen sydd wedi'i effeithio yn unig

---

To be used on *external preparations* that should be applied sparingly (e.g. corticosteroids, dithranol).

29

Do not take more than 2 at any one time. Do

not take more than 8 in 24 hours

Peidiwch â chymryd mwy na 2 ar unrhyw un adeg. Peidiwch â chymryd mwy nag 8 mewn 24 awr

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To be used on containers of dispensed *solid dose preparations containing paracetamol for adults when the instruction on the label indicates that the dose can be taken on an 'as required' basis*. The dose form should be specified, e.g. tablets or capsules. This label has been introduced because of the serious consequences of overdose with paracetamol.

30

Contains paracetamol. Do not take anything else containing paracetamol while taking this medicine. Talk to a doctor at once if you take too much of this medicine, even if you feel well

Yn cynnwys paracetamol. Peidiwch â chymryd unrhyw beth arall sy'n cynnwys paracetamol tra'n cymryd y feddyginiaeth hon. Siaradwch gyda'ch meddyg ar unwaith os ydych yn cymryd gormod, hyd yn oed os ydych yn teimlo'n iawn

---

To be used on all containers of dispensed *preparations containing paracetamol*.

32

Contains aspirin. Do not take anything else containing aspirin while taking this medicine

Yn cynnwys aspirin. Peidiwch â chymryd unrhyw beth arall sy'n cynnwys aspirin tra'n cymryd y feddyginiaeth hon

---

To be used on containers of dispensed *preparations containing aspirin* when the name on the label does not include the word 'aspirin'.

◀ [Previous: Guidance for cautionary and advisory labels](#) | [Top](#) | [Next: Wound management products and elasticated garments](#) ▶

## See Also

### BNF

[Guidance for cautionary and advisory labels](#)

### BNF for Children

[Guidance for cautionary and advisory labels](#)

### BNFC Legacy

[Appendix 3 Cautionary and advisory labels for dispensed medicines](#)

### BNF Legacy (2)

[Appendix 3 Cautionary and advisory labels for dispensed medicines](#)

[Products and their labels](#)

▲ [Back to top](#)

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