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# PHARMACY REGISTRATION BOARD OF WESTERN AUSTRALIA

(A.B.N. 75 635 660 854)

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## Communiqué

20 February 2017

### Outcome of Audits of 2016 Registration Renewal Statutory Declarations

The Board renews the registration of a pharmacy *if* the application supports compliance with the legislation and requirements it considers are in the public interest. Recently, the Board considered the outcome of its audits of three metropolitan and 38 regional applications made by pharmacists with overall responsibility for the pharmacy business (**Responsible Pharmacists**) in May and June 2016 (**Audits**).

Site Audits involved an inspection of the premises and audit of all statements on the applications.

Desktop Audits involved an audit of the following statement on the applications.

- **I confirm that the registered premises have access to the latest edition of each of the reference documents prescribed in *Schedule 1 of the Pharmacy Regulations 2010*.**<sup>1</sup>

The Board is concerned that the Audits did not support the statement(s) made by a significant number of Responsible Pharmacists and indicate that:

- Responsible Pharmacists –
  - do not routinely check compliance with the Minimum Standards when making their Statutory Declaration,
  - who have previously completed an application to –
    - establish new premises,
    - relocate existing premises, or
    - make significant alterations to existing premises,by providing evidence that such premises comply with the Minimum Standards at that time do not routinely ensure the premises maintains compliance with the Minimum Standards,
  - do not routinely check compliance with the Minimum Standards on acceptance of their appointment or on a regular basis following their appointment; and
- Purchasers do not routinely check that the premises complies with the Minimum Standards prior to settlement of the sale of pharmacy businesses.

The Board:

- reminds Responsible Pharmacists and proprietors of their obligations in relation to the Minimum Standards;
- recommends Responsible Pharmacists immediately check the premises complies with all the applicable requirements of the Minimum Standards<sup>2</sup> and implement routine checks to ensure the premises complies at all times; and

- reminds Responsible Pharmacists and proprietors of its expectation that the outcome of –
    - an inspection of the premises supports compliance with all assessed legislative requirements, and
    - audit of an application supports compliance with the assessed requirement(s) of the Minimum Standards.
1. *Schedule 1 of the Pharmacy Regulations* prescribes the minimum standards of fitness for the competent and safe practice of pharmacy (the Minimum Standards).
  2. If a pharmacy registered under the *Pharmacy Act 1964* was not in compliance with the Minimum Standards requirements for the dispensary to have a minimum floor area of 10 square metres and/or an area for private consultation on 17 October 2010, then that requirement applies only after significant alterations are next completed.

## **Schedule 1 of the Pharmacy Regulations, Change to prescribed reference documents**

The enactment of the *Medicines and Poisons Act 2014* and the subsidiary *Medicines and Poisons Regulations 2016* on 30 January 2017 necessitated a change to *Schedule 1 of the Pharmacy Regulations 2010*.

From 30 January 2017, the Minimum Standards prescribes that the premises are to have a copy of, or immediate electronic access to, the latest editions, and all published amendments or supplements to those editions, of each of the following reference documents.

**The editions of the reference documents shown below are the latest editions on 20 February 2017, the date of this Communiqué.**

### **Australian Medicines Handbook (AMH)**

The latest editions of the AMH are the publications of 18 January 2017:

- AMH 2017
- eAMH (January 2017)

### **Australian Pharmaceutical Formulary and Handbook (APF)**

The latest editions of the APF are the publications of 18 February 2015:

- APF23
- eAPF23

### **MIMS Annual or eMIMS or AusDI**

The latest edition of the MIMS Annual is the publication of July 2016:

- MIMS Annual 2016

The latest editions of the eMIMS is:

- always the current month

The latest edition of AusDI is:

- always the current month

### **Therapeutic Guidelines (complete series)**

The latest editions of the Therapeutic Guidelines books are:

- Analgesic v6, 2012
- Antibiotic v15, 2014 (November)
- Cardiovascular v6, 2012
- Dermatology v4, 2015 (November)
- Endocrinology v5, 2014 (March)

- Gastrointestinal v6, 2016 (April)
- Neurology v4, 2011
- Oral and Dental v2, 2012
- Palliative Care v4, 2016 (September)
- Psychotropic v7, 2013 (July)
- Respiratory v5, 2015 (March)
- Rheumatology v2, 2010
- Toxicology and Wilderness v2, 2012
- Ulcer and Wound Management v1, 2012

The latest edition of the eTG is the publication of November 2016:

- eTG (November 2016)

#### **Pharmacy Act 2010**

The latest edition is always accessed if the premises has a link to [Pharmacy Act 2010](#) on the [State Law Publisher website](#)

#### **Pharmacy Regulations 2010**

The latest edition is always accessed if the premises has a link to [Pharmacy Regulations 2010](#) on the State Law Publisher website

#### **Medicines and Poisons Act 2014**

The latest edition is always accessed if the premises has a link to [Medicines and Poisons Act 2014](#) on the State Law Publisher website

#### **Medicines and Poisons Regulations 2016**

The latest edition is always accessed if the premises has a link to [Medicines and Poisons Regulations 2016](#) on the State Law Publisher website

Given the outcome of its Audits and the change to the Minimum Standards, **the Board recommends that Responsible Pharmacists:**

- use the above checklist to **ensure that the premises currently has access to the latest editions of all reference documents** prescribed under the Minimum Standards;
- implement systems, practices and/or processes to **ensure that they are aware of the publication dates of new editions of each reference document**; and
- implement systems, practices and/or processes to **ensure that the premises maintains compliance with the access to reference documents requirements of the Minimum Standards at all times.**

**John Harvey**  
Presiding Member