



Information for vendors: Applying for approval of an electronic prescribing or dispensing system

The Commonwealth Department of Health has overall responsibility for the electronic prescribing project and they have partnered with the Australian Digital Health Agency (the Agency) to develop the technical aspects of the project. This includes a conformance framework to support the legal prescribing and dispensing of medicines as well as the claiming of electronic prescriptions through the Pharmaceutical Benefits Scheme (PBS).

In Western Australia (WA), the [*Medicines and Poisons Regulations 2016*](#) require each product that is part of an electronic prescribing system be approved by the WA Department of Health.

Approval of an electronic prescribing and/or dispensing product will only be considered where:

- The Agency's Electronic Prescribing Conformance Process has been fully completed with addition of the Conformance ID for the vendor's product to the Agency's Register of Conformance and
- The software vendor has provided information to the WA Department of Health to show their product complies with the requirements of the *Medicines and Poisons Regulations 2016*.

Application requirements

Applications must be in writing, addressed to the Chief Pharmacist at the WA Department of Health and include the following information:

1. Software vendor and product details including:
 - Name and address of vendor
 - Name of contact person and their contact details
 - Name of the electronic dispensing and/or prescribing product, including version number
 - Conformance ID text string.
2. Evidence that the Declaration of Conformance for the product has been received by the Australian Digital Health Agency and
3. Information to show the product satisfies the requirements of the *Medicines and Poisons Regulations 2016* as specified in Table 1.

The WA Department of Health will assess each application on a case by case basis and applicants may be required to provide a demonstration of the working product.

Applicants will be advised in writing whether their product has been approved as an electronic prescribing and/or dispensing component for use in Western Australia.

A list of West Australian approved software vendors can be found at : [Electronic prescribing and dispensing software approved in Western Australia](#)

General information for health professionals can be found at: [Electronic prescribing systems](#)

Table 1: Additional Western Australian requirements for electronic prescribing and dispensing software products

Medicines and Poisons Regulations 2016	Applies to	WA specific requirements	Electronic Prescribing Participating Software Conformance Profile requirements
10	Electronic prescribing software product	<p>The electronic prescribing product SHALL generate a prescription that must contain the following information specified in Regulation 10:</p> <ol style="list-style-type: none"> 1. the name, address and telephone number of the prescriber, 2. the date on which the prescription is issued, 3. the name and address of the patient for whom the medicine is prescribed, 4. a description and the quantity, dose, strength and form of each medicine that is to be supplied, 5. precise directions for use of each medicine that is to be supplied, 6. if the document provides for the medicine to be supplied on more than one occasion – the maximum number of times it may be supplied and 7. if the prescription is for a Schedule 8 medicine : <ol style="list-style-type: none"> a. date of birth of the patient and b. if the prescription is for the supply of a Schedule 8 medicine on more than one occasion – the interval at which it may be supplied. 	<p>PRES-17 The system SHALL include, within the electronic prescription, all data fields as required by Jurisdictional Regulations.</p> <p>PRES-24 The system SHALL display the electronic prescription in a format that meets the requirements of the National Regulations and relevant state and territory legislation to the prescriber and obtain a final approval from the prescriber prior to finalising the prescription for transmission.</p> <p>DISP-50 The system SHALL display the particulars of the prescription repeat required by state and territory legislation to the dispenser and obtain a final approval from the dispenser prior to finalising the prescription repeat.</p>
19(4) (b) (i) 19 (4) (d)	Electronic prescribing software product	The electronic prescribing product SHALL require the user to re-authenticate when prescribing Schedule 8 medicines.	PRES-7 The system SHALL require the user to re-authenticate as and when required under state and territory regulations when prescribing controlled medicines (or attain an additional stage where multi-stage authentication is used).

Medicines and Poisons Regulations 2016	Applies to	WA specific requirements	Electronic Prescribing Participating Software Conformance Profile requirements
19 (4) (d) 19 (5) (b) (c)	Electronic prescribing and dispensing software product	<p>The electronic prescribing or dispensing product SHALL have an individual designated as the system administrator for the product to:</p> <ol style="list-style-type: none"> 1. authenticate individuals to prescribe or dispense, 2. give access to individuals to prescribe or dispense and 3. remove access to individuals to prescribe or dispense. 	<p>PRES-2 The system SHALL allow access to electronic prescribing capability only to designated user accounts.</p> <p>PRES-11 The system MAY provide for an option to enable/disable electronic prescribing capability on a per user account basis.</p> <p>DISP-5 The system SHALL allow access to the capability for dispensing against electronic prescriptions only to designated user accounts.</p>
20(g)	Electronic prescribing and dispensing software product	<p>The electronic prescribing or dispensing product SHALL record the details of each individual system administrator and SHALL retain the details of the administrator for a minimum of seven years after the person ceases to be an administrator.</p>	<p>Not covered by the Electronic Prescribing Participating Software Conformance Profile</p>

Medicines and Poisons Regulations 2016	Applies to	WA specific requirements	Electronic Prescribing Participating Software Conformance Profile requirements
20(h)(iii)	Electronic prescribing and dispensing software product	<p>The electronic prescribing or dispensing product MUST be able to produce reports of entries made in the system and can sort the entries according to:</p> <ol style="list-style-type: none"> 1. medicine type, strength or dose or 2. patient. 	<p>DISP-34 The system SHALL maintain audit logs associated with electronics dispense events in accordance with relevant legislation and regulation.</p> <p>DISP- 51 The system SHALL allow generation of a prescription file, able to be transmitted to regulatory body. This file SHALL include:</p> <ul style="list-style-type: none"> • the original electronic prescription; • any subsequent repeat authorisations; • any associated annotations; • any details about when the electronic prescription was downloaded from the PDS; • date and time of dispense; • date and time of PDS acceptance; • copies of any relevant Token(s) (DSPID) provided to the subject of care/ agent.
20(i)	Electronic prescribing and dispensing software product	The records of the prescribing or dispensing product can be produced on demand to investigators appointed under the Medicines and Poisons Act 2014 (Section 95).	DISP- 51 as above.

Medicines and Poisons Regulations 2016	Applies to	WA specific requirements	Electronic Prescribing Participating Software Conformance Profile requirements
143 (1) (e)	Electronic dispensing software product	<p>The electronic dispensing product must ensure that the following information is recorded each time a prescription is dispensed:</p> <ol style="list-style-type: none"> 1. the name, quantity, strength and form of the medicine dispensed 2. the name and address of the patient 3. the date on which the medicine is dispensed 4. the prescription reference number 5. the date of issue of the prescription 6. if the medicine is a Schedule 8 medicine, the date of birth of the patient and <ol style="list-style-type: none"> 6.1 If the date of birth on the electronic prescription differs from the date of birth on the existing patient profile, the electronic dispensing product must alert the pharmacist to update the patient profile so that the correct date of birth is recorded on the patient profile. 6.2 if there is no date of birth on the existing patient profile, the dispensing product must alert the pharmacist to update the patient profile so that the date of birth is recorded on the patient profile. 7. if the medicine is a Schedule 8 medicine, the name and address of the prescriber. 	Not covered by the Electronic Prescribing Participating Software Conformance Profile

Medicines and Poisons Regulations 2016	Applies to	WA specific requirements	Electronic Prescribing Participating Software Conformance Profile requirements
143 (2) (a)	Electronic dispensing software product	<p>The electronic dispensing product must ensure that the record of the dispensing of a Schedule 8 medicine can be provided to the Western Australian Department of Health in a report of all Schedule 8 medicines dispensed and supplied by the pharmacy for a calendar month and must include:</p> <ol style="list-style-type: none"> 1. name, quantity, strength and form of the medicine dispensed 2. name and address of the patient 3. date of dispensing 4. prescription reference number 5. original date of prescription issued 6. date of birth of the patient and 7. name and address of prescriber. 	Not covered by the Electronic Prescribing Participating Software Conformance Profile

Resources

The [Medicines and Poisons Act 2014](#) and the [Medicines and Poisons Regulations 2016](#) are available from the WA legislation website: www.legislation.wa.gov.au.

For more information

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