



healthlinks.net's submission to TGA's  
Discussion Paper

on

'Reforms in the Medical Devices  
Regulatory Framework'

December 2010

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# 1 Executive Summary

healthlinks.net welcomes the opportunity to review and provide feedback to the TGA's 'Discussion Paper' on the most appropriate means for improving consumer and health professionals access to information on devices.

The aim of this submission is to provide feedback based on our extensive involvement and successful participation in the healthcare sector for a number of years, providing a unique service, which has been embraced by the healthcare industry.

In response to sponsor demands, needs and requirements, healthlinks.net developed an internet enabled, centralised repository of Consumer Medicine Information (CMI) and Product Information (PI) data, the Secure Data Warehouse (SDWH).

healthlinks.net participating Sponsors include companies distributing devices and our experience suggests:

- creation of standards (similar to Usability Guidelines for CMI) around the presentation and format of the information ensuring consistency in the marketplace
- expansion of the distribution of the information to the widest possible audience, including dispensing software, for information such as 'Instructions for Use' and 'Patients Information'
- In keeping with the uniformity of the prescription framework, Sponsors should
  - retain the copyright of the information
  - be responsible for the accuracy and currency of information
  - participate in the scheme for all medical devices, including lower risk classification devices

healthlinks.net supports Australia's national strategy for the Quality Use of Medicine, making the best possible use of medicines to improve health outcomes for all Australians. healthlinks.net welcomes any schemes that aids in the achievement of this.

## 2 Company Background

healthlinks.net's business is primarily to manage the collection and distribution of CMI and PI data within a secure electronic infrastructure.

Two services pioneered by healthlinks.net, the electronic distribution of Consumer Medicine Information to point of dispense (the Dispensing Software distribution) and the central repository of CMI and PI, the Secure Data Warehouse (SDWH), are unique to the international healthcare industry.

Dispensing Software distribution was developed over 15 years ago, with the assistance of the Electronic Distribution Working Group (EDWG). healthlinks.net is the provider of electronic CMIs in Australia, with:

- Distribution to approximately 5,400 retail and hospital dispensing software vendors
- Distribution to more than 45 On-Distributors, including MIMs, AusDI, and NPS
- Representation of over 40 pharmaceutical companies
- Approximately 1,500 CMIs in its database

In 2000, at the request of Sponsors (pharmaceutical companies), healthlinks.net developed an internet enabled repository and user application called the Secure Data Warehouse (SDWH). These Sponsors requested a centralised repository of their CMI and PI, which is secure, governed by legal agreements and free of charge to the user, the On-distributor of data. Currently the SDWH houses approximately 1,600 CMIs and 1,500 PIs.

SDWH allows Sponsors to access, update and distribute their CMI and PI data in multiple formats with immediate results. That is, as soon as the document is released by the Sponsor, it is available to the SDWH users, the On-distributors. The Sponsors also retain full control of who accesses their data, in what format and the timing of the release of their documents.

healthlinks.net current business model allows the distribution of CMI and PI to all users free of charge and the costs of housing and distributing these are borne by the Sponsor companies.

healthlinks.net provides Sponsors, who choose to distribute information through the SDWH, with a secure, encrypted 'clearing house' facility. Sponsors have the convenience of dealing with one company and having only one set of documents to update, while achieving excellent market coverage and ensuring the currency of the data they distribute. This eliminates the administrative challenge and associated costs of individually providing information to various On-distributors.

The SDWH allows Sponsors access to various reports, including their documents' history, providing full audit functionality for all their documents in the SDWH.

Recent innovation for healthlinks.net includes increased accessibility to CMI's in expanded formats, such as Large Print, provision for Braille, and Audio outputs to cater for the 17% of Australians with some form of visual impairment.

Furthermore, healthlinks.net has been working with TGA to enable real time delivery of CMI's and PI's to the TGA eBusiness Services website.

The project involved close collaboration with the TGA, resulting in a custom built solution, which provides an automated submission service of CMI's and PI's from the healthlinks.net SDWH to the TGA.

This technology allows Sponsors participating in the service provided by healthlinks.net, to meet their compliance obligations with the TGA, ensuring the most current CMI's and PI's are available on the eBusiness Services website.

These services demonstrate the core values of healthlinks.net, which support Australia's national strategy for the Quality Use of Medicine, making the best possible use of medicines to improve health outcomes for all Australians.

### **3 Response to ‘Proposal 4 – Publication of device product information on the TGA Website’**

healthlinks.net is pleased to provide general feedback relating to the Office of Device Authorisation’s intention to establish device information similar to that currently available for prescription medicines, including CMI and PI.

healthlinks.net participating Sponsors include companies distributing devices and from our experience in processing and distributing information suggests that the format and presentation of any proposed information should adhere to the same standards as the current CMI and PI to ensure consistency in the marketplace as far as practical. The Usability Guidelines enable Sponsors to provide CMIs in a structured and standard format, which ensures consistency for consumers, and we suggest considering the establishment of Usability Guidelines for devices.

Furthermore, healthlinks.net suggests the distribution of the information should be expanded to the widest possible audience, including dispensing software, if applicable. The Reform discussion paper mentions information such as ‘Instructions for Use’ and ‘Patients Information’ that may be suitable for such distribution.

In keeping with the uniformity of the prescription framework, all information should remain the copyright of the respective Sponsor, and all responsibilities for the accuracy and currency of information should also be retained by Sponsors. healthlinks.net is in a position to assist Sponsors with currency through existing legal agreements already in place.

We support the Discussion paper’s recommendations in setting up such a scheme for device information, and suggest that the scheme include product information for all medical devices, including lower risk classification devices. We further support consumer specific information, where applicable, particularly for devices where patient information and/or instructions for use are available.