

Australian Government
Australian Digital Health Agency
Program Delivery and Workplan Development Branch
Medicines Safety Program
Email: ADHA.blueprint@nousgroup.com.au

Re: Discussion Paper: Co-designing and publishing a Digital Medicines Program Blueprint

Medicines Australia welcomes the opportunity to provide a submission to the Australian Digital Health Agency's (ADHA) discussion paper '*Co-designing and publishing a Digital Medicines Program Blueprint*'.

Medicines Australia represents the discovery-driven pharmaceutical industry in Australia. Our member companies invent, manufacture and supply innovative medicines and vaccines to the Australian community. Those medicines keep Australians out of hospitals, prevent disease and play a pivotal role in ensuring a productive and healthy community.

Medicines Australia acknowledges the ambition of the Digital Medicines Program Blueprint (the Blueprint) to enable the digital transformation of healthcare and information about medicines. There are a number of opportunities that the digital availability of medicines information can provide, all of which can improve medicines safety and health outcomes, resulting in a targeted and more efficient healthcare system.

Medicines Australia believes that the digital transformation of health and medicines has the potential to benefit Australians by:

- Enhancing the quality and efficiency of healthcare by enabling health professionals to access health information at the right time, thus enabling fully-informed treatment decisions to be made safely and in a timely manner.
- Improving the data capability of the digital systems which will contribute to the accuracy of adverse event reporting and strengthen Australia's pharmacovigilance system.
- Driving future medical innovation and health research tailored to Australian patient needs by ensuring appropriate access to quality data, and;
- Allowing access to population health data which enables the development of targeted health policies, allowing for the efficient and effective use of government resources.

However, there are several issues with the Blueprint that Medicines Australia would like to raise (see below).

Role of Government vs Industry

The Blueprint collates multiple existing initiatives by industry, funded agencies and various parts of the pharmaceutical medicines sector. Thus, it is important for the Blueprint to further clarify the role of government versus the market in solving these challenges. If the government is aiming to drive these changes, then adequate **funding** will need to be available to enable providers to find solutions. Furthermore, the Blueprint does not appear to provide sufficient **clarity** on how these various ambitions will be achieved or provide many ideas for innovative solutions.

Role of the Australian Product Information (PI) and Consumer Medicines Information (CMI)

Medicines Australia proposes that any work done in the digital health space needs to be cognisant of, and done in conjunction with, any other projects that may be delivered in a digital format to ensure both projects are codesigned with each other's requirements.

Medicines Australia is currently working with a range of stakeholders to improve the format, content and digital accessibility of CMI. However, there is no reference to the CMI, a document required by legislation, which medicine sponsors are responsible for creating and maintaining (e.g. diagram on page 11 does not include CMI). The current work being done on CMI is thus a project which could be referenced as related work.

Additionally, on the topic of medicines information, an important source of evidence-based information on medicines which is evaluated and approved by the Therapeutic Goods Administration (TGA), is the PI. However, there are no references to the role of the PI in the context of information about medicines within the document.

Access to adverse event data

The healthcare and well-being of patients is the first priority for pharmaceutical companies. Australian pharmaceutical companies have clear and strict obligations around pharmacovigilance in Australia which also aligns with a global medicines safety network. The Blueprint states that there will be development of solutions to enhance adverse event reporting, giving pharmaceutical companies **greater insight into real-world data**, however it is not clear whether companies will have direct access to this data. Currently the TGA does not proactively share their adverse event data with sponsors or have the capability for an electronic data exchange with sponsors (although sponsors can electronically send data from their databases to the TGA database). Currently sponsors need to periodically request a report of adverse events from the TGA database and manually cross check the information against their own database. Enablement of pharmaceutical companies to access real-world data would be a welcome advance which would further improve the understanding on the safe and effective use of medicines.

In summary, Medicines Australia supports the work of the Australian Digital Health Agency on the development of a Digital Medicines Program Blueprint, which can be enhanced by greater clarity regarding the role of various stakeholders, inclusion of the PI and CMI, and the enablement of pharmaceutical companies to access real world data.

For further correspondence on this matter, please contact Betsy Anderson-Smith on banderson-smith@medaus.com.au.

Yours sincerely,



Dr Vicki Gardiner
Director Policy and Research
Medicines Australia