



SHPA response to Medicine shortages in Australia – consultation on challenges and opportunities, March 2024

Consultation Questions

1. What is your name?

Jerry Yik

2. Please provide your email address if you consent to us contacting you with consultation updates (separate to receiving a copy of your submission). Email:

[jyik@shpa.org.au](mailto: jyik@shpa.org.au)

3. Which of the following best describes you?

Health professional representative organisation

4. Organisation name:

The Society of Hospital Pharmacists of Australia (SHPA)

5. Size of organisation:

Medium (20-199 employees)

6. Have you been affected by a medicine shortage or discontinuation in the last 12 months?

Yes

No

Unsure

7. If yes, please list which medicine shortage(s) and/or discontinuation(s).

Key medicine shortage(s) and/or discontinuation(s) reported by SHPA members in the last 12 months include, but not limited to:

- Morphine products, e.g. oral morphine liquid
- Further critical medicines used in palliative care and chronic pain management, e.g. oxycodone, controlled release morphine, hydromorphone tablets
- Fludarabine phosphate injections
- Various antibiotics, e.g. rifampicin, phenoxymethylpenicillin
- Dexamethasone injection
- Semaglutide and dulaglutide injections



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Planning for medicine shortages and discontinuations

8. What do you do to plan proactively for a medicine shortage or discontinuation? Select all that apply:

- a. monitor medicine availability (supply, demand)
- b. seek out information about shortages and discontinuations
- c. manage stock levels
- d. plan for alternative treatments in case of shortage
- e. change the way medicine is prescribed/dispensed/taken (e.g. rationing)
- f. other

9. Please explain in more detail how you plan proactively for a medicine shortage or discontinuation, including any barriers or challenges you experience.

SHPA members report that establishing a close relationship with their wholesalers and manufacturers is critical in planning for medicine shortages or discontinuations. For example in Queensland Health, hospital pharmacies rely heavily on Central Pharmacy to provide feedback on availability of products and timely updates on stock shortages. Unfortunately, as Central Pharmacy Queensland often does not have a clear understanding of the clinical implication of shortages and discontinuation that affect the front-line health staff, communication of information may not be appropriately triaged or communicated to the relevant health professionals in the timeliest manner possible.

Hospital pharmacy departments may also have a procurement manager or dedicated number of pharmacy staff who regularly monitor trusted information sources for updates on medicine shortages and discontinuations, including the Therapeutic Goods Administration's (TGA's) Medicine Shortage Information Initiative (MSII) website.¹

Overall, there continues to be a heavy reliance on wholesalers to alert hospitals of upcoming shortages, as SHPA members report lack of accuracy and timeliness of the information updated on the MSII website, which presents as a barrier for pharmacists to fully maximise the potential of this tool in proactively managing medicine shortages or discontinuations.

Another challenge is the lack of a centralised medication monitoring system at a state-wide level in most jurisdictions, which results in reduced visibility over current stock levels at wholesalers. Ideally a proactive central medication bulletin that monitors all wholesaler orders and backorders can be hugely beneficial in early identification of issues and trends in stock supply that can be communicated to clinicians.

10. [Pharmaceutical companies only] What measures do you use to monitor and predict medicine supply including disruptions and increases in demand? Are there any barriers or challenges?

Not Applicable



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Responding to medicine shortages and discontinuations

11. Please outline how you respond to a medicine shortage or discontinuation, including any barriers or challenges you experience.

There is currently no nationally coordinated approach to managing medicine shortages and discontinuation in Australia, with varying degrees of state-level response between jurisdictions. More than often, the intra- and inter-jurisdictional duplication of efforts in managing medicine shortages or discontinuations results in significant consumption of local systems and clinical resources. In the case of hospital pharmacists, medicine shortages and discontinuations overburden their already stretched workload, taking pharmacists away from delivering quality, patient-facing clinical services.

Currently in most hospitals across Australia, the management of the medicine shortage or discontinuation is governed by either a procurement manager if the role exists, or by the pharmacy procurement team. Initial management usually includes assessment of which clinical areas would be impacted by the medicine shortage or discontinuation and subsequent consultation of the respective clinical leads in those affected areas. Consultation to obtain expert advice is required to fully understand the extent and impact of the medicine shortage or discontinuation on clinical workflow, potential changes in therapeutic management, and scoping of the next best alternative product where required. Once a management plan has been established, the procurement manager and or the pharmacy procurement team would communicate any changes to relevant clinicians across the whole hospital, in parallel with sourcing alternative products, and providing educational or administrative support in implementing any significant changes, including but not limited to:

- Enforcing supply restrictions and/or redistributing stock to critical wards
- Updating existing clinical guidelines
- Providing education on prescribing and administration of alternative products
- Updating electronic management systems

Regardless of the governance process, access to accurate and timely information regarding the specific medicine shortage or discontinuation is a key to establishing an effective and efficient initial response. Currently the lack of accuracy and timeliness of information communicated to hospital pharmacies present as a significant barrier for pharmacy departments in formulating an effective response strategy. As depicted in the *Medicines Shortages in Pharmacy survey 2022*², 83% of respondents reported a lack of improvement in the information about medicine shortages being communicated to pharmacies in a timely manner.

While understandably medicine shortage or discontinuation is multifactorial and initial timelines can change depending on the dynamic landscape of the global and local supply market, pharmacists can better prepare and coordinate response strategies if up-to-date information is made accessible as soon as possible. Early communication of potential stock outages also provides more time for pharmacists to appropriately scope out the implication of the shortage or discontinuation, allowing for safer and more considered strategies to ensure potential health risks are minimised for the patient.

State-wide coordination in responding to a medicine shortage or discontinuation is also advantageous in reducing workload and duplication of effort. In jurisdictions where there are centralised procurement capabilities (such as Central Pharmacy in Queensland), this service not only helps to identify shortages and discontinuations in a timely manner, but also provides solutions of alternative stockists or alternative therapies where required, saving the workload of individual sites investigating these issues on their own.³



SHPA members also report that in Queensland, medicine shortages affecting oncology patients are discussed at a state-wide level, to ensure appropriate stock sharing amongst hospitals and reserving of the affected medicine patients who need it the most. A recent example of where this has been successful was the management of fludarabine shortage, where pharmacy leaders from Queensland hospitals discussed the impact of the shortage, and ultimately decided on reserving fludarabine for CAR-T only, as it was the only indicated T-Cell depleting agent. This change was communicated through a memo from the statewide cancer network, which was distributed to all clinical directors and pharmacy directors to help manage and change clinical therapies accordingly. This downstream approach of communicating effective strategies can support hospitals to reduce substantial workload in conducting individual investigations and ensures consistency in the expected treatment for patients regardless of their location within the state.

12. Please describe in detail where any of the following have helped you to respond to a medicine shortage or discontinuation:

- a. Seeking support or advice (including from whom)
- b. Policies or legislation
- c. Access to information/data
- d. Technology
- e. Other

Access to accurate and timely information, and subsequent knowledge sharing and liaising with expert clinicians and peers are helpful in increasing intra- and inter-jurisdictional collaboration and cooperation in managing medicine shortages and discontinuations. As previously mentioned, a state-wide collaborative approach in dissemination of information and response planning can help to reduce administrative workload and resources for all involved clinicians. It can also prevent stock piling of critical medicines and support greater collaboration in sharing strategies and redistributing stock to hospitals who may have patients with limited alternative treatment options.

Continued relationships with wholesalers, pharmaceutical representatives, and Special Access Scheme (SAS) suppliers also remain key to ensuring timely receipt of medicine shortage information communicated to hospital pharmacies.

Communicating about medicine shortages and discontinuations

13. Where do you get information about a medicine shortage or discontinuation (select all that apply):

- health professional organisations
- patient organisations
- industry organisations
- the TGA and other federal government agencies
- state and territory government agencies
- the media, including social media
- other sources, please specify:

SHPA members report using a variety of source to obtain information on medicine shortage or discontinuation, including but not limited to:



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- Jurisdictional based agencies and commissions
- Clinicians
- Correspondence from the manufacturer
- SHPA forums
- SHPA newsletter
- COSA newsletter for products affecting oncology and haematology practice

14. What information or updates about a medicine shortage or discontinuation do you find most helpful and from where?

The duration of supply interruption in the case of medicine shortages, or the anticipated availability of alternative products in case of medicine discontinuations are highly useful information when formulating response strategies. In cases where the shortage is expected to be of short duration, pharmacists can help rationalise usage on wards in the shorter interim, suggesting changes to therapy where appropriate and safe. Alternatively, long-term shortages or discontinuation of products in near future may require larger collaboration of relevant clinicians in performing impact assessment and formulating an appropriate response strategy.

The persisting discrepancies and disconnect in the information made available by the TGA and what stock and supply level is available at wholesalers have escalated frustration amongst pharmacists in recent years. The recall of ranitidine products in 2019⁴ is an example where the lack of accurate and timely up-to-date information caused significant issues in the management of ranitidine supply in hospitals. Ranitidine had a significant impact particularly for oncology patients as it was a widely established premedication for vast range of chemotherapy regimens. The initial anticipation from TGA that supply disruptions due to the ranitidine recall may be short-lived implied that hospital pharmacies initially implemented interim solutions, as making substantial changes in clinical guidelines and adjusting therapeutic pathways for hundreds of chemotherapy regimens would entail a considerable amount of work and resources, only to have it all reversed once stock returned to normal levels within the expected timeframe.

However, the subsequent prolonged shortage and eventual suspension of ranitidine from the Australian Register of Therapeutic Goods (ARTG) spanning over the course of the last two years have delayed hospital pharmacies from efficiently implementing safer solutions, potentially exposing hospital patients to unsafe clinical practices due to inadequate medication shortage strategies.

Having an accurate and up-to-date information on expected medicine availability, expected stock return dates and supply arrangements is critical to inform how patient's therapy is to be managed in the short and long term. As previously alluded to, a central medication bulletin that monitors wholesaler stock levels and incorporates this information with medicine shortage or discontinuation information from the TGA, as well as any mitigation measures at a national level would support pharmacists to better manage medicine shortages and discontinuations, which are highly resource intensive.

15. What challenges do you face when receiving information about medicine shortages or discontinuations?

While there has been vast improvement in the reporting of medicine shortage and discontinuation and improvements in communication between the TGA and key stakeholders in recent years, SHPA members report that the lack of planned alternative products with references or evidence on suitability leaves local



hospitals and pharmacies to undertake their own assessments, duplicating efforts in procuring alternative therapies. In the *Medicines Shortages in Pharmacy* survey 2022², 50% and 59% of respondents reported medicine shortages were managed in hospitals by switching the patient to a non-ARTG product procured through the Special Access Scheme (SAS) or Section 19A approval processes, respectively. Accessing medicines through the SAS scheme and S19A processes is complex and time consuming for pharmacists already burdened with patient-facing roles, and often results in higher costs for hospitals and patients, and other challenges such as product labelling and packaging of alternative products that are not up to Australian standards.

Information communicated from TGA also lacked detail on the nature of the shortage, particularly in relation to whether it was a manufacturing issue, a global supply issue, or localised to Australia. This information was often required for procurement teams to understand whether they could plan to source alternative products quickly from their local SAS suppliers. Furthermore, the timeliness of the shortage or discontinuation notification currently does not appear to be triaged based on clinical necessity and the clinical setting in which the product is most utilised. For products which is more commonly used in acute care and within hospitals, prioritisation of shortages or a traffic light system in communicating information may be useful.

The timing of the information released during the week can also impact how quickly hospitals can respond, particularly for significant supply issues. For instance, any delays in communication at the national level resulting in hospitals being informed on Friday afternoons or on weekends would prove difficulty in response planning due to reduced staffing during these hours.

16. What challenges do you face when sharing information about medicine shortages or discontinuations?

As iterated above, the lack of accuracy of information communicated to hospital pharmacies including the duration of shortage and corresponding availability of stock at wholesalers, can make sharing of information amongst affected clinicians very difficult, as constant change in messaging can confuse clinicians on how they should adjust their clinical management of patients.

Conversely, health professionals can experience fatigue from an overloading of information that may not be relevant to their area of practice. SHPA recommends that communication methods are streamlined, enabling health professionals to selectively subscribe to medicine shortage or discontinuation updates that are relevant to their area of practice, thereby improving clinician engagement.

Another concern reported by SHPA members was the challenges faced when biosimilars are introduced. Unlike generic medicines, biosimilars are not considered to be completely interchangeable between different brands. While biosimilars have the potential to expand treatment options for many diseases and enhanced affordability for hospitals and patients, the potential differences in clinical efficacy that may be discovered in post-marketing surveillance implies considerable resourcing is still required for staff education.

17. What do you think about the information on the TGA website about [medicine shortages and discontinuations](#)?

SHPA commends TGA's efforts in improving the reporting of medicine shortages and discontinuations in Australia. The establishment of the MSII, whilst intended to provide clarity and information to prescribers and pharmacists through voluntary sponsor reporting scheme, initially failed to report critical shortages in a timely manner. In SHPA's landmark survey on medicines shortages in Australian hospitals in 2017⁵, members



identified only 15% of reported shortages appeared on the MSII website. This prompted several regulatory reforms, including one which mandated the reporting of shortages from 1 January 2019. This change saw a vast improvement in the reporting of medicine shortages, where respondents identified 71% of medicines are now reported on the MSII website.²

Unfortunately, the reporting of medicine shortages on the MSII website has yet to see further improvement in the management and coordination of medicine shortages, with 86% of respondents indicating a lack of improvement in the management and coordination of medicine shortages by government in the last 12 months.² Furthermore, 75% of respondents were aware of the TGA's MSII website, but only 24% indicated they refer to it for information on medicine shortages. Instead, 76% respondents reported that they relied on information displayed in their wholesaler online ordering portal to find information on prescription medicine shortages.²

A key barrier in maximising the full potential of the MSII website was the lack of consistency in the information presented. Hospital pharmacy departments heavily rely on timely communication of correct information on anticipated timeframes and current wholesaler stock levels in order to respond appropriately and effectively. SHPA members report that at current state, estimated stock arrival dates of affected medicines are rarely accurate and uploading of the shortage or discontinuation information often coincides with significant depletion of accessible stock, resulting in hospital pharmacies scrambling to source alternatives. Medicines appear to no longer be in shortage on the MSII website when the manufacturers/sponsors indicate that the shortage has been resolved however, this does not often correlate with wholesaler stock levels and a pharmacy or pharmacy department's ability to purchase stock. Pharmacists therefore find it more useful to use their wholesaler online ordering portals as an accurate source of information on medicine shortages.

18. Do you have any suggestions to improve the TGA's communication of this information?

The hospital pharmacy sector has experienced frustration and uncertainty as medicine shortages do not follow a regular pattern; some shortages may have a long duration while other medicines may 'go in and out' of shortage with no clear resolution timeframe. Improved management and coordination by government, and better alignment of information displayed on the TGA's MSII website with availability of stock through wholesalers, would support pharmacists in dealing with medicine shortages, reducing time wastage and improving safer patient care. Other information to consider including in TGA's MSII website and database to improve the TGA's communication include:

- Improved accuracy of ETAs,
- Detailed information regarding alternative products, including references to the safety of the replacement therapy,
- Detailed rationale for the shortage,
- Details on national strategy to mitigate the risk if currently underway.

SHPA also suggests that with implementation of a prioritisation system of medicine shortages and discontinuation, any information updates are notified through emails to key stakeholders, Directors of Pharmacies, in addition to individual pharmacists who may have registered for email updates. Early engagement of peak professional bodies for which the medicine shortage or discontinuation would impact the most, e.g. SHPA, Palliative Care Australia, can facilitate timely dissemination of information to professional members and help coordinate response strategies and advocacy work.



Impact of medicine shortages and discontinuations

19. Over the past 12 months, how much time did you spend on medicine shortages or discontinuations? What activities took the most time?

Managing medicine shortages and discontinuations is time and resource intensive, creating additional burden on the already stretched workload of hospital pharmacists and taking pharmacists away from providing direct patient care. Overall, it was identified in the *Medicines Shortages in Pharmacy* survey 2022²:

- The average number of pharmacist hours spent investigating and addressing prescription medicine shortages was 5 hours per week, and the average number of non-pharmacist staff hours per week was 4.5 hours.
- 40% respondents indicated medicine shortages often take more than 48 hours to resolve; 48% of community pharmacy respondents claimed that patients often/sometimes missed doses until then.

SHPA members report that time and resources were taken up initially in understanding the clinical impacts through wider consultation with relevant clinical teams and clinical experts, while initiating a parallel process in confirming an alternative product and liaising with wholesalers and SAS suppliers to secure stock. Since SHPA's surveys, the time required to deal with shortages has increased according to our members, and the cumulative time required by pharmacy resources to deal with all aspects of shortages, would easily amount to 1 FTE. This is occurring against a backdrop of workforce shortages in the pharmacy sector, with medicines shortages contributing to an inefficient-but-necessary use of constrained workforce resources.

For significant supply issues that would implicate long term changes in clinical management of patients, this entailed wider involvement of the pharmacy department, facilitating the update of clinical guidelines, changes in electronic medication management (EMM) systems and automatic dispensing cabinets, providing education to nurses and doctors on the product change, and delegating the ongoing re-distribution and or rationing of medicines.

20. What were the most challenging activities and why?

As already discussed, the initial scoping of the implications of medicine shortage or discontinuation is often challenging and resource intensive, partly due to lack of information or timeliness of the information communicated to hospital pharmacies, combined with the lack of nationally supported collaboration and coordination in strategising a response. The impact of time delays in receiving key information is emphasised for rural, remote and regional hospitals due to geographical barriers and associated logistical challenges, as well as lack of resources and staffing including clinical expertise to respond effectively in comparison to metropolitan hospitals.

Subsequent modification of internal systems to account for new or slightly different products is also challenging, especially if Pharmaceutical Benefits Scheme (PBS) restrictions led to additional cost to hospitals as well as the patient in the community, and procurement of SAS products resulted in additional administrative paperwork.

21. Tell us about the health-related impacts of medicine shortages or discontinuations.

Supply of essential medicines is critical for healthcare delivery and for the ongoing health of Australians. Unfortunately, disruptions in medicine supply continue to remain a common occurrence in Australia, resulting



in non-treatment, undertreatment, the use of less appropriate alternatives, and medicine safety issues that negatively impact on patient health outcomes.

The extent of various health-related impacts of medicine shortages or discontinuations were reported *Medicines Shortages in Pharmacy survey 2022*². Delays in medicine access were common, with 36% of survey respondents reporting that when a patient presents and it is necessary to contact the prescriber to discuss options for managing a medicine shortage, the prescriber is often unavailable (i.e. clinic is closed, prescriber's shift has ended). 39% of respondents noted that patients often/sometimes did not receive any medicine due to the shortage, which caused distress for patients, and increased out-of-pocket costs in cases where the alternative product did not have PBS listing. Where appropriate resolution was not available, 12% of community pharmacist respondents referred their patients to hospital emergency departments for management of a medicine shortage, straining the already stretched capacity at hospital emergency departments.

Medicine shortages had significant impact on hospital-related outcomes, with 31% hospital pharmacists reporting that medicine shortages led to increased length of admission, and 88% respondents reporting medicine shortages often/sometimes resulted in patients missing doses until the shortage was resolved. 39% of hospital pharmacy respondents also claimed patients were often/sometimes switched to medicines with higher risk of adverse effects and side effect profiles, negatively impacting patient health outcomes. There are also increased risks of medication errors when non-English alternatives have to be sourced, increasing risk of errors in selection and dispensing, prescribing, and administration to patients.

The increase in potential adverse outcomes of second line or non-standard therapies which may be inferior or less effective is also an important consideration in managing medicine shortages and discontinuations. A recent example was the shortage of etoposide phosphate, leading to substitution with another etoposide base product. Not only did this lead to longer administration times, over-burdening hospital capacity with longer bedtimes, resources were required to change clinical workflow, educate clinicians involved in the supply, prescribing and administration of the changed product, and increased patient monitoring by nursing staff due to increased risk of adverse reactions to the alternative product.

22. Are there other impacts of medicine shortages and discontinuations that you would like to mention?

No further comments.

Improvement opportunities

23. What is the biggest problem within the following areas that you want fixed, and why:

- medicine shortages
- medicine discontinuations
- the broader medicine supply chain

Medicine shortages and discontinuations

Our submission has so far outlined that improvements in accuracy, transparency and timeliness of communication related to potential medicines shortages and discontinuations are fundamental to ensuring



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safe implementation of effective response strategies in managing medicine supply disruptions. Improving communications by manufacturers/sponsors to pharmacists, prescribers and patients should be made high priority to improve medicine shortage and discontinuation issues. Furthermore, increased collaboration between key stakeholders to provide advice on alternative treatment options where necessary, supported by national frameworks and local governance at jurisdictional level will ultimately support timely and safe patient care.

The broader medicine supply chain

There are many factors that feed into medicine shortages and discontinuations including forecasting, supply and demand globally and locally, and communication. These issues can only be resolved through a collaborative approach between key stakeholders. Australia can vastly benefit from a federally sponsored approaches through the TGA in designing a policy framework that could underpin some of the innovations required to provide complete supply chain clarity.⁶

SHPA commends the Australian Government on their continuing work in improving Australia's medicine access, particularly with the recent ongoing review into the Health Technology Assessment (HTA) Policy and Methods Review.⁷ Ongoing reviews into current policy frameworks and policies such as the HTA, and introduction of new legislations such as the recently proposed Medicine Repurposing Program⁸ will help fortify the broader medicine supply chain in Australia.

24. What do you think of the current TGA regulatory framework around medicine shortages and discontinuations?

The introduction of mandatory reporting of medicine shortages in 2019, as well as Minimum Stockholding Requirements in 2023⁹ which saw the commitment of pharmaceutical companies to holding at least 4-6 months of onshore stock of certain medicines have provided some benefit in recent years, improving the early communication of information and mitigation of supply chain disruptions.

In response to Mundipharma's announcement to discontinue Ordine (morphine oral liquid) last year, SHPA collaborated with Palliative Care Australia and the Australian & New Zealand Society of Palliative Medicine to advocate for longer notice periods for the discontinuation of palliative care medicines.¹⁰ While Mundipharma was aware of the likely discontinuation of Ordine two to three years prior, they were under no legislative obligation to notify Australian authorities until six months before discontinuation. The current minimum notice period of six months for supplier notification do not allow for safe, effective, and timely response. To minimise distress for patients who rely on such critical medicines for their ongoing care, a review of current legislations for sponsor notification should be considered.

There is also potential to consider regulatory reforms to improve Australian sovereign capability of medicines manufacture, particularly given 90% of medicines accessed in Australia are sourced overseas³, highlighting the fragility of the domestic manufacturing capacity. Creation of a long-term plan to promote domestic manufacturing of medications and Australian-owned and operated business could contribute to the sustainability of the supply chain.

25. Do you have any suggestions about how to improve medicine shortages and discontinuations in Australia (i.e., what does good management of medicine shortages and discontinuations look like for you)?



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Medicines shortages continue to remain a common occurrence in Australia, impacting on pharmacists across both the hospital and community sectors, and importantly their patients. While it is accepted that medicine shortages are multifactorial and can often stem from global supply chain issues, the continuing negative impact of medicine shortages on patient care and unnecessary burden on the professional practice of pharmacists imply further work is required.

To prevent, manage, and communicate medicine shortages and discontinuations in a timely manner, SHPA proposes the following recommendations:

Recommendation 1: Improve the accuracy, timeliness, and communication of medicine shortages information to relevant stakeholders.

- Manufacturers/sponsors of medicines should improve the accuracy, timeliness and consistency of information being communicated to pharmacists, prescribers and patients on issues relating to medicine shortages.
- The Therapeutic Goods Administration's (TGA's) medicine shortage reports database should accurately reflect the availability of medicines that can be purchased through wholesaler ordering portals.
- Improvements should be made to the usability and visibility of TGA's medicine shortage reports database.

Recommendation 2: Establish a nationally coordinated approach to managing medicine shortages.

- The Australian Government should engage and partner with key pharmacy organisations in a proactive and timely fashion to improve the management and coordination of medicine shortages, including coordinating a timely national approach to providing advice on alternative treatment options.

Recommendation 3: Improve early warning systems.

- Reconfigure TGA's Medicines Shortage Information Initiative to act as a national early warning system for critical medicine shortages
- Support the national linking and collaboration between jurisdiction-level warning systems.
- Pharmacy leaders should be supported by Federal government to coordinate intra-jurisdictional collaboration and cooperation to share stock holding information and essential medicines list to promote equity of access.



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