

19 April 2018

Technical and Safety Improvement Section
Pharmacovigilance and Special Access Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
PSAB.Communications@tga.gov.au

Dear Colleagues

Re. Management & Communication of Medicines Shortages: Proposed Implementation Consultation

Thank you for the opportunity to provide comments for the consultation into the management and communication of medicine shortages in Australia. Hepatitis Australia is the peak community organisation to progress national action on issues of importance to people affected by hepatitis B and hepatitis C.

Hepatitis Australia does not claim expertise in pharmaceutical production and supply; however we recognise the potential impacts on people affected by hepatitis B and hepatitis C. Our perspective is informed, in part, by the recent global shortage of hepatitis B vaccines.

Proposed Medicines Watch List

The proposed medicines watch list does not include antiviral treatments for hepatitis B (i.e. adefovir, entecavir, lamivudine, and tenofovir). Treatment of hepatitis B is very rarely curative; instead aiming to suppress viral multiplication. This decreases the risk of serious liver disease developing. As hepatitis B reactivation flares can eventuate from treatment withdrawal, potentially leading to liver decompensation and death, we recommend that these medicines are added to the watch list.

Role of consumer organisations

The Management and Communication of Medicine Shortages in Australia – A new Protocol notes on p23 (with a typo) that “consumer organisations, particularly disease-specific consumer groups, may have a role in supporting consumers with information and/or advising medical experts of considerations when considering alternative regimens, substitute medicines or therapeutic alternatives.”

During our recent (ongoing) experience with hepatitis B vaccine shortages, Hepatitis Australia and member organisations at a jurisdictional level have played an important role supporting consumers with timely and accurate information. This was mostly informed by communications with sponsors and information requested through the Office of Health Protection to the Australian Technical Advisory Group on Immunisation (ATAGI).

We note (on p15) that "a range of stakeholders will need to work together to ... where appropriate, notify peak consumer organisations – to manage patient cohort expectations". To maximise the benefits of our knowledge of consumer groups, and our networks and channels for communication we suggest:

- it would be beneficial for consumer groups to be part of the prescribed TGA and Sponsor notification process for extreme or high patient impact shortages (on p13)
- that TGA and Sponsor communications relevant to the National Immunisation Program vaccines be provided directly to ATAGI
- regardless of severity rating, that consumer groups such as Hepatitis Australia be notified of shortages to enable discretionary circulation of relevant advice through member organisations and stakeholder networks to inform communities of interest, and
- it may help if consumer groups are approached for registration for notifications from the TGA regarding shortages, as there may otherwise be some instances where a consumer group is inadvertently overlooked as shortages are communicated.

Thank you again for providing the opportunity to comment on this important matter.

Yours sincerely,



Helen Tyrrell
CEO, Hepatitis Australia