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Technical and Safety Improvement Section
Pharmacovigilance and Special Access Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Submitted on-line

Dear Sir / Madam,

Consultation: Management and communication of medicines shortages

We refer to your call for submissions re the above.

ASMI appreciates this opportunity to provide comment on the proposed reforms.

About ASMI

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care therapeutic goods (non-prescription over-the-counter and complementary medicines including vitamins, minerals and supplements) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants. More information about ASMI and our membership is available on our website.

Summary of key concerns

Sponsors try to avoid medicines shortages and will try to avoid the interruption that they cause to patients and health care professionals as well as wholesalers and retailers. There are usually genuine reasons as to why a shortage may occur and while reporting obligations can increase awareness of a shortage, they will not prevent shortages from happening.

The TGA should, in addition to imposing reporting obligations and sanctions and penalties, look at the reasons for shortages and whether other initiatives could feasibly assist in managing and preventing shortages.

Although some non-prescription medicines have been included in the new Management and Communication of Medicines Shortages Protocol, the non-prescription medicines industry has not been closely involved with the Working Group that delivered the strategy and therefore has not

been adequately consulted on key criteria and proposed processes in the lead up to publication of this document[1].

By way of summary, ASMI's key concerns are:

- the absence of consultation with the non-prescription medicines industry
- the potential unnecessary capture of non-prescription medicines
- the ambiguous definitions used
- the potentially unrealistic sponsor obligations
- the disproportionate penalties in some cases

For more comprehensive responses to the questions raised in the consultation paper, please refer to the attachment.

The ASMI submission is necessarily limited in scope and pertains to the potential impact on non-prescription medicines. Some ASMI members are also members of Medicines Australia (MA) and we refer the TGA to submissions made by MA for a more detailed discussion of the potential impact of the proposed protocol for management and communication of medicines shortages.

Please feel free to contact me if you have any additional queries.

Yours sincerely,

[redacted]

[1] Although ASMI are mentioned on page 5 of the consultation paper as a member of the MPA, there has been no consultation with ASMI prior to this public consultation.

The consultation paper: Management and communication of medicines shortages – proposed implementation approach. Version 1.0, March 2018

Consultation Issue 1 – Definition of a medicine shortage and proposed scope

ASMI is concerned that the proposed definition of a medicine shortage is very broad particularly since it is linked to the care and treatment of an individual patient, through the use of the following words: "…….*all instances where a patient's care may need to be revised as a result of…".* Linking a definition of a medicine shortage, which has reporting and compliance obligations together with onerous sanctions and penalties, to all instances where an individual patient's care may need revision is unrealistic and difficult to apply. Furthermore, the proposed definition also includes the interpretations "*partial availability of a medicine from the sponsor, wholesaler or manufacturer"* or "*other constraints on the medicine's availability",* adding additional uncertainty for sponsors.

By relating the definition of a medicine shortage to all instances where a patient's care may need to be revised as a result of "*partial availability*" and "*other constraints*", ASMI believes that the definition is unclear and problematic in its interpretation and application.

It is foreseeable that in some rural and remote areas, an individual patient may be unable to obtain a particular medicine at a given time (through no fault of the sponsor), and this may require revision of patient care. Under the proposed definition, a sponsor may have reporting obligations, possibly for partial availability in specific geographic areas or for situations outside of sponsor control, e.g. transportation issues.

ASMI believes that the definition of a medicine shortage should not be in the context of "all instances" and it should not relate to an individual patient's care. The terms "partial availability" and "other constraints" are vague and unworkable.

ASMI notes that the proposed scope of the management and communication of medicines shortages includes a small number of non-prescription medicines (page 7 of the Consultation paper). On the other hand, the proposed new Protocol states that the TGA's Medicines Watch List (MWL) is derived from the WHO Model List of Essential Medicines[2] which includes many non-prescription medicines, including commonly available medicines such as analgesics, anti-allergy medicines, laxatives, anti-diarrhoeals, anthelminthics, ferrous salts, folic acid, and more.

The paper also outlines two key criteria that determine which non-prescription medicines would be included under the proposed reporting procedures. The criteria include whether the medicine is critical to the ongoing health of the patient, and whether the medicine is critical to public health (see page 6 of the draft new Protocol).

While there are several S3 medicines that have been included in the TGA's proposed MWL (p. 10 & 11 of consultation), it is not clear whether any other non-prescription medicines, not included in the MWL, are subject to the proposed reporting requirements by virtue of them being included in the WHO Model List of Essential Medicines.

The implication in the paper is that inclusion in the MWL assists in determining the level of risk; the consultation paper and protocol do not clearly state that the only non-prescription medicines

[2] WHO Model List of Essential Medicines http://www.who.int/medicines/publications/essentialmedicines/en/

subject to the reporting requirements are those non-prescription medicines specifically included in the list. This is a key area of concern for ASMI members.

ASMI believes that the new protocol should clearly exclude all medicines that are exempt from scheduling, or are in Schedules 2 or 3 of the Poisons Standard unless these medicines are specifically included in the Medicines Watch List (MWL).

There should be no expectation that <u>any</u> non-prescription medicines, other than those already identified for inclusion in the MWL, should be subject to the proposed reporting requirements.

ASMI also requests prior consultation with individual affected sponsors and industry, so there is sufficient notice of any S3 medicine being considered for inclusion in the MWL. Medicines should not appear on the MWL without there having been adequate prior consultation with affected sponsors.

CONSULTATION ISSUE 1 - SOME QUESTIONS TO CONSIDER:

- *Is the definition of a medicine shortage clear?*

ASMI Response: No – the inclusion of terms such as "partial availability" and "other constrains on the medicine's availability" make the definition broad, vague and not effective.

- *Is the definition of a medicine shortage appropriate, noting that it will be required to be stated in the Therapeutic Goods Act through the proposed amendments?*

ASMI Response: No – for the reasons described above. The vague wording of the definition of a medicine shortage will be tied to onerous sanctions and penalties, including jail time. Expectations of sponsors must be clear and workable.

- *Is the proposed scope for covered medicines clear?*

ASMI Response: No. As described above, the proposed scope for non-prescription medicines is not clear. While several S3 medicines are included in the MWL, the scope for other non-prescription medicines is not clear. Many common and widely available non-prescription medicines are included in the WHO Model List of Essential Medicines. The proposed new Protocol for Management and Communication of Medicines Shortages should clearly state that the only non-prescription medicines to be covered are those included in the MWL.

- *Is the proposed scope for covered medicines appropriate?*

ASMI Response: No. The proposed new Protocol for Management and Communication of Medicines Shortages should clearly state that the only non-prescription medicines to be covered are those included in the MWL.

<u>Consultation issue 2 – Reporting obligations</u>

ASMI refers to the MA submission for a more comprehensive assessment of the reporting obligations.

We do however wish to raise concerns at the suggested timing for reporting of anticipated discontinuations.

Although each sponsor's supply chain and lead times may differ, ASMI believes that the 3, 6 or 12 months' notice of discontinuation (for low – medium - high impact level respectively) may be difficult to achieve in practice and we question whether most or all sponsors or affiliate offices in Australia would have sufficient prior notice to enable them to meet these targets. There are quite onerous sanctions and penalties involved for non-compliance, therefore care should be taken to ensure that the compliance requirements are achievable, realistic and risk-based.

Non-prescription medicines, other than those on the Medicines Watch List, should not be included in the reporting obligations. Generally, medicines that are self-selected by consumers are not indicated for serious medical conditions; there are generally other treatment options (other generic or therapeutic alternatives) that consumers can use should common OTC medicines be out of stock or discontinued.

ASMI has no specific comment on the required notification content.

CONSULTATION ISSUE 2 - SOME QUESTIONS TO CONSIDER:

- *Do you support the suggested timeframes? Do you have an alternative proposal?*

ASMI Response: The TGA should, through appropriate consultation, ensure that the timeframes for reporting are feasible and clear. ASMI suggests that the 3, 6 and 12 months' notice of discontinuation (for low – medium – high impact level respectively) may not be realistic for a considerable proportion of sponsors and affiliates.

- *Do you support the required notification content?*

ASMI Response: ASMI has no specific comment on the required content for notification.

Consultation issue 3 – Which products should be on the medicines watch list

ASMI has no objection to the medicines included in the Medicines Watch List.

Of the S3 medicines included in the list, ASMI acknowledges that some of these have extreme or high patient impact (e.g. naloxone, adrenaline injections, nitrates, salbutamol, chloramphenicol).

It should also be noted that for most of these medicines, there is generally a choice of brands, i.e. the innovator and in most cases, generic brands are also available. In the case of ulipristal, there is no generic option; There are other emergency contraceptives, however these options can only be used within a shorter timeframe (72 hours).

ASMI has no specific comments on the Medicines Watch List and refers the TGA to the MA submission.

Of the S3 medicines included in the list, most of these have alternatives (generic or other therapeutic options). ASMI believes that the S3 medicines included in the MWL are medicines of lower risk and lower impact, with the exception of adrenaline and naloxone injections.

Proposed additions or removals from the Medicines Watch List should only take place after proper consultation with the sponsor initially; and in some cases, public consultation may be appropriate.

CONSULTATION ISSUE 3 - SOME QUESTIONS TO CONSIDER:

- *Is the list comprehensive/adequate?*

ASMI Response: ASMI believes that the list of S3 medicines included in the MWL is adequate. No additional S3 medicines should be included without prior consultation.

ASMI also believes that the MWL should not include any S2 or unscheduled / exempt medicines. There are generally many different brands of Pharmacy and general sale medicines such that consumers have choice. Any consumers who have concerns regarding possible shortage or non-availability of non-prescription medicines can discuss the matter with their healthcare professional, who may recommend appropriate treatment.

The new Protocol should clearly state that the only non-prescription medicines included in the scope of the document are the S3 medicines included in the MWL.

- *Are there other products that would have an extreme or high patient impact if they were to be in short supply?*

ASMI Response: ASMI has no specific comment.

- *What would be the best mechanism to add or remove medicines from the list?*

ASMI Response: The TGA should ensure that addition or removal of any medicines from the MWL should take place only after consultation with the sponsor and key stakeholders.

Consultation issue 4 – Compliance obligations and potential penalties

ASMI believes that the requirements should be clear, unambiguous and that the reporting requirements and timeframes should be practical, achievable and proportionate.

Some of the sanctions and penalties appear to be quite onerous and involve criminal liability and imprisonment. These should be reserved only for very serious cases that involve extreme risk and very serious impact on public health. It appears from the consultation that there is no information included on reasonable defences.

It is concerning that the TGA is considering pursuing the more substantial penalties from the outset (i.e. from the first instance of non-compliance) if a sponsor's behaviour is assessed to be "particularly serious", with no explanation on how that assessment will take place and whether sponsors will have a right of reply. There appears to be an assumption that the TGA's access to more powers and higher penalties will resolve perceived problems with medicines shortages.