23rd April 2018

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

Dear Sir/Madam,

RE: Management and Communication of Medicine Shortages

Juno Pharmaceuticals thanks the TGA for providing us with the opportunity to provide comment on the consultation paper, Management and communication of medicines shortages.

Please find our input to each of the consultation issues included in the paper on the following pages. Should you require clarification of any of the points raised or wish to discuss anything, please feel free to contact me on [redacted] or at [redacted]

Yours sincerely,

[redacted]

[redacted]

Juno Pharmaceuticals Pty Ltd
ABN: 55 156 303 650
Level 2, 6 Bond St
South Yarra, 3141, AUS
P +61 3 8888 1288
F +61 3 8888 1299
info@junopharm.com.au
www.junopharm.com.au

Consultation issue 1: The definition of a medicine shortage

In general, we are in agreement with the proposed definition of a medicine shortage.

An important consideration to note is that medicines shortages can have a negative impact on the reputation of a company, and in many cases, rightly so. However, there are instances where a supplier can rapidly find itself in a shortage situation as a direct result of a medicines shortage from another supplier. This may be due to the need to supply a direct replacement product or an alternative therapy.

Juno expends considerable time and effort to ensure our products remain in supply at all times. In situations as described in the paragraph above, we feel it is important that the supplier/sponsor causing the original shortage is identified above other suppliers who would otherwise not have been out of stock except they were called on to fill a gap in the market.

Juno also believes that a more detailed list of non-prescription medicines to be included in the reporting requirements should be prepared and perhaps published as a separate list similar to Appendix IV.

Consultation issue 2: Reporting obligations

In general, we agree with the proposed reporting obligations.

We would like to highlight a minor typographical point. Item 15 on Page 9 of the 'New Protocol' document should refer to 'examples 'b and c' for consistency rather than 'examples 2 and 3'.

Juno believes that the 'New Protocol' document could be improved by providing more information relating to how the TGA plans to involve other sponsors of products with multiple suppliers, or alternative therapies, when notified of a shortage and how these other sponsors will be involved in the decision-making process.

Consultation issue 3: Which products should be on the 'Medicines Watch List' defining an 'extreme' risk shortage

The proposed list appears to be appropriate.

Consultation issue 4: Compliance obligations and potential penalties

As mentioned above, reputation is very important within the pharmaceutical industry hence Juno believes that Option 1, Publicly identifying non-compliant sponsors, without additional sanction, should be a sufficient deterrent to ensure companies comply with the mandatory requirements.

Option 2, Focus on civil penalties and infringement notices, should be reserved for suppliers who have multiple instances (the number could be pre-defined) of non-compliance with the mandatory reporting requirements.

Juno Pharmaceuticals Pty Ltd
ABN: 55 156 303 650
Level 2, 6 Bond St
South Yarra, 3141, AUS
P +61 3 8888 1288
F +61 3 8888 1299
info@junopharm.com.au
www.junopharm.com.au

We believe that Option 3, Substantial civil penalties and criminal offence, should be reserved for suppliers that are serial offenders for not meeting the mandatory reporting requirements or have undertaken deliberate efforts not to report a shortage.

General Comment

To help ensure uninterrupted supply of the medicines listed in Appendix IV, Juno believes that the TGA should make a commitment to treat with priority all regulatory changes submitted in relation to these products, regardless of whether a medicines shortage exists, but of course in particular when a shortage does exist. This needs to extend to the GMP Clearance Unit where GMP Clearance activities are often on the critical path to ensure continued supply (such as manufacturing site changes).

Juno Pharmaceuticals Pty Ltd
ABN: 55 156 303 650
Level 2, 6 Bond St
South Yarra, 3141, AUS
P +61 3 8888 1288
F +61 3 8888 1299
info@junopharm.com.au
www.junopharm.com.au