# Submission from Allergy & Anaphylaxis Australia

# 23 April 2018

## Consultation: Management and communication of medicines shortages

## Consultation issue 1: The definition of a medicine shortage

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

  ***Yes***

- *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?*

  ***Yes***

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

  ***Allergy & Anaphylaxis Australia considers the proposed scope for covered medicines could be clearer as adrenaline is mentioned on pages 10 and 11 however adrenaline (epinephrine) autoinjectors are not mentioned. This omission may cause confusion with sponsors thinking ONLY adrenaline ampoule shortages need to be reported in accordance with this new legislation.***

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

  ***Allergy & Anaphylaxis Australia strongly encourages the inclusion of venom immunotherapy and prescribed amino acid formulas which are currently prescribed and on the PBS.***

  ***Venom immunotherapy is given to those at risk of anaphylaxis and as the desensitisation treatment is over 3-5 years both health professionals and patients need to be aware of shortages sooner rather than later so a plan of care can be implemented.***

  ***Babies, toddlers and a limited number of older children and adults rely on prescribed amino acid formulas because of IgE and non IgE mediated food allergy. For many, this is a sole source of nutrition and a shortage greatly impacts their health and wellbeing. Ample notification must be given on shortages so consumers and health professionals can work on possible substitution of the formula from an already limited range.***

## Consultation issue 2: Reporting obligations

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

  ***Yes***

- *Do you support the required notification content?*

***Yes, however it is essential that peak consumer bodies whose members are affected are notified of the shortage. This is especially important with regards to shortages of emergency and critical care medication, especially when other suppliers are limited or non-existent..***

***Importantly, it would also be helpful for the sponsor to clearly communicate the cause of the shortage and a distribution plan of remaining product (if any) and other actions taken/measures implemented to help ease the critical situation to both consumer bodies and health professionals. This open communication will help health professionals and consumer groups manage in-coming and out-going communications with their key stakeholders more effectively.***

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

- *Is the list comprehensive/adequate?*

  ***No***

  ***Allergy & Anaphylaxis Australia strongly encourages the inclusion of venom immunotherapy and prescribed amino acid formulas which are currently prescribed and on the PBS.***
  Venom immunotherapy is given to those at risk of anaphylaxis and as the desensitisation treatment is over 3-5 years both health professionals and patients need to be aware of shortages sooner rather than later so a plan of care can be implemented.

  ***Babies, toddlers and a limited number of older children and adults rely on prescribed amino acid formulas because of IgE and non IgE mediated food allergy. For many, this is a sole source of nutrition and a shortage greatly impacts their health and wellbeing. Ample notification must be given on shortages so consumers and health professionals can work on possible substitution of the formula from an already limited range.***

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

  ***As mentioned previously, adrenaline autoinjectors would also have an extreme or high patient impact if they were in short supply.***

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

***Formation of a group comprising of health professionals with expertise in specific area impacted by the shortage, consumer representative from a peak consumer body impacted and the TGA could review addition or removal of medicines from this list.***

## Consultation issue 4: Compliance obligations and potential penalties

- *Do you support particular options? Why?*

*Compliance penalties should not only include naming and shaming the sponsor of the medicine in short supply if it is not reported appropriately. It is Allergy & Anaphylaxis Australia's view that there must be some financial loss so a combination of option 1, 2 and 3 is supported but not option 1 alone.*

*Which option, or combination of options, do you believe would be the most effective?*