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CONSULTATION RESPONSE

MANAGEMENT AND COMMUNICATION OF MEDICINES SHORTAGES

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INTRODUCTION

Sanofi provides a diverse range of prescription and OTC medicines, vaccines and devices as well as an extensive portfolio of vitamin and mineral supplements. These products deliver much needed treatment options that extend and improve people's lives and keep people healthy. Sanofi's products include treatments for diabetes, multiple sclerosis, cardiovascular and renal disease, cancer, rare diseases, influenza as well as a range of childhood and travel vaccines.

A number of the medicines that Sanofi supplies are considered medically critical and management of shortages is prioritized to ensure supply is maintained or alternative options are arranged whenever possible. The Sponsor has a history of working collaboratively with the TGA to manage shortages and has supported the voluntary system of notifying shortages already in place.

Sanofi welcomes the opportunity to comment on the consultation document titled *Management and communication of medicines shortages – proposed implementation approach*. Sanofi is supportive of the submission by Medicines Australia for this consultation and has included commentary in this submission relevant to particular products that are in the company portfolio.

CONSULTATION ISSUE 1: THE DEFINITION OF A MEDICINE SHORTAGE

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

Sanofi supports the MA response.

- *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?*

Sanofi supports the MA response.

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

Sanofi found the proposed scope clear but would appreciate TGA clarification if medical devices would be covered under this protocol. Furthermore Sanofi requests TGA to consider developing a separate guideline for biological medicines (including vaccines) considering complex and lengthy manufacturing process and unique supply arrangement (e.g. for vaccines, there are NIP supply vs. private market supply). A guideline outlining the reporting requirements that recognise the lengthy and complex manufacturing process and the oligopoly nature of biological medicines market would assist the sponsors to comply with the requirements set out in the proposed protocol.

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

Sanofi found the proposed scope appropriate.

CONSULTATION ISSUE 2: REPORTING OBLIGATIONS

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

Sanofi agrees with the suggested timeframes.

- *Do you support the required notification content?*

Sanofi supports the MA response.

CONSULTATION ISSUE 3: WHICH PRODUCTS SHOULD BE ON THE 'MEDICINES WATCH LIST' DEFINING AN 'EXTREME' RISK SHORTAGE

- *Is the list comprehensive/adequate?*

Sanofi found the list comprehensive and adequate except for seasonal influenza vaccine on the Medicines Watch List.

In the case of seasonal influenza vaccines, the Sponsor is continuously managing "in" and "out" of stock situations. For example, there will be no or limited stock available after influenza season and while a batch is undergoing TGA release. In light of this, Sanofi finds it difficult to apply the medicine shortage definition. It is unclear when and what to report when influenza vaccines are unavailable for reasons not relating to manufacturing issues or increases in demand. Consequently, Sanofi requests that the reporting requirement for influenza vaccines should be limited to shortages relating to manufacturing issues or increases in demand. Any artificial shortage experienced while managing stock or "perceived" shortages once the influenza season is over, should not be required to be reported.

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

No as other products will be covered through case-by-case assessment on public health grounds.

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

Sanofi supports the MA response

CONSULTATION ISSUE 4: COMPLIANCE OBLIGATIONS AND POTENTIAL PENALTIES

Do you support particular options? Why?

Based on the scheme being newly implemented Sanofi supports Option 1 ie publicly identifying non-compliant sponsors, without additional sanction as appropriate. After a 12 month period of implementation if a review identifies ongoing concerns then then further actions to ensure compliance could be considered..

Sanofi strongly agrees with the MA response relating to the severe and disproportionate penalties in Option 3.