GSK Comments on TGA Consultation: Proposed new classification rule for medical devices that administer medicines or biologicals by inhalation (March 2019)

Overall Comment

GlaxoSmithKline (GSK) welcomes the opportunity to comment on the TGA consultation *Proposed new classification rule for medical devices that administer medicines or biologicals by inhalation.*

GSK is a global research-based pharmaceutical and healthcare company operating in more than 100 countries around the world. Our mission is to improve the quality of human life by enabling people to do more, feel better and live longer.

Overall, GSK is supportive of the proposed classification rules which are intended to address the current lack of specific classification rules for invasive medical devices (MD) intended to administer medicines or biologicals by inhalation (hereafter, "invasive inhalational devices").

Whilst GSK recognises that the rationale of the proposed classification rules is also to align with the European Union (EU) medical device regulations (MDR), GSK would like to emphasise the importance of consistent interpretation and application of the regulations with the EU MDR. As stated in the consultation paper, neither the EU MD Regulation nor Australian MD Regulations define the terms "essential impact" or "life-threatening conditions". As the interpretation of these terms are key in determining whether an invasive inhalational device should be classified as Class 2a or 2b, adoption of a consistent definition is important to ensure alignment across both regions. This is particularly important for the many Sponsors, including GSK, who often rely on the recognition of EU device regulation approvals for supply of products to Australia.

Further, due to the TGA's recognition of EU device regulation approvals, GSK believes that transitional arrangements for the implementation of proposed invasive inhalation device classifications should also follow timelines overseas, so that any new requirements are not adopted in Australia prior to the EU. GSK believes that this is particularly important for the existing class 1 devices identified as requiring reclassification. In spirit of harmonisation and to facilitate a seamless transition, GSK proposes that the reclassification of such devices in Australia should occur after the reclassification has occurred in the EU as this would reduce workload at the Sponsor and TGA level.

GSK supports the TGA's proposal to continue regulating non-reusable devices prefilled with medicine (e.g. multi-dose asthma inhalers) as medicines, rather than medical devices.

We thank the TGA for providing GSK with the opportunity to participate in this very important consultation process.