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Dear Therapeutic Goods Administration team,

Thank you for this opportunity to respond to this TGA consultation. The Pharmacy Guild of Australia does not wish to respond to these consultation questions as they are not directly relevant to the Guild or our membership of community pharmacy owners. However, we would like to note the following for your consideration.

Page 10 of the Discussion Paper notes that "exemptions to mandatory reporting of medical device-related adverse events might apply to general practices, specialist medical practices, allied health practices, community-based ambulatory care clinics and community nursing services."

We recommend that community pharmacies should also be exempt or excluded from the list of "healthcare facilities" that would be required to undertake mandatory reporting, because the medical devices sold by community pharmacies are generally low risk. The proposals in this consultation are primarily concerned with higher-risk devices, which are not applicable to community pharmacies.

Kind regards,

