

SHPA feedback to the TGA's consultation on the revision of 'Compounded medicines and good manufacturing practice (GMP) – Guide to the interpretation of the PIC/S guide to GMP for compounded medicinal products', Version 3.0, September 2020.

Review by:	SHPA
V3 line number	Comment
153-154	Remove these two lines
673	SHPA does not agree with the following statement in the draft guidance. "The expiry date applied to a product should be as short as possible, and only sufficient to allow the product to be manufactured, supplied and administered to the patient. The application of periods longer than the minimum necessary or extended expiry dates for economic reasons is not permitted."
	Justification
	<p>SHPA notes that this is an addition from the Version 2 of the Compounded medicines and good manufacturing practice (GMP).</p> <p>SHPA believes this addition is not necessary, and would cause confusion to public hospital compounders, who are non-TGA licensed compounders, as they follow PIC/S Guide to good practices for the preparation of medicinal products in healthcare establishments PE010.</p> <p>This guideline assists TGA-licensed compounders to interpret PIC/S Guide to Good Manufacturing Practice for Medicinal Products PE009, which is not applicable to public hospitals as they do not undertake wholesale manufacturing for commercial purposes.</p> <p>Expiry dates applied to a product should be led by robust medicines stability data and cognisant of the practicalities of compounded medicines supply chain workflows intersecting with timely and quality patient care.</p> <p>This is especially important when considering that many rural, regional and remote health services do not have capacity to compound medicines and outsource these functions to third-party TGA-licensed compounders who would have to adhere to this guidance. SHPA does not believe the draft guidance, which suggests the application of expiry dates that are "as short as possible", is feasible or definitive, and is very open to interpretation. Whilst the guidance states the expiry date should only be "sufficient to allow the product to be manufactured, supplied and administered to the patient", this assumes that the delivery of healthcare for patients requiring compounded medicines (such as life-saving antimicrobials, long-term intravenous infusions and chemotherapy) operates in a perfect environment, however this is not the case.</p> <p>There are various reasons as to why applying the shortest possible expiry date is not practical and threatens the safety and quality of healthcare for patients requiring compounded medicines. These include:</p> <ul style="list-style-type: none"> • Compounded medicines may require dose changes or adjustments as their health status changes, and this should be factored into the expiry dates that are applied when supported by stability data (i.e. response to treatment, changes in renal function and hepatic function, body weight) Application of the shortest expiry date

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| | <ul style="list-style-type: none">• Many hospitals that require third-party compounders to supply compounded medicines are often in non-metropolitan areas. The geographical challenges and time required for delivery to hospitals, means that the shortest possible time for expiry dates may be a hindrance to safe and timely delivery of medicines if there are any disruptions to delivery schedules. This risk has been more apparent during the COVID-19 pandemic with restrictions on travel.• Patients may have last minute changes to their appointment times where they are expected to have compounded medicines administered, and having the shortest possible expiry date would be very inflexible for patients who have last minute changes to their administration times. |
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SHPA recommends this guidance be revised to allow for the application of expiry dates that account for the complex nature of healthcare delivery where perfect systems do not always exist.

To support the safe and timely delivery of compounded medicines, especially in non-metropolitan health services, SHPA recommends that the expiry dates applied to compounded products only need to be underpinned by robust stability data and evidence to support the allocated expiry dates.