

## **PQMD Member – Required Minimum Standards (RMS) for Medical Donations**

### **October 2023 FAQs**

#### ***Background***

The Partnership for Quality Medical Donations (PQMD) is the preeminent alliance of non-profit and corporate organizations committed to bringing measurable health impact to under-served and vulnerable people through active engagement with global partners and local communities. The organization was formed to provide coordinated input into WHO activities on drug donations and to raise the donations standards of the industry. Its founders mobilized in response to growing concerns that medical product donation practices at the time (mid-1990s) were not implemented responsibly and were damaging the viability of host country healthcare programs.

Among the organization's earliest activities, the PQMD Guidelines for Medical Donations were created to promote best practices for the industry and are a leading standard bearer together with the WHO Guidelines for Medical Product Donation. Its Guidelines for Medical Donations have been updated and its portfolio of guidelines have expanded over time to continually improve practices in the sector.

#### ***Why create Required Minimum Standards (RMS)?***

Because a set of foundational best practices remain essential, the PQMD Guidelines Committee has identified the following set of guidelines as the Required Minimum Standards to which member policies, procedures and practices align. Note, many of the RMS have long existed in the PQMD Guidelines for Medical Donations. As organizations of the highest caliber, PQMD members are seen to uphold the highest standards and practices. The establishment of Required Minimum Standards ensures that the full membership and prospective members involved in product donation/distribution demonstrate they uphold basic and essential best practices.

#### ***How will the Required Minimum Standards benefit PQMD and our members?***

Adopting required minimum standards ensures the highest operating principles in donations essential to protecting public health and promoting the best practices upheld by PQMD and the World Health Organization. Additionally, RMS serves to protect PQMD's reputation and that of our members.

#### ***What are the PQMD Member - Required Minimum Standards (RMS) for Medical Donations?***

- Do not ship donations that are not wanted by the recipient organization; ensure there is a demand (as defined in the Guidelines).
- Do not offer or donate or ship expired stock.
- Donated product is to not be sold on – it must be distributed free of charge in recipient country.
- Donated product should have an expiration date of 12 months or more. Product with less than 12 months to expiration can be donated with Field approval provided the **Distributing Partner** is aware of the product expiry *prior to* the donation, and there is an agreement between the **Donor** and **Distributing Partner** that the product can be utilized. Country specific expiry guidelines and regulations should be followed at all times, unless approval per the above has been obtained.
- Prior to making or accepting a donation, make sure there is a contract or formal agreement in place that reflects clear and common understanding and responsibility for the following:

- Financial terms
- Specific product, quantities, and expiry dates
- Policy and procedures for product complaints, adverse event reporting, safety, and security requirements (i.e., cold-chain versus ambient shipping, product stability and tracking)
- Product disposal, proof of destruction and product recall
- Monitoring and evaluation requirements, if applicable

**What was the process this year for PQMD Guidelines Annual Review, Required Minimum Standards (RMS) Development, and proposed implementation schedule?**

July - Oct 2023:	Guidelines Committee undertook annual review and update of Guidelines for Medical Donations, including identifying the need to highlight existing guidelines as “Non-Negotiables” or Required Minimum Standards (RMS) for all current and future PQMD members.
September 2023:	<p>Guidelines Committee presented final 2023 update of PQMD Guidelines for Medical Donations and recommended RMS to the Executive Committee, stating:</p> <p>PQMD’s Donation Guidelines ensure that international protocols for the delivery of donated medical products are followed and inform the work in supplying critical donated medical products, devices, and services to those in need across the globe. Although the Guidelines provide general principles and best practices, the list covers the Guidelines Committee recommendations that are non-negotiable.</p>
October 2023:	<p>Nominations and Governance (N&amp;G) Committee proposed updates to PQMD documentation to reflect Required Minimum Standards, including:</p> <ul style="list-style-type: none"> <li>• Membership policy <ul style="list-style-type: none"> <li>○ Membership expectations</li> <li>○ Membership criteria</li> </ul> </li> <li>• Initial Membership Application</li> </ul> <p><b>Proposed implementation:</b> N&amp;G Committee proposes implementation timeline, including 9-month grace period (11/2023 – 9/2024) for existing members to update their policies, procedures, and practices, if applicable. Requirement is applicable to all applicants.</p>
November 3-17, 2023:	Annual member review and comment period for updated PQMD Guidelines for Medical Donations, which includes the RMS.
November 30, 2023:	Executive Committee votes regarding updated PQMD Guidelines for Medical Donations, including the RMS
December 2023:	Annual launch of PQMD Member guidelines self-certification
Ongoing thru Sept 2024:	Alignment period for existing members to update their policies, procedures, and practices, if applicable.

***What if a member (or applicant for membership) is unable to meet the Required Minimum Standards?***

If a member self identifies as not being able to meet the RMS and *desires to work towards the requirements*, then PQMD will provide support.

- Members who self-identify as not meeting the minimum standards will have a maximum of 1 year to put practices in place to meet the requirements.
- The PQMD guidelines committee will help provide guidance and support to any member who requests it.

If a member self identifies as not meeting the Required Minimum Standards and *does not desire to work towards the requirements*:

- Membership in PQMD will not be renewed.

The RMS requirements apply to any new application submissions as well as to any under review at this time.

***What if I become aware that a member organization is not being compliant with the Required Minimum Standards?***

Please bring any concerns you have to the leadership of PQMD or an officer of the Executive Committee.

Per the PQMD By-Laws:

- PQMD is a global alliance of non-governmental organizations ("NGO") and medical product, device, pharmaceutical and supply corporations ("Corporate", and together with NGO, each a "Member Organization") that develops and champions high standards in medical supply and service donations. This global collaboration promotes sustainable access to quality health care in underserved communities and populations in crisis.
- Any Member may be expelled from membership, by the affirmative vote of 2/3 of the Executive Committee for any reason or no reason at a duly convened meeting, provided that fifteen (15) days written notice of the intention to expel and reasons therefore have been provided in the notice of the meeting to the affected Member. No Member shall be expelled without having the opportunity to be heard by the Officers and Executive Director, either in writing or in person not less than five (5) days prior to such meeting, but no formal hearing procedure need be followed.

***What if I have additional questions about Required Minimum Standards and their implementation?***

Please reach out to PQMD leadership or an officer of the Executive Committee.