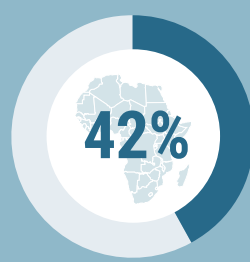


# Prequalification at the Heart of Safe and Sustainable Health Supply Chains

## The Partnership for Supply Chain Management

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### Product quality challenges



The World Health Organization (WHO) estimated that **42% of all fake medicines reported to them between 2013 and 2017 were from Africa.**



**COVID-19 pandemic fuelled the demand for certain categories of medicines** increasing the demand and manufacture of **subpar/fake medicines.**



To address the issue, manufacturers and supply chain stakeholders have for many years been taking critical actions. Manufacturers deploy **anti-counterfeiting solutions** like authentication and serialization, and buyers and resellers undertake **stringent quality assurance** like prequalification and due diligence.



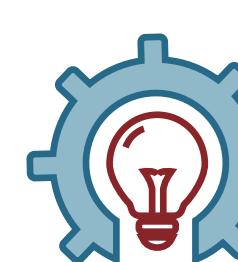
### Best practices

- Use international and/or regional classifications to assess products' risk or create an in-house risk assessment process.
- Only procure products that are registered by mature regulatory bodies and manufactured by ISO certified manufacturers.
- Use verified product data to determine key product characteristics like shelf life, dimension and temperature requirements to limit risk along the supply chain.
- Establish a dedicated team, outside procurement, to ensure balance in the organization's decisions.
- Use the Plan-Do-Check-Act cycle, the process will is key for continuous improvement.
- Proactively develop and maintain a knowledge base of quality and regulatory affairs. This helps organizations to navigate burgeoning markets and become market leaders.



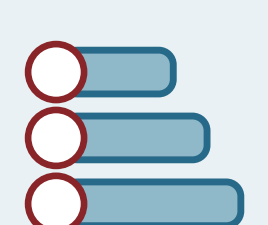
### Role of prequalification

- Product prequalification is a process whereby experts verify that health products that meet international and/or local quality and regulatory requirements.
- Prequalification can be a component of a wider Product Quality Assurance and may complement other quality systems.
- Prequalification ensures products are safe, fit-for-purpose and sustainable.
- Prequalification also creates the opportunity to capture valuable product information early in the supply chain.
- This product information is used for risk management and data-driven decision-making in multiple areas of supply chain management.
- Effective data use at the prequalification stage, not only ensures patient safety, but also drives efficiencies to save costs and reduce lead times.



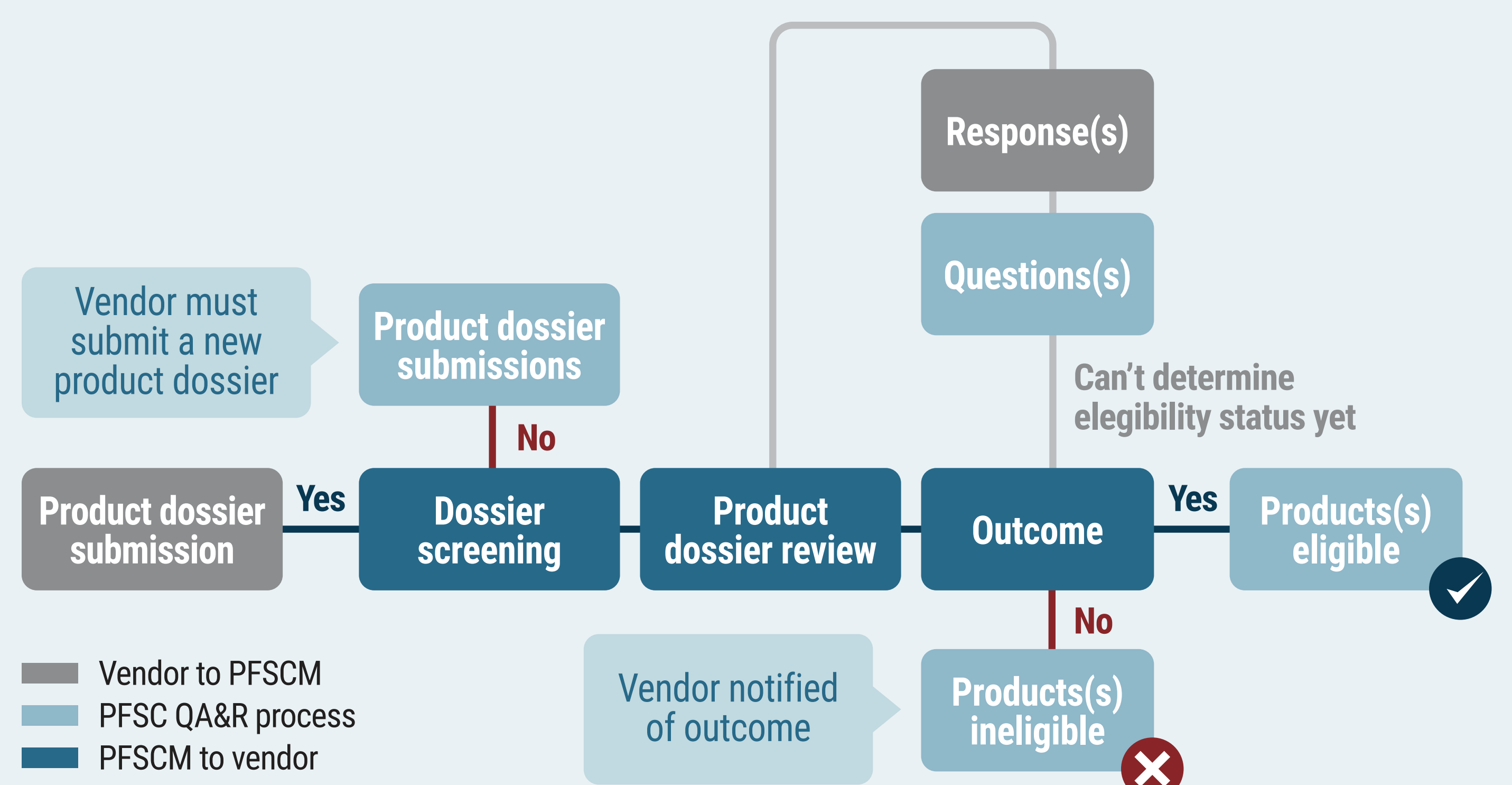
### Key considerations

- What are the international and/or regional requirements and regulations for health products that my country, or organization is buying?
- How can my organization implement a risk-based approach to ensure we only procure quality products?
- Who is responsible for quality, prequalification and product quality assurance in our value chain, and how can we map these entities' roles and responsibilities?
- Is our product prequalification process streamlined? Does it drive development, and does it encourage continuous improvement for a more sustainable health supply chain.
- How can the product prequalification process give us access to new technologies, tools and opportunities?



### PFSCM's process

- 1 Prequalification and Product Quality Assurance is a core component of the Partnership for Supply Chain management's (PFSCM) work.**
- 2 PFSCM adheres to the highest standards for prequalification and follows the WHO Model Quality Assurance System (MQAS) for procurement agents.**
- 3 PFSCM implements robust Product Quality Assurance policies and we only procure products that are prequalified by the WHO, or approved by stringent regulatory authorities (SRAs) and meet client and/or national regulatory requirements.**
- 4 PFSCM's Quality and Regulatory Unit is composed of knowledgeable staff with a medical and scientific background.**



### Outcomes

PFSCM has undertaken **prequalification of more than 100 regional suppliers and wholesalers** and has prequalified a wide range of products.

PFSCM's current portfolio includes more than **4,200 health products**, all of which were prequalified by PFSCM.



Having a list or catalog of prequalified products available to buyers and recipients, helps to **drive demand for trusted quality goods**. This in turn helps to optimize the use of quality-assured health resources. Ultimately, this prequalification helps to **improve access to top-quality health products helps improve health outcomes**.



### Conclusion

- Putting the product prequalification process at the heart of the supply chain has a significant positive impact.
- Prequalification is an inherent supply chain best practice and is critical in the development and ongoing improvement of any supply chain organization. Having a prequalification process prevents pitfalls that could result in financial, relationship, and reputational damages, by ensuring compliance.
- Prequalification contributes to the safety and wellbeing of healthcare workers and patients, and drives positive health outcomes.

#### References

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