





BRIEFING NOTE

Global Standards for Menstrual Products: Shaping a Thriving Menstrual Health Market for All

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1. Executive Summary

The Sanitation and Hygiene Fund (SHF), a United Nations fund, aims to structurally improve the way women and girls can access a variety of safe, quality and affordable menstrual products, especially across low and middle income countries (LMICs). With a quarter of the world's menstruating population who cannot access purpose made products, the scale of the issue is too big to rely on free distributions. By strengthening supply chains, regulations and trade, markets can improve access for hundreds of millions of people. These markets, especially in LMICs, are not yet delivering on this potential. One crucial factor inhibiting access is the gap in regulation of menstrual products through product quality standards.

Quality standards set minimum requirements for products to ensure their safety and efficacy, and limit health effects for consumers. They are also an important prerequisite for import and export, for sale to consumers and are perceived by customers as a government guarantee of quality and safety. Currently, only single-use menstrual pads are governed by standards across the majority of LMICs. In recent years, the variety of products to manage menstruation has increased. These novel menstrual products (including cups, reusable pads or period underwear) are more durable and sustainable, increase choice to users and significantly reduce cost. The absence of standards for these products have prevented their introduction across many markets in LMICs.

With more than 613 million people who rely on non-purpose made menstrual materials such as cloth or mattress foam, a lack of product standards forms an invisible barrier to import, sell and ultimately to access a product on markets in LMICs. In addition, a lack of harmonization of standards between countries limits the movement of products across regions, while the difference in requirements for existing standards can have serious implications for the quality of products available on a local market and ultimately the health and safety of users.

To remove these barriers, LMICs require standards for all major categories of menstrual products. This would lead to improved quality and safety of products, open up the market to enable private actors to develop cost-effective business models and explore different routes-to-market to provide a range of affordable menstrual products to all, including Base of the Pyramid (BoP) consumers. This document outlines the Sanitation and Hygiene Fund's (SHF) vision for comprehensive coverage of menstrual product standards and the activities the fund aims to support for their development, roll out and adoption across LMICs.

2. The Status Quo

Menstrual products come in a variety of:

- designs (cups, pads, tampons or underwear),
- functions (collect or absorb),
- shapes and sizes,
- materials (e.g. silicone, cotton, high performing textiles, super absorbent polymers).

They are designed to be used in different ways (external or internal) and may be used once or multiple times (single use or reusable). The purpose of a menstrual product standard is to ensure that users have access to safe menstrual products that fulfill their core purpose of collecting or absorbing menstrual flow, no matter the type of product.



With a variety of menstrual product innovations that have gained popularity in recent years, the landscape of menstrual products has changed and users have an increasing number of options to match their personal needs and preferences. These may offer increased durability, limit environmental impact and, most importantly, significantly reduce the cost of managing menstruation. The regulation of these innovations through product quality standards has lagged behind in many countries. High income countries have placed these products within the framework of existing regulation, enabling consumers to access an increasing variety of products, while specific standards that are better fit to control their quality and safety have not yet been developed. Across most LMICs, the absence of standards has created a regulatory vacuum that imposes an effective import and resell barrier for novel products. Simultaneously, an increased understanding of both reproductive health and product safety has led experts to identify gaps in existing product standards for single-use menstrual products. This has underscored the need to revisit existing standards.

Several countries have made efforts to introduce product standards for some innovations, most notably the efforts to develop reusable menstrual pad standards across East and Southern Africa and Southern Asia¹. However, these efforts address only one group of products, are adopted by only a handful of countries and they differ in their requirements. A joint effort by standards regulators is required to address the gaps and misalignment in standards.

3. The Effects of a Failing Framework

The absence- or incomplete nature of menstrual product standards has severe consequences for users, especially for women and girls in Low and Middle Income Countries (LMICs) to access and afford menstrual products, to protect them from potential health effects and to access product innovations. Meanwhile, governments, investors and the private sector are faced with barriers to development of and investment in regional industries, confronted with difficulties or inhibitions to trade and face a market that includes sub-par quality products and counterfeits².

Market barriers

The absence of menstrual product standards in LMICs has resulted in a market barrier to entry for novel menstrual products. As a result, women and girls are prevented from accessing more affordable options, while current options in the market exceed their purchasing power. There are four ways in which this regulatory gap has created this barrier.

Importation - For the importation of goods, the importer is required to provide documentation in the form of certification and test results that confirm the quality of the imported goods. This quality is compared against the requirements in a national standard. If a national standard does not exist, it can be substituted with an internationally recognized standard, most often an ISO, US or EU standard. In the absence of any of these standards for a variety of menstrual products, importation is practically impossible and the importer cannot bring goods into a country. This gap in regulation at both national and international level has curtailed the introduction of novel menstrual products in many LMICs.

² An economic assessment of menstrual hygiene ProductTax cuts - BMGF



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¹ Standards Database for disposable and reusable menstrual pads in LMICs - RHSC

Resell - Even if a product is produced in a country, and no importation is required, specific regulation for the sale of products exists to safeguard consumers. For retail of products on a national market, companies require certification of a national standards board against the national, or sometimes international, standard. In many countries, an additional approval may be required from the institution responsible for enforcement (e.g. FDA). In LMICs, these requirements are especially important when listing products in formal shops - including supermarkets, (online) retailers and pharmacies. At small scale, companies and initiatives in LMICs that produce locally may sell directly to consumers or via informal shops, but they are not able to sell their products in the formal market and at scale.

Perception - Without certification or listing of products in established and trusted vendors, consumers are more skeptical about a brand or product category. They might have increased concerns about the product, and question its legitimacy if a brand is not available in established and publicly recognized stores. Especially in LMICs where scandals with product quality and counterfeit products are reported to occur more often, consumers look for quality assured products that are sold by trusted retailers. Brands providing novel menstrual products cannot achieve this without certification and can suffer negative effects on both the brand- and product-image, which ultimately influences consumer choices.

Investment - As a result of limitations on importation, sale and consumer perception, investment in the introduction of novel menstrual products in LMICs markets has been extremely limited. Despite their appeal to a broad range of users at a price point that could unlock access to a significant portion of the population, the risks and limitations associated with investing in these products in LMICs is considered too high.

Health & safety

Existing menstrual product standards have focused on the technical requirements for these products to perform their primary purpose of collecting or absorbing menstrual flow. Safety considerations have been included with regard to chemicals and pathogens that can have an immediate harmful effect on the users. What has been left unexplored, and has gained interest in recent years by health experts, regulators, companies and consumers, are the long term health effects of exposure to materials used in menstrual products. No requirements currently exist for brands to provide the exact composition of their products, and standards fail to cover requirements on long-term health effects that are common in other areas such as medical devices³. Recent findings from a <u>study by Columbia University</u> found heavy metals in all tested samples of Tampons from the US and Europe. SHF and the Gates Foundation are funding the Phase II of this study to conduct testing on samples from all ISO categories for menstrual products across 18 countries, representing all regions in the world. Further information is available in a separate brief. Any future effort to introduce or harmonize quality standards for menstrual products should encompass these considerations.

Poor quality

The quality of menstrual products available to women, girls and others who menstruate is not the same across the world. The gaps in, differences between and absence of menstrual product standards across countries results in varying quality of menstrual products. This is further aggravated by a lack of enforcement. This can result in discomfort or health complications. Moreover, products of poor quality fail to provide protection during menstruation, which impedes women and girls from participating in school, work or social engagements. Finally, poor quality products can influence users' perception of a

³ <u>ISO 10993</u> includes a specific section on health and safety for products in contact with the vagina. More details available <u>here</u>.



product type and harm their reputation. Especially among novel menstrual products which are often not governed by standards, there is a risk that users will disregard a promising solution such as a menstrual cup or reusable pad, because of a singular bad experience with a poor quality product.

4. Quality Standards Governance

Quality standards are developed, implemented and enforced at three levels: national, regional and global. The responsibility for product quality and safety ultimately rests at country level, or in certain cases (e.g. EU) at the regional level. Governments often separate the responsibility for quality standards development and testing, and the enforcement of quality standards across different entities.

National level

At the country level the National Standards Boards (NSBs) are responsible for the development, revision and implementation of product quality standards. These government institutions can work together with specific line ministries (i.e. health, food or trade) and may collaborate with other government entities for the enforcement of standards. This includes collaboration with border control at ports of entries for the authorization of import and export, as well as food-, drug-, and consumer goods- safety authorities for sale to consumers.

Regional level

At the regional level, national governments may be engaged in voluntary regional standards bodies, trade partnerships or political unions.

- Regional standards bodies are a platform for NSBs to collaborate at a technical level to increase
 the quality of national standards and ensure harmonization of national standards to facilitate
 movement of goods. The <u>African Regional Standards Organisation</u> (ARSO) is one example.
- **Trading zones / communities** collaborate on a range of different trade related priorities, such as standards, tariffs, import procedures. These arrangements are often negotiated at a political level and, once agreed, become binding to all parties involved. One such example is the East African Community (EAC).
- Regional Political Unions A third option for governing product standards is through
 intergovernmental institutions that are part of a common economic and/or political union.
 Product standards for member states of the EU are governed the <u>European Committee for Standards</u> (CEN) and apply to all member states.

Global level

At the global level, the <u>International Organization for Standardization</u> (ISO) - an independent, non-governmental international organization - is the governing body with a membership of 168 NSBs. Through its members, it brings together experts to share knowledge and develop voluntary, consensus-based, market relevant international standards. The organisation identifies priorities through its members to create global voluntary standards and aims to harmonise standards by ensuring adoption of the global standards by its members base.

In October 2021, ISO opened a voting process among its 165 members on developing a global harmonized standard for menstrual products. With more than a two-thirds majority, the creation of the Technical Committee (TC), ISO/TC 338 on Menstrual Products was approved. This TC, comprised of 19 participating member countries



and 17 observing members, is tasked with developing global quality standards for all purpose made menstrual products.

5. Harmonized Quality Standards, from Global to Local

SHF has identified the development, adoption and harmonization of quality standards across LMICS for all categories of purpose-made menstrual products as a crucial priority to ensure the introduction of novel menstrual products in markets across LMICs, to drive public and private investment, to scale models for route to market for the BoP and structurally improve product access for women and girls. The development of global ISO standards are central to achieve this and offer a unique opportunity to set global requirements that will ensure the safety and efficacy of menstrual products. However, the quality, applicability and acceptance of these standards rely heavily on the participation of NSBs from LMICs, as well as the representation of and accountability to national stakeholders. To achieve this, SHF has developed a Global-to-local approach that focuses on three pillars: global standards development; national participation and local accountability.

Global standards development

The development of ISO quality standards has been approved, initiated and supported by its member base of NSBs. Under the leadership of The Case for Her and the Swedish Institute for Standards (SiS), who led the proposal for the creation of TC 338 and as the secretariat for the TC, a framework of activities has been laid out to develop the global standards. This process is expected to be completed by mid 2027. SiS has received grants and support from The Case for Her, The Gates Foundation and SHF to run key activities for the standards development process. A specific focus includes increasing support for and engagement by NSBs from LMICs, and increase the capacity of the secretariat as more NSBs will join the TC. From 2024 - 2027, a set of key activities and deliverables will be funded to ensure the secretariat can deliver the quality standards within the set timeframe.

National participation

In order to ensure product access in LMICs, it is important that their NSBs participate in the process, take ownership of its content, provide product use considerations and quality requirements that reflect the needs and realities of their populations and ultimately adopt the final ISO standards at the national level. Without their adoption, ISO standards remain what they are, voluntary global standards that do not provide binding requirements at country level, nor provide the regulatory certainty for companies and funders.

Currently, participation of LMICs and especially sub-Saharan African countries, in TC 338 is limited. To increase their participation, SHF is providing technical assistance to governments across LMICs and is developing partnerships with UNFPA and RHSC to further engage national governments and NSBs. The purpose is to raise awareness of the ISO development process, highlight the importance of participation, provide technical assistance and showcase the Social Returns on Investment (SROI) the outcomes of this process can provide.

Local representation & accountability

National stakeholders, including companies, civil society and consumer interest groups, may have an interest in the development of menstrual product standards for their context and may want to ensure that the interests and rights of local organisations and peoples are represented. To ensure their perspectives are taken into consideration in the standards development process, a platform for national stakeholder



engagement will be set-up. As part of the UNFPA-SHF partnership, UNFPA will convene government ministries, the NSB and relevant stakeholders, on a regular basis to discuss the ISO development process, provide inputs and nominate liaisons to the process. Stakeholders will be provided with technical assistance and access to expertise in standards development.

More detailed briefs for each of these grants is available upon request.

6. Contact and Additional Information

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