Reproductive Health
SUPPLIES COALITION

MENSTRUAL HEALTH

Menstrual product standards

A pathway to quality product access

The most common menstrual product categories include disposable sanitary pads and tampons, reusable sanitary pads and wearable period panties, and reusable menstrual cups. Standards refers to the norms, guidelines, or rules that offer acceptable, efficient, and safe parameters for manufacturing a product, managing a process, or delivering a service. Creation and adoption of standards is an important pathway for ensuring access to quality products and informed choice for the management of menstruation.

Status of Standards in Low and Middle Income Countries (LMICs)

Disposable sanitary pad standards exist in some LMIC settings and include pads/ napkins/towels and in some cases, tampons. Standards for reusable cloth pads exist in a few countries in Africa (e.g. Kenya, Uganda, Tanzania, Zimbabwe, and South Africa) and one country in South Asia (India). There are no existing standards for menstrual cups across LMICs. At least eight East and Southern African countries have standards which is the highest number for any region, followed by five countries in the South Asian region and two countries in the West and Central African region having standards for disposable sanitary pads. There are no standards for menstrual products in the Latin American region currently. Standards for menstrual cups exist only in wealthier countries. Classification for product categories varies greatly in both wealthy and LMIC countries. In the United States, sanitary pads are defined by the USFDA as Class I medical devices while in the European Union, they are treated as consumer products. Menstrual cup classification also varies across geographies from being a class 2 medical device (US) which does not require approval, a personal hygiene product (EU) which has only a general product safety directive, and a therapeutic good (Australia).

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STANDARDIZATION PARAMETERS

Standards for any supplies help define a minimum level of quality in quantifiable terms. Standards for menstrual products include parameters that address the following key categories:

Physical parameters, packaging and marking of the product makes it identifiable by consumers for the specific need. These parameters include information on materials, components and workmanship. For disposable sanitary pads and reusable cloth-based products, these include a top cover, absorbent core and other layers, bottom leakproof barrier, fasteners/adhesives and may include other additives for fragrance/colour etc. For menstrual cups, these include the shape and design of the product as well as the nature and grade of material (silicone, TPE, latex) to be used. Physical parameters also include size definitions as per menstrual flow (eg. light, medium, heavy), and information on size, absorbency and use case. Information on the packaging such as manufacturing details, expiry date, raw materials, and guidance on storage, use and disposal allow consumers to make an informed choice. Raw materials disclosure is typically not included raising concerns by activists across the globe about potential health effects.

Performance parameters ensure that the product is effective in performing the desired function as per minimum permissible limits. These include measures that define the product's capacity, absorption, dispersion and retention, without leakage, of menstrual blood and other fluids. These are minimum standards and many products in the market may exceed this minimum permissible limit. Test methods and defined ranges for these parameters also vary across geographies.

Safety parameters ensure that the materials, production processes and final products are safe from a user's health and environmental perspective. This includes:

- guidance for manufacturing protocols or compliance with existing norms like GMP
- testing the physical properties and bio-burden of the product to ensure it will not aid undue microbial growth that could interfere with the natural vaginal flora or lead to reproductive and/or urinary tract infection
- safety of raw materials, final products for use against the sensitive vulval region. This is done through certification of raw materials or tests for the product against the ISO standard for biocompatibility evaluation of medical devices that includes guidance for cytotoxicity, skin irritation and sensitization testing (ISO 10993)
- tests for compostability of disposable sanitary pads given increasing concerns around environmental safety. This can help check claims of potentially harmful materials like oxo-degradable plastics which are being used in LMICs and marketed as environmentally friendly.

Methods of demonstration included in standards define the overall methodology including test methods or existing certifications and frequency and sampling of testing.

Challenges and Areas of Exploration

Where standards exist, particularly for wealthy countries, specific definitions of quality as well as their measurable ranges vary across geographies. Manufacturers of both disposable and reusable menstrual products, face the challenge of complying with different quality benchmarks across countries, limiting their ability to make good quality products available across different LMIC settings. Hence, harmonization of standards is an important area of exploration. There is need for a global standard or guidance for menstrual supplies to ensure harmonization as well as ease adoption by countries that have not yet developed standards.

Even where standards exist, consumer awareness related to this is low and with standards being voluntary in many countries, the markets are flooded with products across the price range that may not be up to the desired quality standards. Efforts on enhancing consumer awareness on minimum quality features would be important for ensuring consumer safety.

Many of the existing standards are difficult to access with variance in approaches, nomenclature, parameters covered and test methodologies. Most of the existing standards are limited to components and performance, and very few cover issues of health and environmental safety. Enforcement and compliance of standards across regions are not well understood as most are not mandatory, and this has become even more complicated with the sheer number of small players entering the menstrual supplies market. This requires deeper exploration and understanding of the technical parameters of standards to determine minimum necessary parameters and those that can be add-ons to ensure consumers have the ability to make an informed choice of quality products.

Many small and medium-size manufacturers face issues in compliance due to lack of information on a set of minimum acceptable parameters, laboratories for testing, lack of internal quality control resources and costs of external testing. Institutional buyers like hospitals, Government and NGO programs on menstrual product distribution are also often unaware of the standards and do not ask for compliance certificates so may base decisions on price alone.

Reusable cloth-based products and menstrual cups, had been left out of global humanitarian and local Government procurement processes due to absence of minimum quality benchmarks. This has limited the availability, choice and equity for consumers in LMIC settings. A joint initiative by the UNICEF-UNFPA-UNHCR has recently made progress by defining procurement specifications for a basket of reusable and disposable menstrual products. However, coordinated efforts by international humanitarian organizations and Government regulators are still lacking.

Guidance is required on the process of new standards development in countries which are initiating the process. This includes information on key technical parameters to be included, ISO or other national or international standards that can be referenced, stakeholders that should be included in the consultation process in addition to manufacturers, test methodologies for enhancing compliance including testing facilities and associated costs, and inclusion of labelling to indicate products meet standards

There are also multiple evidence gaps related to some of the technical parameters:

- There is little evidence in the public domain on how duration of use of sanitary pads influences the risk of RTIs/UTIs, especially in LMIC settings where temperatures and humidity are more conducive to microbial growth and where products increasingly are super absorbent.
- Cost of tests and accessibility of labs is a concern for biocompatibility testing. An alternative is that raw material vendors provide certifications. However, due to the different types of players across the supply chain, more investigation is required on the feasibility of this.
- Existing standards on menstrual cups do not cover quality, health, safety, or performance adequately and technical guidance for material sciences experts are required on this.

Enforcement of standards is dependent on the product classification. If a product is classified as a medical device, then enforcement is more stringent than if they are classified as consumer products. There is need for evidence generation and consensus development on the classification for all menstrual product categories to enhance compliance.

All these challenges limit availability, equity, quality and choice of menstrual products for menstruators in LMIC settings. They also pose challenges for agencies or governments wishing to make an informed procurement decision regarding menstrual products. Addressing these supply side barriers requires coordinated advocacy in standards development for menstrual products categories at a country, regional and global level.

RECOMMENDATIONS

- Coordinate advocacy in standards development for menstrual products categories at a country, regional and global level.
- Develop minimum acceptable global standards or guidance for all types of menstrual products to ensure harmonization and adoption by countries that have not yet developed standards.
- Enhance consumer awareness on menstrual product standards to ensure informed choice and consumer safety.
- Ensure global standards include issues of health and environmental safety and not just physical and performance parameters.
- Explore enforcement and compliance of standards across regions to ensure the existence of minimum required parameters does not become an obstacle to small and medium-scale manufacturers and to consumers, especially those at the last mile.

Informing and in line with these recommendations, the Reproductive Health Supplies Coalition supported a series of webinars in 2020 on menstrual product standards and funded an initiative to understand the Development and Compliance of Disposable and Reusable Sanitary Pad Standards in LMICs. The initiative has helped create a database of standards and lessons on processes and parameters, which can be used for advocacy on menstrual products standards across LMIC regions.