

Development and compliance of standards for menstrual products in South Asia and Africa

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Table of contents

1	ABBREVIATIONS
2	INTRODUCTION AND OBJECTIVES
4	METHODOLOGY
5	KEY FINDINGS
13	CALL TO ACTION
15	ANNEX 1: REFERENCES

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Abbreviations

ACMHM	African Coalition for Menstrual Hygiene Management
ARSO	African Organization for Standardization
CAGR	Cumulative Average Growth Rate
CSO	Civil Society Organization
EAC	East African Community
EU	The European Union
ISO	International Standards Organization
LMIC	Low and Middle Income Countries
MHAI	Menstrual Health Alliance India
MHH	Menstrual Health and Hygiene
MHM	Menstrual Hygiene Management
MHMPA Nepal	Menstrual Hygiene Management Partners' Alliance Nepal
NGO	Non-government Organization
QC	Quality Control
RHSC	Reproductive Health Supplies Coalition
SME	Small and Medium Enterprise
SRHR	Sexual and Reproductive Health and Rights
UNGM	United Nations Global Marketplace
US FDA	United States Food and Drug Authority
WASH	Water, Sanitation and Hygiene
WHO	World Health Organization

Introduction and Objectives

Menstrual products range from disposable sanitary pads and tampons, reusable sanitary pads, and menstrual cups. The creation and adoption of standards is an important pathway for ensuring access to quality products and informed choice for management of menstruation.



Disposable Sanitary Pads

The global market size for disposable sanitary pads was USD 19.5 billion in 2017 and growing at a CAGR of 5.4 percent. In low-and-middle income countries (LMICs), the largest manufacturers are experiencing double digit growth annually. An assessment by Population Services International in India and Ethiopia found that this growth is driven by aspirational demand from adolescent and young girls. To serve evolving consumer segments, disposable sanitary pads have seen innovation in materials and design for enhanced comfort and absorbency. A study from India showed that girls in LMICs often use disposable products for long periods due to lack of female-friendly water and sanitation facilities or affordability constraints, exposing them to reproductive tract infections (RTIs). Many of the materials and additives potentially enhance the risk of RTIs, especially with long use.



Reusable Sanitary Pads

Market penetration of disposable pads and large-scale efforts by public health programs have increased access in LMICs in Asia and Africa. Despite these gains, adolescent and young girls from the lowest wealth quintiles remain under-served. Studies in India, Uganda and Kenya have found that when affordable reusable cloth pads are offered as an alternative along with balanced information on products and use, they are an acceptable alternative and can address the access gap amongst the lowest wealth quintiles. Promotion of reusable menstrual products at scale requires parallel investment in puberty education with informed choice, driven by public sector health programs or public health NGOs, as manufacturers for these products lack the capital for this. Creation and enforcement of regulatory standards can help establish the safety and effectiveness of products, which is a necessary precondition for governments and others to invest in such efforts.

Hence, creation and adoption of standards for disposable and reusable sanitary pads is essential for providing choice to adolescent girls in managing their menstruation in all contexts and addressing unmet need for menstrual materials. A number of LMICs such as Kenya, Uganda, Tanzania, Ethiopia, South Africa, India, Sri Lanka, Pakistan and Bangladesh have existing standards for disposable sanitary pads. However, in many cases, these standards do not include benchmarks for hygiene and material safety and when they do, they need updating. Standards for reusable pads exist in Kenya, Uganda and Ethiopia due to recent advocacy efforts and are under development in India. However, they vary widely in terms of the technical benchmarks. Manufacturers struggle with divergent regulatory norms across regions leading to non-compliance. Harmonization of standards can help in ensuring compliance by manufacturers across LMICs. This process also needs to account for the increasing number of small and mid-scale manufacturers who face specific challenges in meeting standards and the harmonization process can help develop compliance pathways for the same.

OBJECTIVES

To achieve these goals, Development Solutions, supported by the Reproductive Health Supplies Coalition (RHSC), implemented a project with the following objectives:



Develop policy guidance for harmonization of technical benchmarks for disposable and reusable sanitary pads in South Asia and Africa, with a focus on India, Nepal, Kenya and Uganda



Build consensus around policy recommendations for the enforcement of quality standards for disposable and reusable menstrual health pads at the state level in India

Methodology

In order to achieve the outlined objectives, a qualitative methodology was adopted to gather insights through in-depth interactions conducted with 61 stakeholders.



SUPPLEMENTARY SOURCES OF INFORMATION:

- Secondary review of menstrual products standards from 36 LMICs in South and South-East Asia and Africa; and other reference standards
- Insights from a technical consultation conducted by MH Hub with social enterprises operating in India and Uganda
- Insights from a consultation conducted by WHO were also incorporated
- For objective 2, 12 additional interactions were conducted with representatives of regional and Central government offices in India; regional offices of multilateral agencies and manufacturers operating in-country
- Secondary review of procurement documents published by regional governments for menstrual hygiene promotion programs

Key Findings

Current Standards Landscape

A review of standards across LMICs found that the most number of standards exist in the East and Southern African region, for both disposable and reusable sanitary pads. Ethiopia, Kenya, Malawi, Tanzania, Uganda, South Africa, Zambia and Zimbabwe, all have standards for both product categories along with regional standards by the East African Community (EAC) and the African Organization for Standardization (ARSO). Most of these were formulated after 2015 with advocacy efforts by members of the African Coalition for MHM. There is now scope for advocating for adoption of the regional standards by West and Central African countries where only Ghana and Nigeria have standards for disposable pads currently.

Details of these standards can be accessed through the database available as Annex 2.

In South and South-East Asia, few countries including India, Bangladesh, Pakistan, China, South Korea, Vietnam and Indonesia have standards for disposable sanitary pads. Some like the Pakistan standard were created over 20 years ago and need to be updated with product changes. However, only India has a standard for reusable sanitary pads which was created in 2021 through advocacy efforts. The same committee in India also revised the standard for disposable pads in 2019 to be compatible with the evolving products in the market. Singapore, Cambodia, Malaysia, Thailand, Myanmar, Brunei, Timor-Leste, Laos do not have standards. Some countries like Indonesia and Thailand have requirements for import of sanitary pads wherein manufacturers need to comply with the ISO standard for a manufacturing facility for medical devices (ISO 13485).



The standards review showed that developed countries like the United States, Australia, European Union and Japan have standards for disposable sanitary pads. The United Nations Global Marketplace (UNGM) procurement specifications have been developed for disposable and reusable sanitary pads and menstrual cups and those for tampons are under development. These are also used for procurement of products by UN organizations for distribution in emergency settings.

Technical Specifications

are the tangible aspects for which quality assurance is done through either observation, testing using pre-defined methodologies or furnishing evidence available from other sources like raw material suppliers. Insights from the in-depth interviews and secondary review of standards were triangulated to understand the variance in technical specifications across different standards. 7 of the 20 standards for disposable sanitary pads and 6 of the 11 standards for reusable sanitary pads from LMICs were available publicly and could be reviewed in detail. Insights for the same have been included below. Technical specifications for menstrual product standards include the following categories:

Material and Design Specifications require information that makes the product identifiable for consumers and includes materials, components, workmanship and information required on the product and packaging. These were included in all the reviewed standards with varying degrees of detail and input. However, experts stated that materials and sizes are a source of innovation in the product and stringent regulatory limitations are detrimental to consumer choice, for both disposables and reusables.

For any specification that is mentioned e.g. softness, a test should also be included for ensuring compliance.

Performance specifications ensure that the product performs the desired function. Absorbency and retention limits were included in all the reviewed standards. However, experts mentioned that the fitness for purpose for a sanitary pad—disposable or reusable, is truly reflected by considering dispersion and rewetting along with absorbency and retention.

There is also limited evidence to suggest what should be the ideal minimum absorbency limit and this has been a point of concern for small scale reusable pad manufacturers who are unable to meet requirements for disposable pads. In such a scenario, independent testing to understand the appropriate minimum combination of absorbency, retention, dispersion and rewetting is needed.



Product design is driven by consumer preferences and needs flexibility within standards.

R&D specialist, MNC

Safety Specifications

Hygiene specifications ensure that the bio-burden of the product will not aid undue microbial growth that could interfere with the natural vaginal flora or lead to reproductive and/ or urinary tract infections (RTI/UTIs).

Standards from all LMICs include pH as the first level of testing for ensuring that the product is compatible for use with the vulvo-vaginal region. However, the range used for pH varies across countries and more evidence is needed to ascertain the appropriate pH range for menstrual products which would inhibit undue microbial growth.

Testing for bio-burden on the product and the absence of specific microbes, is included in all LMIC standards except the reusables standard in Ethiopia. In India too, reusable pad manufacturers have raised concerns about the bio-burden criteria being too stringent and that textile products may not be able to meet them. Experts have stated the need for bio-burden testing for both disposable and reusable sanitary pads as both would provide a medium for absorption of menstrual blood and can lead to risk of infections.

For reusable sanitary pads, experts also state that the bio-burden should be tested after the number of washes that would signal end of life for the product, as the potential for microbiological risk changes with subsequent washes.

One microbiologist and one product development expert have also suggested that the moisture content of raw materials is another important factor for microbiological risk and related specifications should also be considered.

Guidance for ensuring minimal contamination in the sourcing and manufacturing processes can also be considered to minimize burden of testing on SME manufacturers. This is pertinent as hygiene testing is required for every batch and can amount to a significant cost for SMEs, if incurred regularly.

Another area where more primary evidence is needed is the risk of bacterial vaginosis (BV) and pelvic inflammatory disease (PID) with long hours of use of both disposable and reusable sanitary pads.

Data on the same is not available in the public domain currently.

Material safety ensures that raw materials and final products are safe for use against the sensitive vulvo-vaginal region through biocompatibility evaluation as per ISO 10993.

An increasing number of countries have opted to include this specification in recently developed standards, with increasing concerns of the safety of raw materials used in menstrual products. Of the standards that could be accessed and reviewed in detail, the disposable pad standards in Kenya, Tanzania and Uganda are the only ones that do not include the biocompatibility specifications. However, many SMEs shared concerns that the cost of testing, even for one-time testing, is relatively high and this is a deterrent to compliance.

Allowing raw material manufacturers to supply certification of biocompatibility is an alternative means of strengthening compliance. However, this would require a strong demand from the menstrual product industry as buyers of raw materials, to furnish such certification.



Reusable sanitary pads also require testing for color fastness to ensure that the dyes used in the fabrics do not leach and are absorbed through the vulvo-vaginal region. The South African standard for reusable pads also mentions that banned, harmful toxic dyes as per ISO 14362-1 should not be included in the product.

Another alternative pathway for supporting SMEs is to support pooled procurement, which is being done currently by a few sellers of pad making machines. Evidence on material risk of commonly used raw materials may also be generated in the public domain to support strengthening of this specification. Another resource for strengthening this specification is also an exhaustive list of harmful materials mentioned as part of the Japanese standard for disposable sanitary pads.

Environmental safety ensures that products that claim to be compostable are tested to be so and that consumers are provided sufficient information on the safe disposal of the product. In LMICs, as concerns around the environmental impact of disposable sanitary pads is increasing, there are various products in the market that claim to be environmentally friendly. An increasing number of government guidelines also require products to be bio-degradable. However, many such products are made of oxo-biodegradable materials which break down into micro-plastics and can further enter the water and soil, especially where waste management systems do not exist or are decentralized. To address this, compostability testing as per ISO 17088 has been included in standards for disposable pads in Ethiopia, India, Nepal and also the UNGM procurement specifications. However, further research is needed to evaluate the impact of compostable products on the soil and water through decentralized systems.

Most standards have fairly rigorous testing requirements and in such cases, compliance from small scale manufacturers is limited due to the financial burden of testing and lack of awareness on compliance pathways.

However, experts suggest that this is not a reason for evasion of compliance. Instead, SMEs should be supported to better conform to existing standards.

An example from India for such support is where manufacturers of small scale pad production machines support the enterprises who use their machines by procuring quality assured raw materials. Pooled procurement has helped reduce the cost of materials and cost of quality assurance for SMEs.



Standards for menstrual products are not unique and they exist for many sectors, hence it is not reinventing anything. It is not a massive cost (~\$200) and shouldn't stand in the way of a serious company conducting business. The tests are not very high-tech and drip tests etc. are simple to conduct..

Standardization advocate, procurement stakeholder

Standards Advocacy and Process Lessons

Interviews with key stakeholders helped explain pertinent challenges in the standards development process and suggest potential pathways for addressing them. These have been outlined below:

There is a **need for sensitization of relevant government stakeholders** and regulatory authorities on the necessity of standardization for menstrual products. The initiation of standardization for any product typically requires a formal request to be made by a government stakeholder, hence, it is also important to identify champions working in government departments related to health, education, waste management, development and others who have programs related to health and well-being of menstruators across the reproductive life cycle (adolescents, youth, women of child-bearing age etc.). Sensitization of these stakeholders is the first step to creating a systemic demand for standardization of products as many of these programs also need them for procurement and distribution of products.

Many respondents also shared the **need for engaging a more diverse set of stakeholders** in the standards creation committees. Lack of information and budgetary support often limits the regulatory authorities' ability to engage stakeholders that are both neutral and diverse in their areas of expertise. This leads to a biased representation of medium and large scale manufacturers who can afford to be represented on the committees. This can be addressed by joint advocacy by civil society organizations as well budgetary support for ensuring technical experts from diverse fields are included in the consultative process. A snapshot of the types of experts that should be included is given on the next page as Table 1.



An overall limitation of the standards creation process is that regulatory authorities have limited budgets that are able to support only convening of meetings and other contributions including time and logistics for participation of experts, primary and secondary evidence generation, advocacy with other government authorities is voluntary and dependent on committee members. This leads to lack of evidence necessary for creation of practical and enforceable technical specifications and also brings in bias from large manufacturers who contribute to the process more than independent stakeholders.

TABLE 1: STAKEHOLDERS TO BE INCLUDED IN STANDARDS CREATION AND THEIR POTENTIAL CONTRIBUTION

Stakeholders	Potential Guidance
Small and mid scale manufacturers, social enterprises	<ul style="list-style-type: none">• Ensure that QC protocols are practical and include sufficient guidance for implementation by small scale manufacturers
Advocacy groups (ACMHM, MHAI, Nepal MHM Alliance etc.) and researchers working on MHH policy	<ul style="list-style-type: none">• Assimilate secondary evidence• Ensure representation from all stakeholders• Advise if testing parameters are practical enough for inclusion in MHH policy frameworks
Technical experts: Microbiologists and biotechnologists, Material scientists (manufacturer and independent)	<ul style="list-style-type: none">• Guide process and test specifications for raw materials and final product for ensuring product hygiene• Guide specifications and methods for determining material safety, especially given high costs of testing
Gynecologists	<ul style="list-style-type: none">• Share evidence on reproductive health parameters e.g, impact of use of different products on vaginal flora and risk of infections, pH of vagina etc.
Fibre suppliers	<ul style="list-style-type: none">• Guide on how raw material quality and safety can best be determined
User groups	<ul style="list-style-type: none">• Representative of buyers from across socio-economic settings given the diversity in low and middle income countries

Enforcement of standards by the authorities and compliance by manufacturers are essential for the availability of quality products. It was stated by respondents that enforcement in LMICs across South Asia and Africa is voluntary and follow up for enforcement is very limited. Some countries have situated product standards within comprehensive menstrual health and hygiene (MHH) policies. This helps enforce the standards through state sponsored procurement initiatives. For example,

Compliance amongst small and medium enterprises (SMEs) is also poor on account of the following:

- Limited guidance provided by regulatory authorities after standards creation
- Lack of knowledge amongst SMEs about compliance protocols
- In most countries, standards are paid as it is a source of revenue for the regulatory authority and are thus also, inaccessible to SMEs
- Consumer awareness of standards is low and hence, demand for quality control does not exist



The deep dive on compliance in the Indian context for objective 2 helped strengthen these findings and highlighted the need for practical guidance for both government stakeholders and SMEs on compliance to standards. The findings and recommendations have been synthesized as an operational guidance document included as Annex 3. It provides information on the specifications, methodologies, laboratories offering these tests, costs and other practical considerations.

Best Practices

Nepal, Kenya and many states in India have programs for improving product access for adolescent girls through schools and other platforms. Specifications from the standards are included within government procurement of menstrual products and strengthens compliance.

The South Africa Sanitation Dignity Framework addresses SRHR and MHH comprehensively and hence, monitoring of menstrual product standards is included in the implementation of the Framework.

The South African Bureau of Standards engaged with small scale manufacturers to identify challenges in compliance and trained them in accordance with the standard requirements. The Kenya Bureau of Standards has subsidized the mandated tests at all government laboratories.

Harmonization

The review also showed that the existing standards vary widely in terms of the technical specifications. There is significant international trade in menstrual products and variance in classification and standard specifications creates challenges for manufacturers and consumers. If the quality requirements are different across export destinations, there is an added cost of quality control (QC) which eventually increases cost of the product for the consumer. If QC requirements are less strict in the destination country than the source country, this can provide undue competitive advantage to lesser quality products, especially for newer categories like reusable products. For example, Singapore classifies sanitary pads as 'not a medical device' and 'not a cosmetic product' hence, requiring no clearances. High levels of regional trade with products coming from manufacturing hubs like China, India, Thailand etc. would make lower quality products cheaper. Given these challenges, there is an urgent need for standards harmonization across

countries and regions. Harmonization of menstrual product standards will not only facilitate availability of quality products even in import dependent countries but also reduce cost of standards creation itself, especially given that regulators have limited budgets. The International Standards Organization (ISO) has also initiated the process of standardization for menstrual products at a global level and these will also be available for adoption by member countries by 2025 (estimated).

Based on the findings, the standards advocacy process can be summarized as follows:

MAKING THE CASE

- Sensitization of government and regulatory stakeholders
- Identification of champions

1

STANDARDS CREATION

- Ensure right stakeholders are on the table
- Support availability of context-appropriate references and in-country evidence
- Facilitate participation of neutral and diverse technical experts.

2

DISSEMINATION AND ENFORCEMENT

- Situating withing policy frameworks
- Sensitization of procurement stakeholders
- Advocacy for making standard 'mandatory'
- Consumer awareness and redressal
- Guidance on QC protocols and labs

3

HARMONIZATION

- Adoption of international and regional standards
- Ensure country standards are in line with regional standards and trade patterns
- Advocate through regional trade platforms

4

Call To Action

Based on the key findings, the following pathways for advancing the creation and harmonization of menstrual product standards are recommended, which can be adopted by donors, CSOs, researchers and practitioners working on enhancing access to quality menstrual products:



Engagement of government stakeholders through existing advocacy programs on sexual and reproductive health and rights (SRHR), water, sanitation and hygiene (WASH), environmental sustainability, gender and education to identify champions. Consumer affairs departments may also be sensitized for engaging them on aspects of consumer health and safety.



Supporting development of a common vision for standardization, amongst different government stakeholders, which can be used to make a formal request to the national or regional regulatory authority.



Identification and logistical support for stakeholders for more neutral and diverse representation on standards creation committees.



Investment in primary and secondary evidence generation and engagement with research bodies to strengthen the gaps in technical specifications, specifically those for microbiological and material safety and correlation with the duration of use of products.



Establishment of the feasibility of prescribed testing methods through independent testing.



Investment in operational research for understanding the impact of decentralized composting solutions on soil and water quality, especially in LMIC settings.



Situating quality control within menstrual health policies for enhancing enforcement.



Engagement with organizations like Consumer International and their regional chapters for enhancing consumer awareness and demand for standards compliant menstrual products.



Standards formulation should consider the product life cycle to minimize the burden of testing on manufacturers.

Provision of support to SMEs for compliance to standards by offering access to standards as a pooled resource:



- providing operational guidance and capacity building for SMEs in partnership with the regulatory authority
- improving information about and access to testing facilities through subsidies
- piloting pooled procurement mechanisms for collective quality control at a hub level for a network of SMEs



Supporting creation of global menstrual product standards by the ISO, the process for which has been initiated based on initial advocacy by the Swedish Institute for Standards. Representation of LMIC regulators who have developed these standards in their countries can help ensure that the ISO standards can be easily adapted for LMIC contexts that may be different from developed country settings.



Adopting standards from other countries and regional standards for new standards creation, to avoid duplication of efforts. E.g. ARSO and EAC standards can be adopted by member states. Specifications from these and other reference standards can be adapted by investing in evidence and feasibility testing for relevance to their specific context.

Some reference standards have been mentioned below:

- US FDA guidelines and standards from Australia, the EU, China and Japan
- Guidelines from the European Disposables and Non-Wovens Association (EDANA) and the Association of Non-Wovens Fabric Industry (INDA) for disposable products
- Reusable pad standards from the East and Southern African countries and India, registration guidelines set by the US FDA
- UNGM procurement specifications for disposable and reusable sanitary pads and menstrual cups
- ISO standards (estimated to be available by 2025)

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Annex 2 and 3 and global and regional dissemination materials have been included as supplementary materials to the report. For more information, contact Tanya Mahajan (tanyadargan@gmail.com)