

## 3 PART WEBSERIES ON MENSTRUAL PRODUCT QUALITY & STANDARDS

FEBRUARY – DISPOSABLE MENSTRUAL PRODUCTS  
MARCH – REUSABLES  
APRIL - MENSTRUAL CUPS





**WEBINAR SERIES**

# Standards for Disposable Sanitary Pads





Topics that will be covered:

- Standardization Parameters
- Existing Standards Landscape
- Key Concerns

Please add your points and questions into the chat box !



## SPEAKERS:

**Tanya Dargan Mahajan**, Development Solutions / MHAI, India

**Dr. Michael Moscherosch**, Director R&D, External Innovation & Alliances at Johnson & Johnson, USA

**Louise Klintner**, PhD student, Lund University, Sweden

**Jaydeep Mandal**, Founder and Managing Director of Aakar Innovations, India

**Suhani Jalota**, Founder and CEO, Myna Mahila Foundation, India

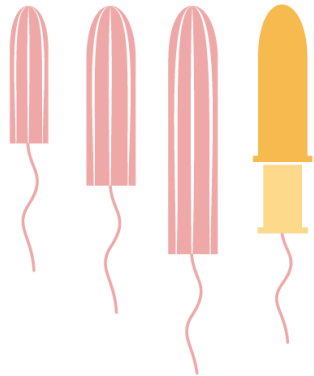
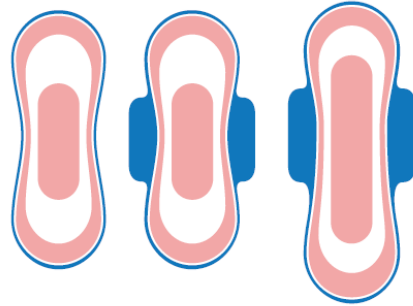
## MODERATOR

**Puleng Letsie**, African Coalition for MHM/ UNFPA, South Africa



# Disposable Menstrual Products

Disposable Sanitary Napkins (DSN) /  
Sanitary Pads/ Sanitary  
Towels



Tampons

## Components

- Top cover
- Absorbent core (Additives like SAP for increased absorption and reduced thickness)
- Bottom (leakproof) barrier
- Fasteners, adhesive etc.
- Additives for fragrance etc.

# Standardization Parameters

Objectives	Standardization Parameters
<ul style="list-style-type: none"> <li>• Identifiable by consumers as per common definitions</li> <li>• Consumers should have sufficient information from the packaging to make an informed choice</li> <li>• Packaging itself should be safe and appropriate for disposal and dispersion</li> <li>• Consumers should have information on appropriate disposal or pooling of used menstrual product</li> </ul>	<p>Physical parameters</p> <ul style="list-style-type: none"> <li>• Materials and components</li> <li>• Construction</li> <li>• Size (linked to dimensions or absorbency/flow)</li> </ul> <p>Packaging</p> <ul style="list-style-type: none"> <li>• Materials - Type, construction and dispersion</li> <li>• Marking               <ul style="list-style-type: none"> <li>• Manufacturing details and date of expiry</li> <li>• Raw materials</li> <li>• Duration of wear (linked to absorbency and hygiene)</li> <li>• Method of disposal</li> </ul> </li> </ul>

# Standardization Parameters

Objectives	Standardization Parameters
<ul style="list-style-type: none"> <li>Perform the desired role - absorption of menstrual blood and other fluids without leaking</li> </ul>	<p>Performance parameters</p> <ul style="list-style-type: none"> <li>Absorbency and Retention</li> <li>Dispersion</li> <li>Moisture content of absorbent core</li> </ul>
<ul style="list-style-type: none"> <li>Comes in close contact with skin and mucosa hence, should not harm vaginal flora or lead to RTIs through growth of harmful microbes</li> </ul>	<p>Hygiene/Microbiological parameters</p> <ul style="list-style-type: none"> <li>Total viable bacterial count</li> <li>Specific microbiological testing - Enterobacteriaceae, Staphylococcus aureus, and Pseudomonas aeruginosa, Candida albicans</li> </ul>
<ul style="list-style-type: none"> <li>Raw materials should be safe</li> </ul>	<p>Biocompatibility i.e Material safety - toxicity, irritation, skin sensitivity etc. (ISO 10993)</p>
<ul style="list-style-type: none"> <li>Standardization parameters are vetted through appropriate testing samples representative of the manufactured batches</li> </ul>	<ul style="list-style-type: none"> <li>Frequency of testing - One time, Batch testing, change of raw materials etc.</li> <li>Sampling for each type of frequency</li> </ul>

# Questions

1. How would you look at classification for disposable pads and tampons?
2. What are the considerations for bioburden related testing? Are testing for both pH and microbial testing required?
3. Do all raw materials have proven safety profiles for biocompatibility testing for prolonged contact with vaginal tissue - SAP, bleach, fragrance?



# Questions

4. What are the concerns with quality control in the context of re-packaged products?
5. What are the challenges and solutions in ensuring quality in the case of small scale production?

# Questions

6. What are the existing certifications for compostability and considerations for waste management given lack of related infrastructure in LMIC settings?

# Existing Standards

Africa				
Country/Region	Authority	Standard Name	Parameters Covered	Others
East African Community (Burundi, Kenya, Rwanda, South Sudan, Tanzania, Uganda)	East African Standards Committee	EAS 96-1:2008 Sanitary towels Specification- Part 1: Disposable	Construction, performance, hygiene	Uganda standard for reusable pads DUS 1782: 2017 Kenya KS 507: Sanitary towels
Ethiopia	Ethiopian Standards Agency	ES 6345:2018 Part 2: Disposable	Construction, performance, hygiene	ES 6346:2018 Part 2: Reusable
UNECA and AU	African Organization for Standardization	DARS 653:2017 Sanitary towels		DARS 1575 Textiles – Reusable sanitary towels
South Africa	South Africa Bureau of Standards	SANS 1043:2010	Size and construction, performance, hygiene, sterility and autoclavability	SANS Draft for Reusable pads
Zimbabwe	Standards Association of Zimbabwe	ZWS 730:2015 Manufacture of Sanitary Pads		ZWS 1023: Reusable sanitary pads

# Existing Standards

Asia				
Country/Region	Authority	Standard Name	Parameters Covered	Others
India	Bureau of Indian Standards	IS 5405:2019	Construction, performance, hygiene, biocompatibility, compostability	Reusable pads, menstrual cups under development
Sri Lanka	Sri Lanka Standards Institution	SLS 111 Sanitary Towels		
Pakistan	Pakistan Standards and Quality Control Authority	PS: 1449-1979		
Bangladesh	Bangladesh Standards and Testing Institute	BDS 1261:2016 Sanitary Towels Mandatory		
Nepal	Nepal Bureau of Standards and Metrology	Under development with recent advocacy		
Cambodia, Vietnam	Institute of Standards of Cambodia; Vietnam Standards and Quality Institute			

# Existing Standards

Others - Reference				
Country/Region	Authority	Standard Name	Parameters Covered	Others
United States	US FDA	Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s) <i>Classified as non-significant risk (NSR) medical devices</i>	Materials, performance, Hygiene (staph, TSST-1 for tampons, normal vaginal flora), <b>Toxicology</b>	Includes disposable pads, tampons, washable cloth pads and intra-labial pads
Japan	Pharmaceuticals and Medical Devices Agency	The Standards for Marketing Approval of Sanitary Napkins  Notification PFSB No.0325-17, March 2015  <i>Sanitary napkins classified as 'Quasi-drugs'</i>	Colour fastness, pH, fluorescence, absorption, exudation, adhesion etc., <b>Safety profile of 150 materials used in a sanitary napkin</b> (including those that should not come in contact with skin or mucosa)	
China	Bureau of Standards, Metrology and Inspection	CNS 9324:2004 Feminine sanitary napkins		

# Existing Standards

Latin America				
Country/Region	Authority	Standard Name	Parameters Covered	Others
<i>Not retrieved any for Latin America</i>				

# Questions

7. What are the key differences in standards across countries? Especially across developed countries and LMICs?
8. What are the different development, compliance and enforcement protocols across LMICs and related gaps?

# Key Concerns

## Technical

- Limited to components and performance
  - Few cover hygiene comprehensively
  - None cover material safety - especially with new varieties of additives
  - None cover compostability, given lack of waste management infrastructure in LMICs, many new products claim compostability; oxo-degradable variants also available
- Clear linkage with waste management systems missing (only SA standard has benchmark for sterility, autoclavability suggesting a preferred process)
- Most not mandatory and difficult to enforce



# Key Concerns

## Operational

- Need for harmonization may be there across countries given many manufacturers supply to multiple geographies
- Nomenclature harmonization also needed (sanitary pads/napkins/towels, menstrual products)
- ISO standards do not exist - many member countries do not have a common standard to follow
- Difficult to access (by manufacturers, as reference for new standard development)
  - Difficult to locate due to differing nomenclatures
  - Many available for purchase only
  - Many available only in local languages

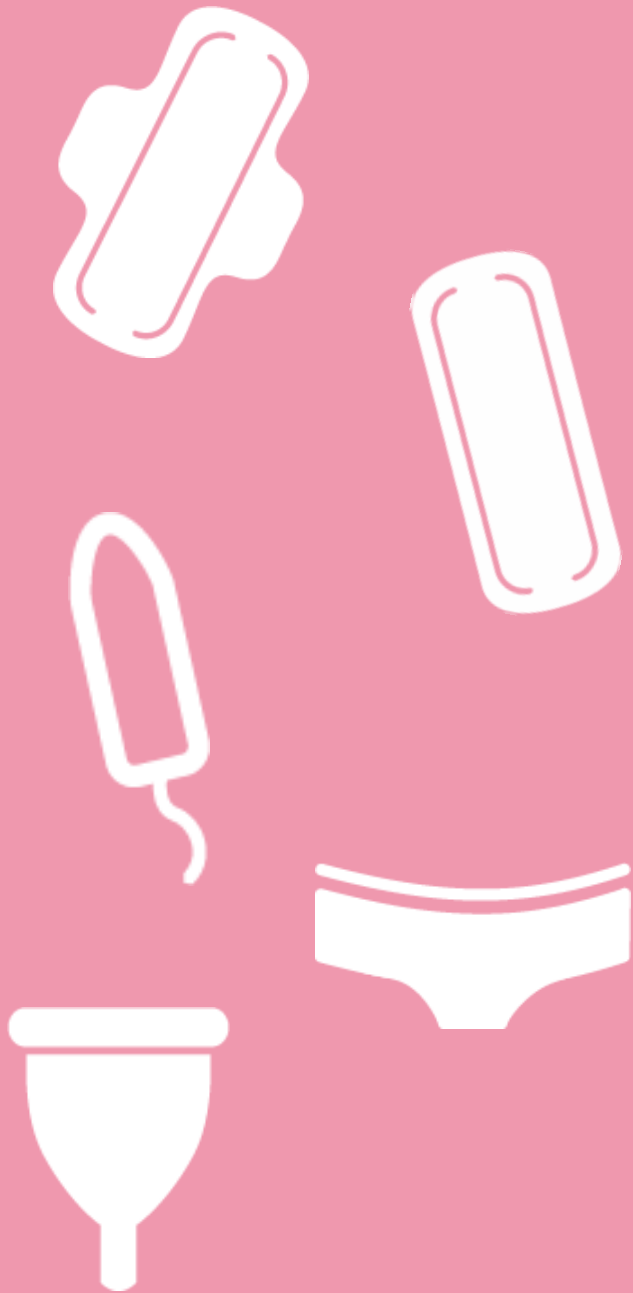


WHAT ARE YOUR QUESTIONS TO THE EXPERTS?

WHAT ARE IMPORTANT POINTS THAT WERE NOT TOUCHED IN THE DISCUSSION?

WHAT ARE THE EXPERIENCES IN YOUR COUNTRY / SETTING?





## 3 PART WEBSERIES ON MENSTRUAL PRODUCT QUALITY & STANDARDS

TODAY – DISPOSABLE MENSTRUAL PRODUCTS  
MARCH – REUSABLES  
APRIL - MENSTRUAL CUPS

[secretariat@rhsupplies.org](mailto:secretariat@rhsupplies.org)  
[info@menstrualhygieneday.org](mailto:info@menstrualhygieneday.org)



# Notes For Moderator

## Michael

1. How would you look at classification for disposable pads and tampons - consumer products or medical device?

*- DSNs and tampons are considered to be on the borderline of consumer products and medical devices given they come in prolonged contact with the vaginal tissue and mucosa (especially tampons). Many LMICs are developing standards and struggle with the classification.*

2. What are the considerations for bioburden related testing? Are testing for both pH and microbial testing required?

*- Appropriate pH by itself should ensure healthy vaginal flora. What added benefit does specific microbial testing provide?*

*- Products have been found to be more alkaline than the typical vaginal pH which is more acidic. Should the pH benchmark be determined by what exists in the market or vaginal pH?*

*- Duration of use of the product is correlated with bioburden growth and the risk of RTIs. Have there been any studies to say that the recommended duration of use (4-6 hours) is safe?*

3. Do all raw materials have proven safety profiles for biocompatibility testing for prolonged contact with vaginal tissue - SAP, bleach, fragrance?

*- 150 materials mentioned in the Japanese marketing approval standard, multiple global players.*

*- Are additives like fragrances needed? Odour is a result of pH being off its normal levels and increased microbial activity. So better information on changing products after the stipulated time period could serve the purpose.*

## Suhani

4. Myna Mahila has five varieties of sanitary pad products with some internally manufactured and some procured from vendors. What has been your experience in ensuring quality in both these contexts?

5. Small and medium scale production with different types of distribution models have helped increase access to sanitary pads in LMICs. What are the challenges in adhering to standards in these contexts? And solutions - protocols, policy support?

**Open to others for comment on ensuring quality in the context of “repackaging and sale of products” and “small scale production”**

## Jaydeep

6. Aakar has a compostable pad - what are the existing certifications that can be sought? Advantages and challenges in gaining this additional certification?

**Open to others for comment on “compostability” and “considerations for waste management in LMICs given lack of infrastructure”**

## Louise

7. What are the key differences in standards across countries? Especially across developed countries and LMICs?

8. What are the different development, compliance and enforcement protocols across LMICs and related gaps?