



IN STANDARDS WE TRUST

Building the case for international standards
for menstrual products

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"Around the world there are an incredible number of menstrual health companies who feel a sense of social responsibility toward ensuring there is transparency around their product ingredients. They are often leading the charge in terms of consumer safety when national or internal standards don't exist. These companies are not just driven by financial profit but social good."

*Nikki van de Veerdonk,
Lead Author*

Images courtesy of: Vullvani & Canva

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FOREWORD

Over the last few years, there has been an exponential increase in the number of businesses entering the menstrual health (MH) market. These often **women-led and/or community driven companies are not only closing the gap in the provision of essential and diverse menstrual products,** but also play a key role as actors in the broader MH movement in terms of education, advocacy and community awareness raising.

While building sustainable and accessible MH markets is not the only step, it is an important one in achieving menstrual equity. **Ensuring that menstruators have access to affordable, accessible and appropriate solutions that meet their MH needs can ensure they have greater freedom to engage in social, economic and educational opportunities.**(1) To date, much of the focus on menstrual products has been on the free distribution of pads through schools or social programming.

Although free distribution is necessary for marginalized populations, there are questions that **we must further explore in terms of the sustainability, efficacy and quality of products provided through these models.**

For those invested in building sustainable, localized and impactful MH markets there are several areas of exploration currently underway:

- the distribution of products through enhanced, multifaceted distribution models;
- greater investment in product innovation (especially beyond just period products);
- the strengthening of support chains and inclusion of menstrual products as essential reproductive health commodities;
- and the safety and efficacy of menstrual products.

1. Menstruators refers to the people who menstruate/have periods, regardless of their gender identity, including transgender men and non-binary people.

Over the past several years, a variety of organizations have been focused on building better evidence around menstrual products and MH market development. This work has focused on better understanding the supply and demand of menstrual products in order to ensure greater investment in MH markets.

PSI conducted a series of notable market assessments in India (2), and Ethiopia (3) to understand the consumer MHM journey, preferences, barriers, and influencers experienced in accessing markets in low-income countries. The Criterion Institute further expanded the conversation around MH markets examining the rise of MH companies within the Pacific region. Their work highlighted **the need to improve companies' financing and address supply chain constraints in order to enhance market performance and the ability of such businesses to meet the needs of last-mile consumers.**(4)

In 2021, Mann Global Health and the Reproductive Health Supplies Coalition released their four country (Kenya, Nigeria, India, and Tanzania) landscaping study on the supply side factors affecting menstrual health access.(5) This comprehensive report outlines in detail the MH market landscape including the types of business models, supply chains and market structures currently in operations and the unique opportunities and challenges in strengthening them.

Lastly and most recently Noru Capital and the Next Health Accelerator have mapped the market dynamics of the African pad market.(6) They argue that **product differentiation within the business models of the companies usually align along one or two axes of safety and health protection, convenience and/or affordability.**

All this work highlights **the vital and growing role of these nascent markets in providing access to essential products, particularly for last-mile customers.**

As conversations around market-based approaches have increased, so has the rising concern around product and industry standards that ensure the safety of menstrual product users.

Development Solutions conducted a landscape analysis of the current standards operating in low- and middle-income countries to map what regulations and specifications are currently guiding manufacturers.(7)

UNICEF and UNFPA have dramatically shifted the conversation around product standards with their recent tender to commission product suppliers for both agencies. Their product standards and specifications per product category are likely to be a game-changer for ensuring greater quality and accountability across the sector.(8)

Noru Capital and the Next Health Accelerator also explored quality standards in the Africa context, finding that **the “absence of largely adopted and publicized standards brings operational challenges in the manufacturing of their products and in the acceptance of the end products by the reluctant consumers, rightly worried with safety, health, and convenience concerns”.**(9)

It is in the context of these important pieces of work that Madami’s own standards consultation was simultaneously being conducted. Our aim is to understand how **MH companies have regulated themselves and created their own standards for quality assurance to safeguard the health of their end users - menstruators across the globe.** The consultation focuses on a bottom-up approach to conceptualizing standards and elevates the voices of producers who are dedicated to building impactful businesses that promote the health and wellbeing of their consumers and the environment.

AUTHOR'S NOTE

Perspectives from menstrual health companies

This paper has placed a focus on innovators and small- and medium-sized enterprises who are not responsible for the majority of the global supply of menstrual products. The business practices, products, quality issues and potential harmful materials used in the predominantly disposable markets of disposable pads and tampons produced by third-party manufacturers and marketed were not examined in this report.

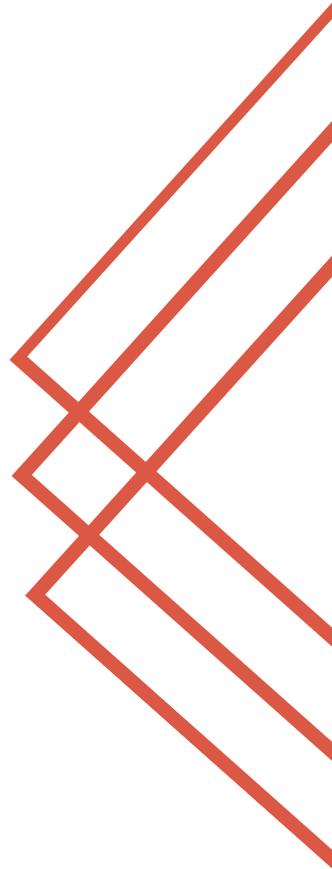
During the completion of this report, historic developments concerning the development of international menstrual product standards took place. In October 2021, after continued efforts by the Swedish Institute for Standards (SIS), the Committee on Consumer Policy of the International Organization for Standardization (COPOLCO) and advocates from the menstrual health community worldwide, the International Organization for Standards (ISO) opened the voting process with their 165 national member organizations to launch a new field of technical activity with a new Technical Committee. The proposed committee would focus on standardization in the field of menstrual products, covering all products intended for both single and multiple use, regardless of material. With a 'yes' vote from at least two-thirds of member countries, the proposal was approved in January 2022, with twelve member countries volunteering their expertise.⁽¹⁰⁾ With this report, we hope to contribute to these historic developments by creating a common understanding of the present-day circumstances in which MH companies operate and advancing global advocacy efforts on menstrual product standards.

It is important to note that the participating MH companies and experts were unable to take this vote into account in their answers as the consultations took place at an earlier time.

OVERVIEW OF FINDINGS

1. Transparency

- Customers demand more transparency around how safe a menstrual product is and increasingly want information related to the entire supply chain. Menstrual product companies are willing to give customers access to a limited amount of information. This **consumer desire for more transparency** translates into businesses providing more information about the materials, processes and / or chemicals used to manufacture their product.
- Although some companies observed that their customers were not concerned with product characteristics, they still felt **responsible for providing a minimal amount of product information**. However, the type and amount of information differed per company.
- As product features connected to performance are what differentiate a product from its competitors, **protection of proprietary rights of the product, production, and suppliers in the market can be a challenge**.
- As the perception of product safety impacts a consumer's willingness to try, adapt to, and accept a product, **product standards can help uplift the MH market as a whole** and stimulate consumers to find a product that best meets their MH needs.
- Offering transparency to other stakeholders in the field and (potential) consumers **helps build trust and helps companies to communicate that they are an ethical company investing in the health and wellbeing of their users** and that they are, as well, more broadly interested in social good. Furthermore, concerns over intellectual property can act as a barrier to full product transparency.
- Environmentally-friendly products are gaining in popularity with an increased call for 'natural' and 'organic' products in developed markets, making it **more important than ever that communications around these products are based on solid and truthful scientific evidence**. Ethical and environmental factors around the supply chain need to be taken into consideration by the private sector.





2. Quality

- **The absence of standards, inadequate standards or a lack of random testing to ensure only qualified products are available can have harmful consequences.** MH products worldwide are also subject to different standards that do not yet ensure product quality.
- Transparent product information is important for detecting products that can be harmful to users. With no system built in to detect if a new product is safe, **bad experiences with products whose quality has not been monitored can lead to scepticism** and refusal to try new products.
- The **lack of quality standards causes brands to educate consumers on product quality and performance**, particularly for reusable menstrual products.
- MH companies strive to legitimize their own products with test results and certifications, and encourage partners in the field to aspire to this as well. **Recognized standards and minimum levels of product testing** should be the first step to ensuring the MH products entering the market are fit for use.
- As long as there are products on the market that are not upheld to a yet-to-be-determined standard, the health of menstruators cannot be guaranteed. **Quality differences between countries and regions are problematic when striving for menstrual equity.**⁽¹⁰⁾⁽¹¹⁾ An example of this is when products donated are not of the same quality as those sold in stores.



3. Materials

- There is room for improvement when it comes to ensuring that materials are compliant with (inter)national standards and aligning these material standards. With regard to materials, it is up to the individual company to determine what they choose to use. **There are different product characteristics (e.g. absorbency, wearing time) available for users, but no industry standardization on what these mean.** This can make it challenging to communicate to consumers what the characteristics used to describe a product mean in comparison to other products in the market.

- MH companies have established their own way to determine the safety of their materials. Standardization in the industry would help **synchronize the terminology used by different menstrual product companies, and help ensure that companies are meeting minimum requirements** regarding certification of use of safe ingredients and absorption reporting. Furthermore, standardized materials can help ensure product quality when unskilled employees join the manufacturing process.



4. Packaging

- Companies are **not obligated to declare the materials used in the production of the products on the packaging, leading to incomplete or misleading information**. Claims about materials and environmental impact of products can be made without supporting data to prove this, and even when packaging has materials on it, it does not need to reflect the full material list.
- The development of menstrual product standards that prescribe **adding a full list of materials on the packaging is essential criteria when aiming to guarantee consumer safety**.



5. Classifications

- **Worldwide, menstrual products are subject to different standards due to how they are classified and which product group they fall under.** Limited resources can cause regulatory bodies to decide to create standards for product categories that have a larger market presence than menstrual products. For the standardization process to be aligned globally, the consulted companies indicated that **menstrual products need to be considered the same type of item**.
- There is a **need for high-level support and acknowledgement** that menstrual products are necessary and not luxury goods, and to place them in an appropriate product category.



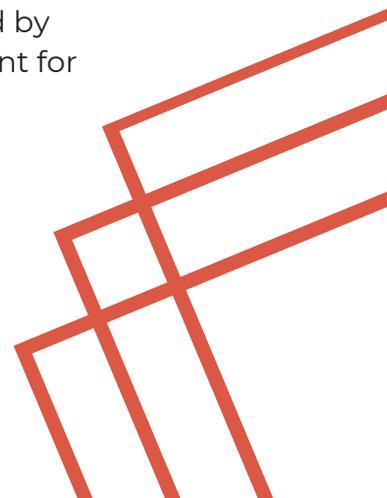
6. Entering the MH Market

- The lack of standards for menstrual products is especially complicated when entering the menstrual health field as a business. When there are no existing standards for MH products, **companies are left to advocate for the development of standards either alone or with other actors in the MH sector.** One of the consequences of the lack of product standardization is that MH companies have taken it upon themselves to lobby for and guarantee product safety to their customers.



7. Existing local and global standards

- A starting point to improving the challenges faced when standardizing menstrual products could be to improve or broaden existing standardization. The creation of comprehensive, enforceable **standards for menstrual health products could ensure that every manufacturer is held to the same quality standard.** An evidence base for the sector could help make standards understandable for all stakeholders.
- The development of global menstrual product standards is considered a possible solution for the challenges around the standardization of menstrual products. **Minimum global criteria would help ensure that if global tenders were issued for menstrual products, informed decisions could be made considering a set of validated performance, quality, and safety standards and not on the basis of price as the primary driver.** Among other things, this would help ensure menstruators everywhere receive safe donated menstrual products and help build menstrual equity on a global scale.
- Important to note: the majority of menstrual products are accessed by individuals through markets, and donations of free products account for a minor amount. In order to prevent the negative side-effect of an unequal division of raw materials, global standards would be accompanied with global agreements on material availability and usage.





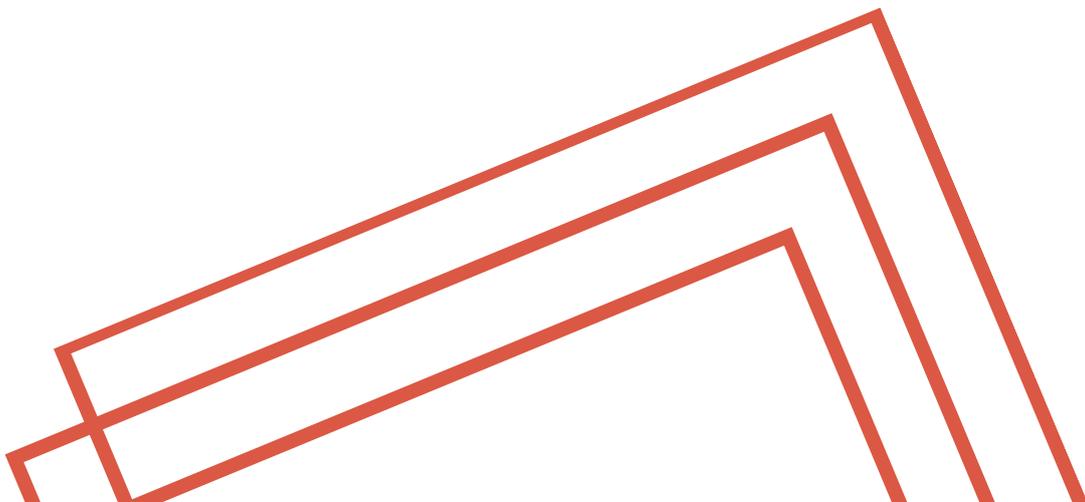
8. Innovation

- Existing menstrual product standards can be a barrier for innovation and **it is very important to consider and facilitate innovation when developing menstrual standards.** Standards need to be developed in a way that ensures effective innovations are not blocked or made too difficult to create, as product innovations can evolve faster than the standards review process. This could mean that when new innovations cannot be tested against existing standards, flexibility is required from the concerned authorities to engage in the pilot/testing process to build the new evidence and knowledge base for these innovations.



9. Responsibility and collaborative efforts

- Many MH companies have taken on a proactive approach to find out how standards are regulated in their region and field of activity, and based on that, established their individual strategy to ensure the safety of their products. As well as following national and international product standards, **MH companies strive to move beyond the required menstrual product standards to ensure consumer safety.**
- Many MH companies have a strong sense of responsibility to guarantee product safety, and it is important to the companies consulted for this research that the industry as a whole takes on this approach. **Sharing perspectives and best practices and mapping key areas of responsibilities for the roles of different regulatory bodies, governments, and other stakeholders** were all suggested as contributing to collaborative efforts to ensure product safety within the MH sector.

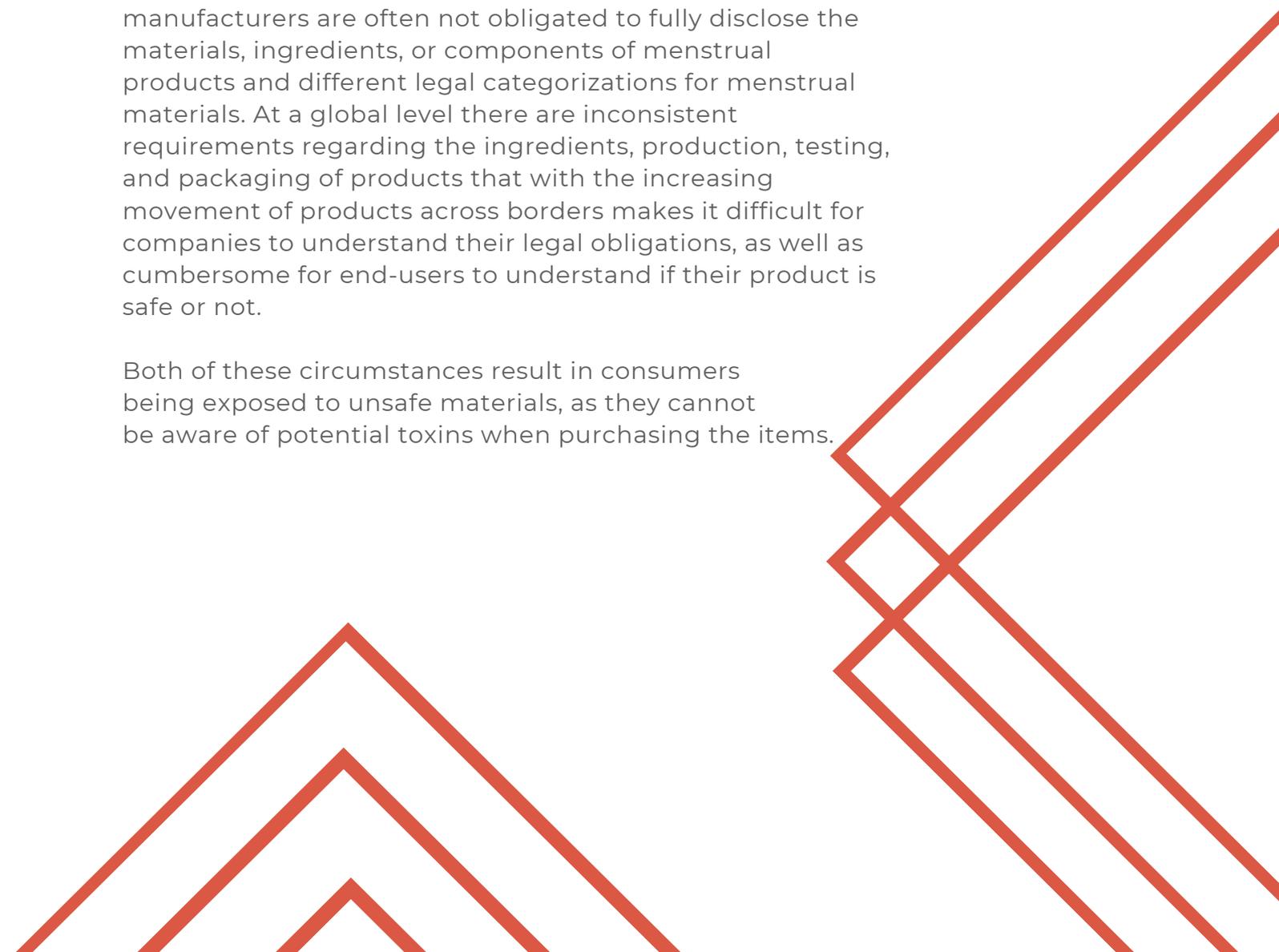


Project details

The promotion of safe and effective menstrual products is a shared aim of menstrual health sector stakeholders. This means that consumers must be able to access and choose from a variety of high-quality and certified products. Yet, in many countries today, product standards that protect the health of users of menstrual products and provide them with product information are insufficient or even nonexistent. Development Solutions have conducted the most comprehensive landscape analysis of the current standards operating in low and middle income countries to map what regulations and specifications are currently guiding manufacturers.(13)

However, it is important to note that in most countries manufacturers are often not obligated to fully disclose the materials, ingredients, or components of menstrual products and different legal categorizations for menstrual materials. At a global level there are inconsistent requirements regarding the ingredients, production, testing, and packaging of products that with the increasing movement of products across borders makes it difficult for companies to understand their legal obligations, as well as cumbersome for end-users to understand if their product is safe or not.

Both of these circumstances result in consumers being exposed to unsafe materials, as they cannot be aware of potential toxins when purchasing the items.



In the last couple of years, there has been **an exponential increase in the number of businesses particularly those who see themselves as social impact-driven**. As a result of their social missions around menstrual equity, they believe they have an integral role to play in protecting the health of menstruators- not only because of legal obligations but ethical ones. Consequently, they regularly engage in social activism and advocacy at the country level in order to create legal or regulatory frameworks to guide their work.

MH businesses have taken the lead in regulating themselves and creating their own standards of quality assurance to safeguard the health of menstruators. Considering the highly complex nature of political regulatory structures within countries and transnationally, sharing perspectives is essential in the larger government-led conversations to advance standards around menstrual products.

The purpose of this report is to **reflect the experiences of concerned companies and MH experts about product standards**.



Methodology

To encourage an active dialogue around menstrual product standards, Madami/MH Hub held informal consultations with seven MH companies from July to November of 2020 in which they reflected on their experiences with menstrual product standards and how they deal with the standardization of their products. Our consultation was divided in two parts: Consultations with MH companies and consultations with MH standards experts.

1. Consultations with MH companies

To explore in which ways we can cater to and encourage the dialogue around menstrual product standards, we held informal consultations of MH companies in the Menstrual Health Hub (MH Hub) ecosystem wherein they discussed with us their roles in self-regulation and/or standards advocacy in order to better understand how period products companies situate themselves within the imperative for standards to assure quality. The companies consulted for this report were:

- Aakar Innovations
- Aisle
- AFRIpads
- Callaly
- DivaCares / DivaCup
- Einhorn
- Kasole Secrets Company / Glory Sanitary napkins

We asked them to provide their insights on the following topics:

- Transparency towards their customers regarding the production and supply chain;
- The standardization of the quality of their products;
- The role of UN agencies, governments, or other regulatory bodies in supporting them;
- Their take on and how they understand social responsibility.

2. Consultation with MH standards experts

Complementary to the consultations with MH companies, several stakeholders currently leading the charge on MH product standards within the menstrual health community analyzed the information provided by the consulted companies and provided their own insights. Among the experts included:

- Tanya Dargan Mahajan (Development Solutions / RHSC MHS workstream);
- Puleng Letsie (UNFPA / ACMHM);
- Nancy Muller (Independent Consultant / RHSC MHS workstream);

- Ina Jurga (WASH United) on behalf of the Reproductive Health Supplies Coalition MH workstream.
- Gerda Larsson, former Managing Director of The Case For Her and Anna Sjögren, Project Manager at the Swedish Institute for Standards (SIS)
- Adrian Dongus, Intersectoral MHM in Emergencies Consultant for the UNHCR-UNFPA Partnership

Taking the lead, the Reproductive Health Supply Coalition (RHSC) hosted a pivotal series of webinars on menstrual product standards together with the Menstrual Health Alliance of India, WASH United, the African Coalition for MHM.(14)(15)(16) In 2021, RHSC supported a research project with Development Solutions to develop policy guidance for harmonization of technical benchmarks for disposable and reusable menstrual pads in South Asia and Africa. The research focused on India, Nepal, Uganda and Kenya, was to develop an in-depth understanding of the country level policies and processes and how they impact standards development.(17)

Purpose

With the consultation, Madami / MH Hub aimed to:

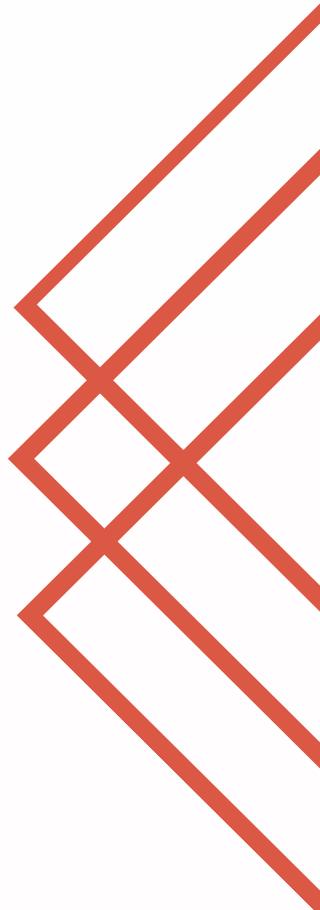
- Illuminate the status-quo of self-regulation and address how this can affect the health and safety of menstruators everywhere;
- Advance the conversations happening around MH standards in light of the rising tide of small business and MH companies on the product market;
- Collect a variety of perspectives on MH standards from within the MH field to be taken into consideration and inspire both stakeholders in MH and regulatory bodies on how to best cater to and facilitate companies engaged with menstrual product standards;
- Call attention to the topic on menstrual health product standards within the menstrual community and inform menstruators worldwide.

In light of existing top-down research around the regulatory frameworks, this paper seeks to provide a bottom up perspective on what companies are doing in absence of strong frameworks which can inform the design and delivery of their products. This paper does not provide an inventory or analysis of existing standards or which can be found in the work of Development Solutions (18) and Nuru Capital/ the Next Health Accelerator. (19) Instead, it focuses on what are the key concerns and modalities that businesses face in how they operate and govern their work. The report refers to several individual standards and laws mentioned by the companies and experts with reference to how they interpret these guidelines within the work.

It is important to emphasize that the findings presented in this document are a summary of the most notable insights from the consultation process. It includes insights from multiple companies from several different regions worldwide, as well as referencing key trends and challenges that must be considered in the larger scheme of the global standardization movement. This report by no means explores the full depth and breadth of all these topics. **Our key recommendation is that there are several key topics identified which warrant further study.** Each of the top-level categories distinguished in this report deserves a deeper dive and more and more extensive data collection per topic and region to determine what concrete actions should be taken regarding menstrual product standards in that context.

This consultation demonstrates that there are many perspectives, challenges and modalities being used to both discuss and regulate MH companies.

We recognize that there are many other players involved in menstrual product standards that have not been addressed here, however hope this work begins a new conversation with companies and other stakeholders who have an important role to creating a scalable, sustainable and safe market of menstrual products which suit the needs of all menstruators.



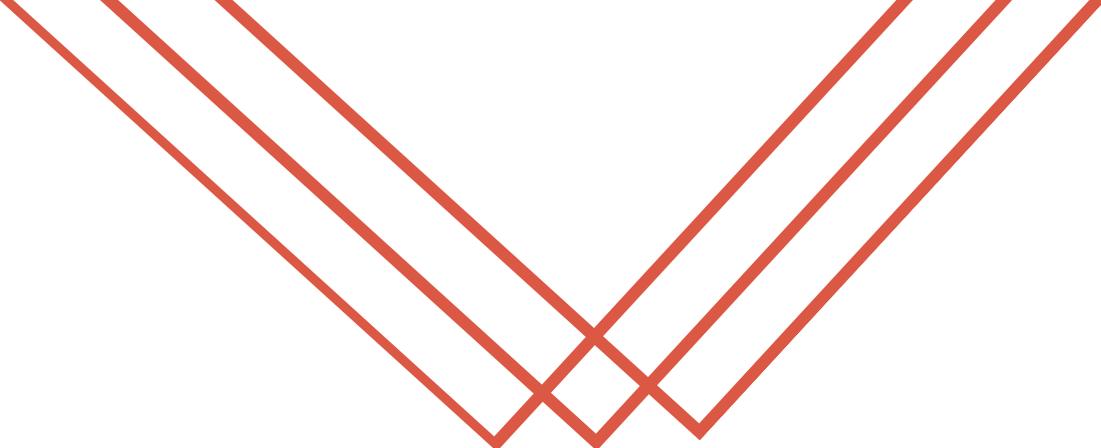
BACKGROUND

In the past decade, the choice of MH products and materials that are available to help manage menstruation has increased substantially.

Despite this continuing growth in product innovation, national and global product standards that protect the health of users and provide them with accurate product information remain limited or non-existent. (20)(21) Product standards are essential accountability mechanisms both for companies and users to ensure that any goods or services are of a certain quality, safe for use, and fit for purpose. In the context of MH product standards, product requirements relate to the components, production, performance, testing, and packaging of the products, including relevant usage and care information.(22)

The development of most existing menstrual product standards has taken place **through the harmonization of technical committees with key stakeholders at organizational, national level, or at regional and international levels.** These actors have included governments, academia, consumer groups, private sector, technical experts, NGOs, consumer groups, etc. When available, these standards have been developed through and monitored by standards bureaus on regional or country level, such as the Standards Association of Zimbabwe,(23) American National Standards Institute (ANSI)(24) or the Bureau of Indian Standards (BIS).(25) Standards developed by the standardization process, like by a national standard bureau, are not the same as laws / regulations, as the standards are (still) voluntary.

As local stakeholders are driving the development of standards, this often leads to different content or regulations inside of them. Consequently, **menstrual products are subjected and regulated by these local requirements rather than a uniform set of global standards.** They are at times similar, but not always equal in the requirements they put forward and expect companies to abide by. As in many countries, manufacturers are not obligated to fully disclose the ingredients or components of MH products. Furthermore, the different legal categorizations of menstrual materials leads to inconsistent requirements regarding the ingredients,



production, testing, and packaging of the products. This could result in consumers being exposed to unwanted materials as they cannot be aware of potential toxins and harmful materials when purchasing the items. (26) Many menstrual products are inserted in the vagina, or come in close contact with vaginal tissue, which can create higher health risks when the product is not safe.

"The lack of a universal agreement upon standards for what constitutes safety for internal and external products and the lack of transparency regarding the components of these products limits the users ability to make informed choices about their menstrual health."

This lack of regulation, coupled with the proliferation of companies around the world, has the potential to negatively affect consumer rights, but more importantly the health and wellbeing of menstruators.(27)

Products used on or intimately with the body are usually strongly regulated and/or standardized. Recent research suggests that one of the fundamental reasons for the structural absence of menstrual product standards and limited innovation in the market over the past two centuries on a global scale, is the stigma that is still attached to menstruation.(28) Therefore product destigmatization and menstrual product standards are affected by broader social taboos around menstruation. Addressing these gaps is essential to the destigmatization of menstruation as a whole.(29) (30)

On a global scale, more efforts have been taken to enhance the MH product market. In 2021, The United Nations Population Fund (UNFPA) and the United Nations Children's Emergency Fund (UNICEF) opened a bidding process for the supply of Menstrual Health Management products (reusable menstrual cups, reusable menstrual pads, and disposable sanitary pads) for their programs and third party clients, worldwide.(31) Also published in the same year is the Landscaping Supply Side Factors to Menstrual Health Access report by Mann Global Health and the Reproductive Health Supplies Coalition with the purpose of outlining key constraints to and opportunities for MH product access, and to outline recommendations for donors, governments, and other actors within the market.(32)



It is without question that the promotion and use of safe and effective menstrual products is a shared aim of MH sector stakeholders. This requires that **consumers are able to access and choose from a variety of high-quality and certified products to be able to make an informed choice about how to address their menstrual needs.**

Understanding how menstrual products might potentially impact one's health and wellbeing is an essential part of gender- and menstrual equity.⁽³³⁾ Central to menstrual equity is ensuring the ability of a user to make the best decision for their body, health, and lives. Product standards can be a critical lever in enabling users to make those decisions.

In the absence of set standards, MH companies are stepping up to regulate their products and create their own standards or advocate for them so as to facilitate transparency for their users and increase trust in the safety of their products. In order to better understand how MH companies deal with the standardization of their products, we asked seven innovative MH companies different questions regarding their view on transparency towards their customers regarding the production and supply chain, the standardization of the quality of their products, and the ways in which UN agencies, governments, or other regulatory bodies could support them and what role they play in assuming social responsibility (see Annex 1 for the company details).

Below we have identified a series of high-level topics and findings from these interviews about the importance of standards to the MH sector as a whole. Under each topic, we provide a series of main insights supported with quotes and context from the held consultation. In addition, these findings were presented and validated by a selection of experts that are involved in the development and/or promotion of menstrual product standards (Annex II).

We asked the experts to share their thoughts on the current menstrual product standard landscape and progress, the changes that have occurred, and their views on the insights provided by the MH companies and all the outlined themes highlighted in this paper. The expert input has been incorporated throughout this chapter, and when relevant indicated with a “*”.

FINDINGS

Transparency

There is growing customer demand for transparency across the industry. Being called for by both the industry and consumer, transparency offers new opportunities for MH businesses to increase their customer base and guarantee product safety.

The consulted companies indicated that customers are demanding more transparency around the safety of their products and increasingly want information related to the entire supply chain. Menstrual product companies are willing to give customers access to a limited amount of chosen information. The consumer desire to have more transparency translates into businesses providing information regarding the materials, processes and chemicals used to manufacture their product. Increasingly, trends are showing that more consumers are questioning what kind of products they use, how they are made, and where they are coming from.

These questions are particularly relevant amongst users aged 25 to 40 who are more conscious consumers about health, the environmental impact of their products, and the profile of the company. It is unclear whether it is the intimacy of menstrual products, or a history of opacity regarding toxins and chemicals being found in them, that is further fuelling these dynamics. However, MH businesses, particularly those who tie a social mission to their business performance, are responding to these dynamics. All the consulted companies indicated that their customers are more actively seeking health information before purchasing products. As a result, they are responding to this supply-side demand. When asked about the desire for greater transparency across the supply chain, all companies consulted responded positively that this was an important and necessary step across the sector.

Although some companies observed that their customers were not concerned with product details, the companies we interviewed still felt responsible for providing a minimal amount of product information. However, what this minimal amount of information was, differentiated per company. In terms of customer transparency, the consulted companies have similar perspectives. Diva Cares (34) expressed that they were committed to transparency in each step of the DivaCup production process.

Regardless of the limited regulations or standards available to inform or standardize their production and quality assurance processes, DivaCup has pushed for transparency in all their manufacturing and in the advertising of the ingredients of their menstrual cups. According to Alexis Biermann, former DivaCares Manager and Positivity Officer:

"We choose our supply chain carefully and audit our key suppliers annually based on many factors such as quality, environmental and sustainable practices, in addition to how they treat their people. For Diva, transparency doesn't stop at distribution, once a consumer purchases our product or someone in need receives the product through our DivaCares social impact program, we take great effort to ensure our commitment to transparency is known."

Similar to DivaCup's position, Aisle(35), also a Canadian company, extends its commitment to transparency from ingredients and components to manufacturing. They guarantee and quality assure their products through their own certification process and by performing due diligence to ensure that their customers can trust the claims that they share. Suzanne Siemens and Madeleine Shaw, co-founders of Aisle, highlighted that **one of the most difficult challenges in terms of transparency is the protection of proprietary rights of the product, production, and suppliers in a market.**

An issue that is only growing as the market of competitors expands: *"It is challenging in today's market as some of these features that are connected to performance are what differentiate us from our competitors. So there is a challenge in being able to be completely transparent while keeping proprietary information to ourselves"*. As product features that are connected to performance are what differentiate a product from its competitors, protection of proprietary rights of the product, production, and suppliers in the market can be a challenge.

Tanzania's Kasole Secrets (36) shares this commitment to quality and transparency, emphasizing the importance of access to knowledge for consumer informed decisions. However, according to CEO Hyasintha Ntuyeko, these concerns and needs for knowledge are not a constant that can be found in every consumer. She explained that some of her clients in Kenya only consider the absorption capacity, the price, and the comfortability at the moment to make a decision, but most of them do not read the information on the package or omit the instructions on it: *"our pads have a big Swahili instruction saying open here and yet many will still tear open the package"*.

According to Aakar Innovations (37) (India) founder Jaydeep Mandal, having to meet national and international standards would dramatically improve transparency in the sector and weed out those companies who do not follow the acquired regulations:

“In the last 3-4 years we have seen mushrooming of MH organisations globally and everyone thinks that they are MH experts which is completely untrue. This is a challenge with many MH machine manufacturers, product manufacturers, product sellers, awareness organisations and individuals. Many of them are making low quality low cost machines, low quality products with harmful materials without following any regulations. They are selling it by fooling clients, governments and consumers with misinformation and fake products, and on the other hand awareness organizations that give out random wrong information. Many of these organizations also have deep pockets or are flooded with funds which is even more dangerous for the sector.”

As the perception of product safety impacts a consumer's willingness to try, adapt, and accept a product, product standards can help uplift the MH market as a whole and stimulate consumers to find a product that best meets their MH needs.

Sophia Grinvalds from AFRipads (38) in Uganda states that when national or international standards are absent, there are also options for submitting products to third party or private laboratory testing, if that is within the means of the manufacturer. According to her, manufacturers should be actively lobbying or advocating for the development of product standards, or minimum quality requirements in their context. She indicated that *“standards and product certification can be very important in terms of MH behavior change, and product acceptability, and adoption.”*

She argues that the perception of the product will be impacted by how much knowledge the consumer has over it, which will impact their willingness to try, adapt and accept the product. Poor quality products not only affect customers but also prevent market penetration for other products and companies: *“If there is no standard there is no way to differentiate one versus the other in terms of product quality or performance.”*

It is likely that when one consumer has a bad experience with a new type of product they will be hesitant to try the product again regardless of the brand. Similar findings have been validated in recent research by Nuru Capital and Next Health Accelerator who raise concerns regarding product quality impacting the overall reliability of the MH market.(39)

Callaly (40) in the UK includes on their website a FAQ area regarding the components of the product and where they are produced. Shaun Knights, its Head of Quality and Continuous Improvement, believes that *“with consumers being increasingly knowledgeable in this field, using it to influence their decision to purchase in some cases, we aim to be as transparent as we can.”*



Offering transparency to other stakeholders in the field and (potential) consumers helps build trust and helps companies to communicate that they are an ethical company investing in the health and wellbeing of their users. Furthermore, concerns over intellectual property can act as a barrier to full product transparency. Aside from external pressure for businesses to adopt transparent practices, the menstrual product market has an ethical obligation to its community to lift up standards and be better. Transparency should not just be considered a legal requirement but as an opportunity to expand their customer base. Offering transparency to other companies and (potential) consumers helps improve trust and provides an opportunity for companies to communicate their social mission to the general public.

Menstrual products and services are more than a solution to a problem, they are deeply tied to women's sense of safety and autonomy over their bodies. However, ensuring that businesses understand that transparency is not just a social imperative but a business one, which will both increase and retain customers, will be critical to overcoming concerns regarding intellectual property, which currently is a key hurdle in increasing product transparency and ensuring and improving customer safety. As smaller and often community-based or women-led businesses, (41) new MH companies differ from their competition - traditional global corporations such as P&G, Essity and Kimberly Clark - in that business metrics are often tied to social metrics with clear expectations that product growth should create a social value for their customers such as health, wellbeing and equity.

Environmentally-friendly products are gaining in popularity with an increased call for 'natural' and 'organic' products in developed markets, making it more important than ever that communications around these products are based on scientific evidence. Sustainability is a key concern for consumers, one that often informs product choice. Sustainability takes many forms across the MH sector and can include such approaches as promotion of reusable products, reduced environmental impact (directly through the product or across the supply chain), relocalizing production chains, or safer, toxin free alternatives.

A growing number of organizations and manufacturers are realizing that both user habits and product design principles will have to adapt themselves to become more environmentally-friendly and/or sustainable. As a result, a new generation of menstrual products have emerged on the shelves which respond to the growing demand for alternative approaches to MH that takes the environment into account. Elena Weidemann from Einhorn (42) in Germany stated that their company also committed to more sustainable products that follow rigorous standards for consumer safety: *"We question the low standards of some certificates because we think that they are not going far enough"*, therefore, she states, Einhorn has built a very strong and reliable partners constellation along their supply chain to try to be as fair and sustainable as possible. With a growing global population, **it is critical that the menstrual product market as a whole becomes more transparent about what is in its products, but also around the environmental impact across the whole supply chain - from production to waste management and disposal.** For all the consulted companies, environmental and sustainability considerations are central to their R&D (Research and Development) process, the marketing of their products, and to the mission of their organization.

★ In line with this, Adrian Dongus addressed the responsibility of private sector actors in relation to their supply chain: *"The issue of varying levels of quality of products, an increase in manufacturers and resellers, and the lack of national and international standards is a genuine issue. Large organisations have the means to assess the quality of products they procure and hold them accountable to internal quality requirements. However, an increasing number of people receive support in the form of cash. Access to products that flood the local market cannot always be controlled and expose beneficiaries to risk of buying products of low quality or which may even be potentially harmful. Holding private sector actors accountable for the quality of their products and setting minimum standards to curtail the rapid growth of low quality products is crucial."* Following this, he addressed that the ethical and environmental factors pertaining to the production process of raw materials should be taken into consideration and companies should take an active effort in mapping their upstream supply chain to identify any potential risks or irregularities.



Quality

The absence of standards, inadequate standards or a lack of random testing to ensure only qualified products are available can have harmful consequences. MH products worldwide are also subject to different standards that do not yet ensure product quality.

All the consulted companies indicated they faced at least one or multiple obstacles related to the standardization process of product quality in the industry. The differences experienced in the standardization process indicates that there is no uniform process or regulations to ensure product quality. One reason for the different standards is that products are subject to different classifications worldwide.

Providing product quality information is important to detect products that can be harmful to users. **With a lack of transparency or information around new products, innovative and new products on the market face skepticism from customers and lower customer uptake.** For AFRIpads, quality assurance is at the core of their operations. According to Sophia Grinvalds, *“quality is one of our most important benchmarks, starting with our raw materials, and running all the way through our manufacturing process to our finished products.... This is really important in countries where ‘illicit markets’ and the existence of fake/copy-cat products are prevalent. If consumers question the authenticity or safety of a (new) product, and there are no credible means of demonstrating that, it can be very difficult to garner consumer interest, trial, and uptake.”*

The quality standards provided by the U.S Food and Drug Administration (FDA) create a limited degree of accountability regarding the safety and efficacy of a product as a whole. Aisle cloth pads are registered by the FDA under the name Lunapads International. According to founders Suzanne Siemens and Madeleine Shaw, the FDA does not provide any standards regarding the quality of menstrual materials. They explain that although not having standards regarding the quality of materials is not a direct challenge for them, the company would welcome the introduction of some form of reporting standards to ensure that other brands are meeting minimum requirements regarding certification of use of safe ingredients and absorption reporting. **There is also no standardization or transparency in regards to claims around absorption and efficacy.** According to Aisle, *“this leads to a lot of heavy lifting for brands to educate (or misinform) the customer about their product's performance expectations. Disposable tampon and pad companies don't have to “self regulate” for performance claims as there are more standard guidelines they have to follow. Companies do not have to prove their claims with third-party test results“.*

All the consulted companies strive to legitimize their own products with test results and certifications and encourage partners in the field to aspire to this as well, whether this is made obligatory by legislation or not. This is especially important with new products arriving on the market and where illegal markets are widespread. **Recognized standards and minimum levels of product testing could be the first step to ensuring the MH products entering the market are fit for use.** Additionally, this would ensure that newer companies cannot make unsubstantiated claims about their products.

★ According to Adrian Dongus, implementing minimum standards and installing methods that would allow holding private sector stakeholders accountable for product quality is essential to address many menstrual product standards related concerns: *“the issue of varying levels of quality of products, an increase in manufacturers and resellers, and the lack of national and international standards is a genuine issue. Large organizations have the means to assess the quality of products they procure and hold them accountable to internal quality requirements. However, an increasing number of people receive support in the form of cash. Access to products that flood the local market cannot always be controlled and expose beneficiaries to the risk of buying products of low quality or which may even be potentially harmful. Holding private sector actors accountable for the quality of their products and setting minimum standards to curtail the rapid growth of low-quality products is crucial.”*

As long as there are products on the market that are not upheld to determined standards, the health of menstruators cannot be guaranteed. A lack of standardized product quality and the risk it poses for consumers is one of the biggest challenges for DivaCup, according to Alexis Biermann and Sophie Zuvku. They consider some of the claims of their competitors as dangerous and comprising the overall industry. *“When the DivaCup was first being created we decided as a company that product quality and consumer safety were going to be our top priority. If there was not a high bar already, we wanted to set it. We know our product surpasses quality standards; we work hard to ensure this is the case. While we put a lot of resources into guaranteeing our product is safe, competitors within the industry do not do the same. While they are adhering to regulations set in place by regulatory bodies, the standards of those are minimal at the very least. This lack of standardization within menstrual hygiene compromises the industry and the health of consumers.”*

Quality differences between countries and regions are problematic when striving for menstrual equity. Alexis and Sophie from DivaCup expressed their concerns about the inequality between developing and developed countries.

They stated that: *“an even more concerning challenge is that when it comes to menstrual equity and alleviating period poverty. Often the products donated or made available in the global south by Western manufacturers are not the same quality as those they sell in retail. We believe strongly that anyone who is receiving a product from our social impact program, DivaCares, should expect to have the same quality period care that we have available for sale and that this should be the standard thinking across the industry. Until there are standardized requirements for all companies, these challenges will continue at the detriment of the consumer.”*

To ensure product quality for all menstruators, menstrual product standards need to be developed and enforced across national and regional borders.

★ Tanya Dargan Mahajan, Puleng Letsi, Nancy Muller and Ina Jurga stressed the importance of educating consumers on what quality entails with shared terminology that they say should be abided by MH companies: *“As mentioned by manufacturers, quality can truly be ensured only when consumers demand the same. Hence, educating consumers on the definition of quality of MH products in terms of effectiveness for absorption or collection of menstrual blood, hygiene and material safety for human use and environmental impact. A related imperative is to ensure that the companies abide by these definitions and if they do not, ensure that they clearly communicate the same to consumers.”*



Materials

It is largely up to the individual company to determine the materials they use, making it difficult to ensure material choices are safe for users.

All the consulted companies indicated they faced at least one or multiple obstacles related to the standardization process of product quality in the industry. The differences experienced in the standardization process indicates that there is no uniform process or regulations to ensure product quality. One reason for the **different standards is that products are subject to different classifications worldwide.**

There is room for improvement when it comes to ensuring that materials are compliant with (inter)national standards and aligning these material standards. With regard to materials, it is up to the individual company to determine what they choose to use and how rigorously they test the materials in their product. There are different product characteristics available for users, but no industry standardization on what these mean (absorbency, wearing time).(43) This can make it challenging to communicate to consumers what the position of a product is in the market.

The consulted companies indicated they had established their own way to determine the safety of their materials. However, **standardization in the industry would help synchronize terminology used by different menstrual product companies.** Ensuring that materials are compliant with the International biocompatibility standard (ISO10993) (44) appears to be a globally acceptable way of determining if your material choice is safe for the user, according to Shaun Knights from Callaly.

Beyond this, there is much room for improvement in aligning standards at national and regional levels. As an example for areas that can be improved, he mentioned the standards for testing the absorbency of a product. *“In Europe, we follow the ‘EDANA Tampon code of practice’, for the US market, syngina requirements are defined in regulation ‘FDA 801.430’ and for Australia (another market we’re exploring) there is the ‘AS2869 standard’. There are probably others too, beyond the markets Callaly is currently focused on. Linked to this, the labeling requirements for absorbency also vary from region to region. More challenging still is the standardization around pads. There are different absorbances available on the shelves, but no industry standardization on what these mean.*

*This has become a challenge for us in terms of communicating to customers who want to know what our 'night pad compares to on the market?' for example. If there were a standard, we would not have to test, and more importantly, the consumer would not need to ask." A solution to this could be a form of reporting standards to some governing body to ensure that companies are meeting minimum requirements regarding certification of the use of safe ingredients, as well as absorption reporting. **There is also no standardization or transparency in regards to claims around absorption and efficacy which results in customers being unaware of which products are truly suitable to their distinct menstrual flow.** When a particular product proves ineffective in this regard, due to incorrect or claims it can have a knock-on effect in terms of undermining that product category or newer producers as a whole.*

★ Gerda Larsson & Anna Sjögren noted that the issue with the ISO10993 series of standards is that these are intended for medical devices. As in many countries menstrual products are not classified as medical devices, manufacturers tend to think that they do not need to test their product against this standard as it is considered to be expensive. They also note that in the current version of the ISO10993, animal testing is still a requirement and that the new, soon to be available version will have an alternative method.

Standardized materials can help ensure product quality when unskilled employees join the manufacturing process. Jaydeep Mandal from Aakar Innovations stated the company has developed trusted vendors working closely with their team to ensure standardized materials. He explained that standardized materials ensure their product quality when unskilled employees join the manufacturing process: *"we face product standardization issues as we engage unskilled village women in the production process and it takes 1-2 months for them to learn it and become skilled in the production process. As we have standardized materials, basic quality doesn't get affected by the process, but the outlook of pads sometimes are different until women workers become skilled in the process."*



Packaging

Companies are not obligated to declare the used materials/ingredients of the products on the packaging which can lead to incomplete or misleading information.

Claims about materials and environmental impact of products can be made without supporting data to prove this, and even when packaging has ingredients on it, it does not need to reflect the full ingredient list.

Elena Weidemann from Einhorn in Germany stated that when companies do not describe the content of products transparently, customers sometimes don't even know that they contain synthetic fibers. *"For example, tampons that are advertised as 'easy to insert' often contain synthetic non-wovens. Organic tampons which do not contain these fabrics may leave the customers disappointed because they are used to the feel of synthetic or semi-synthetic wrappers. Luckily a new EU legislation was implemented that clearly shows customers when single-use-products such as tampons and pads contain plastics."*

Aisle also confirmed that there are many bold, and unsubstantiated claims being made across the sector around the environmental impact of reusable products. *"This can make it challenging as a company who only wants to claim what we actually can support, to stay 'competitive'. This requires an immense amount of research and communication behind the scenes to validate vendor claims, certifications, and performance needs to create our own internal standards since there aren't comprehensive standards to point to for our specific industry."* In contrast to larger corporations, smaller producers are not always held to account for how they communicate or market their products.

In line with this, Alexis Biermann and Sophie Zuvku from Diva Cup state that just because a package has ingredients, this does not mean it is the full ingredient listing. They argue that without this disclosure, the quality of menstrual products becomes compromised and transparency is not upheld for the consumer. **The development of menstrual product standards that prescribe adding a full list of ingredients on the packaging is an essential criteria when aiming to guarantee consumer safety.**



Classifications

Varying product classifications result in products being subjected to different standards worldwide.

Menstrual products worldwide are subjected to different standards, partly due to how they are classified and which product group they fall under.

Shaun Knights from Callaly explained that because of different product classifications between the United States and Europe, quality system standards differ: *"Tampons are class II medical devices in the US and hence any designer and/or manufacturer is required, by law, to follow the 21 CFR part 820 regulation. In Europe, while the manufacturer does have to ensure the product is safe (as required by the EU product safety directive), tampons and menstrual pads are not medical devices, and to this end, there are no quality systems standards or regulations which are required to be followed."* For the standardization process to be aligned globally, the consulted companies indicated that menstrual products need to be considered the same type of item.



STANDARDS

Hyasintha Ntuyeko from Kasole secrets stated that **menstrual products are classified under medical devices to add extra costs to the end-user.** To avoid this, she suggests taking a look at other industries: *“I think putting menstrual products under medical devices is done to add extra cost to the end-user. We should all brainstorm and see what category exactly these menstrual products belong to. We can borrow examples from the category to which condoms belong and see how they have managed to lower costs for condoms and get some ideas on how to go about this regarding menstrual products.”*

There is a need for high-level support and acknowledgment that menstrual products are necessary and not luxury goods, and place them in an appropriate product category. Sophia Grinvalds from AFRIpads also addressed the need for different categorizations for menstrual products indicating they are considered essential goods and pleaded for high-level support for product accessibility: *“Acknowledge that MH is a priority and the MH products are a basic need, not a luxury item. Categorize them as essential goods and treat them as such, in terms of support, attention, and funding. As new and innovative MH products come onto the market, they are often met with skepticism and resistance. It’s important to have high-level support that product access and product choice are necessary. The era of the disposable pad monopoly as the sole option on the market needs to end!”*

★ Tanya Dargan Mahajan, Puleng Letsi, Nancy Muller, and Ina Jurga explain that limited resources can cause regulatory bodies to decide to create standards for other product categories but not for menstrual health products: *“In recent years, there has been a push by civil society for the creation of standards for reusable cloth pads and menstrual cups to support responsible market creation for these products. However, as mentioned by various manufacturers, in low-and-middle-income countries that are resource-constrained, regulators prioritize standards creation for product categories that have a relatively large market presence, making it more challenging to advocate for a relatively nascent product category like reusable menstrual products. Not having standards for reusable products can contribute to the perception that they are inferior and affect consumers’ attitudes toward these newer product categories.”*



Entering the MH Market

The lack of standards for menstrual products is especially complicated when entering the menstrual health field as a business.

When there are no existing standards for MH products, companies are left to advocate for the development of standards together either alone or with other actors in the MHH sector. Sophia Grinvalds from AFRIpads explained that when they started their business in Uganda in 2010, there were no existing standards on the African continent for reusable menstrual products and only some countries had standards for disposable sanitary pads. They were met with skepticism about consumer demand for them, which made it difficult to convince relevant government agencies and stakeholders to allocate time and resources to developing standards and certification requirements. *“At that time there was very little awareness of alternatives to disposable sanitary pads (i.e reusable pads, menstrual cups) and due to the highly prevalent taboos about menstruation, it was difficult to raise awareness and galvanize interest and support for developing standards for these unfamiliar types of menstrual products.”*

One of the consequences of the lack of product standardization is that MH companies have taken it upon themselves to guarantee product safety to their customers. Sophia states that with no product standards present in Uganda when AFRIpads started their business, they had to lobby the Uganda National Bureau of Standards (UNBS) and advocate within the small but growing MHM sector in Uganda for a standard to be developed. After years of lobbying, in 2017 a task force was convened by UNBS and the standard development process was started which eventually led to the approval by the Standards Management Committee in November 2017.



Existing local and global standards

The lack of standards for menstrual products is especially complicated when entering the menstrual health field as a business.

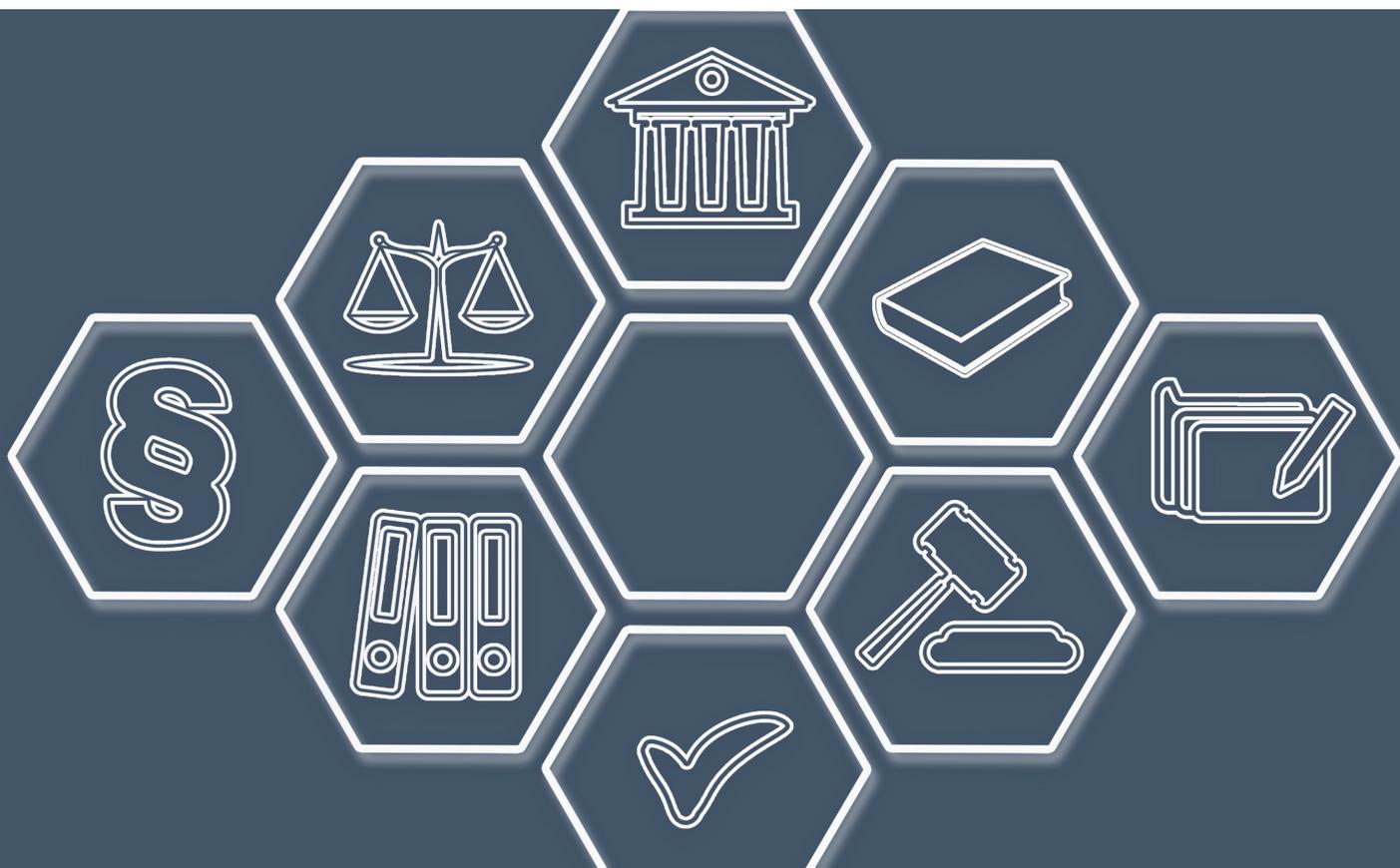
A starting point to improve the challenges faced in standardizing menstrual products would be to improve or broaden existing standardization. Alexis Biermann from DivaCares advocates for the creation of comprehensive, enforceable standards for period care products across the industry. This would ensure that everyone who is working with MH products is held to the same quality standards to protect consumers as much as possible. She states that bringing back the FDA standards or requiring other menstrual cup companies to adhere to the strict ISO 13485:2016 MDSAP medical device rules (46) would be a great starting point: *“For our customers, our ISO Certification ensures that the DivaCup is the best menstrual cup for their health because it is made within the highest of standards, with safety and inspection checks at every level of production. Many US companies do not require the same level of annual audit and proof that they adhere to medical device standards and we see this in the many stories from consumers who have been harmed by substandard materials or unlisted ingredients in their period care products. As a first step, because menstrual cups are classified as a medical device in many regions worldwide, provide guidelines for a quality management system (QMS).(47) A QMS system will ensure that the products are safe and effective.”* According to Shaun Knights from Callaly, organizations like EDANA could broaden the standardization and guidance in Europe, particularly around Quality Systems standardization, the standardization of menstrual pad absorbency, and the standardization of product labelling.

With regard to existing standards, Sophia Grinvalds from AFRIpads stated that standards bureaus often want data and evidence that demonstrates these products are wanted and accepted. She suggests that UN agencies, governments, or other regulatory bodies could provide support to build an evidence base that the sector can use and make the standards understandable for parties involved. *“This can be important at the point of getting a standards body to consider developing a standard, as well as during the actual development process once it is underway. UN agencies, governments and other partners can provide support (in various ways, including funding) to build the evidence base that the sector needs to demonstrate the gaps, needs and options in terms of MH products.”*

Finding out which certifications are required and complying to them can be difficult for smaller companies. For Hyasintha Ntuyeko of Kasole Secrets, the standardization process itself has no complications, especially for the disposable and reusable cloth pads. According to her, the biggest challenge they face as a smaller company is the number of certificates they have to pay for, making it difficult to lower the product prices: *“for example, you have to pay for the laboratory test, then you pay for the pharmacist to supervise your premise, then you have to pay for the TMDA Business License, then again pay for the municipal business license and if you are importing you have to pay for the import permit.”*

Several of the consulted companies stated that challenges around standardization of menstrual products could be solved with the development of global menstrual product standards. This would benefit, among other things, standards and regulation requirements. Shaun Knights from Callaly also stressed that as now many of the existing requirements have the same aim, it would make sense for standards to be globally aligned.

He makes a comparison with the MDSAP (Medical Device Single Audit Program) standard development.⁽⁴⁸⁾ The MDSAP is a way that medical device manufacturers can audit their products once for compliance with the standard and regulatory requirements of up to five different medical device markets: *“Secondly, and more difficult to achieve, is global standardisation. This is starting to happen in the medical device field, with the recently introduced MDSAP standard. This is where six organisations have come together to harmonize their requirements into a single standard. I would love to see a similar harmonisation for the FDA, EDANA and AS standards as an example.”*



Alexis Biermann from DivaCares states that there should be a development of globally recognized, universal standards for donated menstrual products to organizations in need to ensure people are receiving safe products: *“One of the core tenants to the menstrual equity movement is to ensure that all people with periods have access to the safe and effective products to be able to care for their cycles with dignity. That being said, without having uniform standards for companies in the period care industry we have seen examples of organizations being given products that are not only sub-standard, but also dangerous to the health and wellbeing of those who receive the donations.”* The majority of menstrual products are accessed by individuals through markets, and donations of free products account for a minor amount. However, **the development of globally recognized, universal standards for donated menstrual products to organizations is needed to ensure people are receiving safe products.** This would help build menstrual equity on a global scale.

According to Suzanne Siemens and Madeleine Shaw from Aisle, global standards should be created through the consultation of all participants within the supply and value chain and not solely the most dominant companies in the industry. They also note that it is important to question how regulation would affect raw materials supply in a global market: *“If disposable tampons are regulated to use only organic cotton and ingredients, how does this affect the global availability of these materials, who can access them and how is that resolved so everyone can succeed?”* **In order to prevent the negative side effect of an unequal division of raw materials, global standards would need to be accompanied with global agreements on material availability and usage.**

★ Tanya Dargan Mahajan, Puleng Letsi, Nancy Muller and Ina Jurga recognized the extensive efforts of MH businesses to advocate for the development of product standards and even develop their own, but emphasized that without a set of minimum global standards, multiple parties involved cannot make a fully informed decision: *“without a set of common global standards, consumers, producers, and those procuring products worldwide still will not be able to make informed choices based on an established set of minimum criteria. Having these minimum criteria would help ensure that if global tenders were issued for menstrual products, informed decisions could be made considering a set of validated performance, quality, and safety standards and not on the basis of price as the primary driver. Some UN agencies and other global partners, with input from a wide range of stakeholders, are beginning to take up this call for standards. They are engaging in developing global product specifications, beginning with disposable products.”*



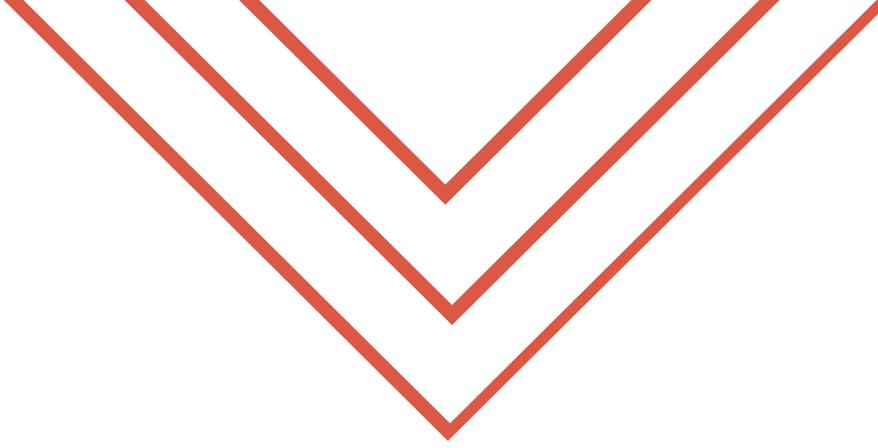
Innovation

Existing menstrual product standards can be a barrier to innovation, and it is important to consider and facilitate innovation when developing menstrual standards.

Innovation is crucial in the MH sector, and menstrual standards need to be set up in a way that guarantees the safety of users but does not discourage or make it impossible for new companies to enter the market and develop new products. Sophia Grinvalds from AFRIpads explained that innovation does not refer only to the emergence of new products, but also to the evolution of existing product categories. Supporting innovation means acknowledging that, in order for products to be improved and for new products to emerge, change needs to be facilitated. In line with this, she concludes that standards need to be reviewed and updated as necessary: *“Most standards bodies require standards to be reviewed after a fixed period of time (ex. 10-years) but innovation is moving at a faster pace in the MH sector and this may require standards to be reviewed more frequently, which demands understanding, support, and resources. When product innovations evolve/advance faster than the standards review process, we need to have ways of adapting so that effective innovations are not blocked.”*

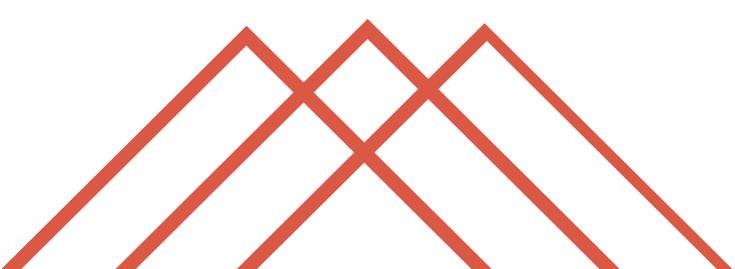
Furthermore, she states that although standards are important and should be advocated for, it is equally important and necessary for standards or regulatory requirements to be able to be bypassed at times in regards to the development and trial of product innovations: *“[Often] these innovations cannot be tested against existing standards because they are a new innovation and do not conform. [Consequently,] flexibility is required [or we will] simply block and stifle innovation because of regulatory requirements. In these cases, a new standard will emerge as a result of a successfully proven product innovation. Governments need to have flexibility here, and UN agencies and other partners should be willing to engage in the pilot/testing process to build the new evidence and knowledge base for these innovations.”*

Hence, standards need to be developed in a way that ensures effective innovations are not blocked, as product innovations can evolve faster than the standards review process. This could mean that when new innovations cannot be tested against existing standards, flexibility is required from the concerned authorities to engage in the pilot/testing process to build the new evidence and knowledge base for these innovations.



Suzanne Siemens and Madeleine Shaw from Aisle state that in addition to creating more cohesion between policy and scientists to ensure that people understand what these regulations mean in relation to products to not incite fear over claims or standards, policy development and societal transitions should be supported when appropriate:

“Create a more detailed approach to sustainability, including reviewing the efficacy to disposable products in our environment. Create chemical and material management policies transparent for both disposables and reusables, to ensure that people know more about the products they are using. Since disposables are already the status quo, it takes a lot of information for people to transition to reusables. If regulations are created, they need to be both for disposables AND reusables, not just reusables.”



★ Tanya Dargan Mahajan, Puleng Letsi, Nancy Muller, and Ina Jurga commented on the state of existing menstrual product standards and addressed that while the process of developing standards is a careful multistakeholder endeavor, the number and nature of the criteria prescribed in the standard can put a restraint on smaller manufacturers: *“Appropriateness of existing standards for menstrual products (mainly disposable pads) has been limited by the lack of data and evidence on health impact. On the other hand, including extremely stringent quality control protocols can make products more expensive and limit availability by adding the cost of testing. This becomes more important as small and medium scale manufacturers may be unable to sustain these additional costs. Regulators have to take this factor into account so as not to penalize consumers who are seeking more affordable products and small manufacturers who are ensuring that access. Ensuring that only necessary standardization parameters are included thus becomes imperative.”*



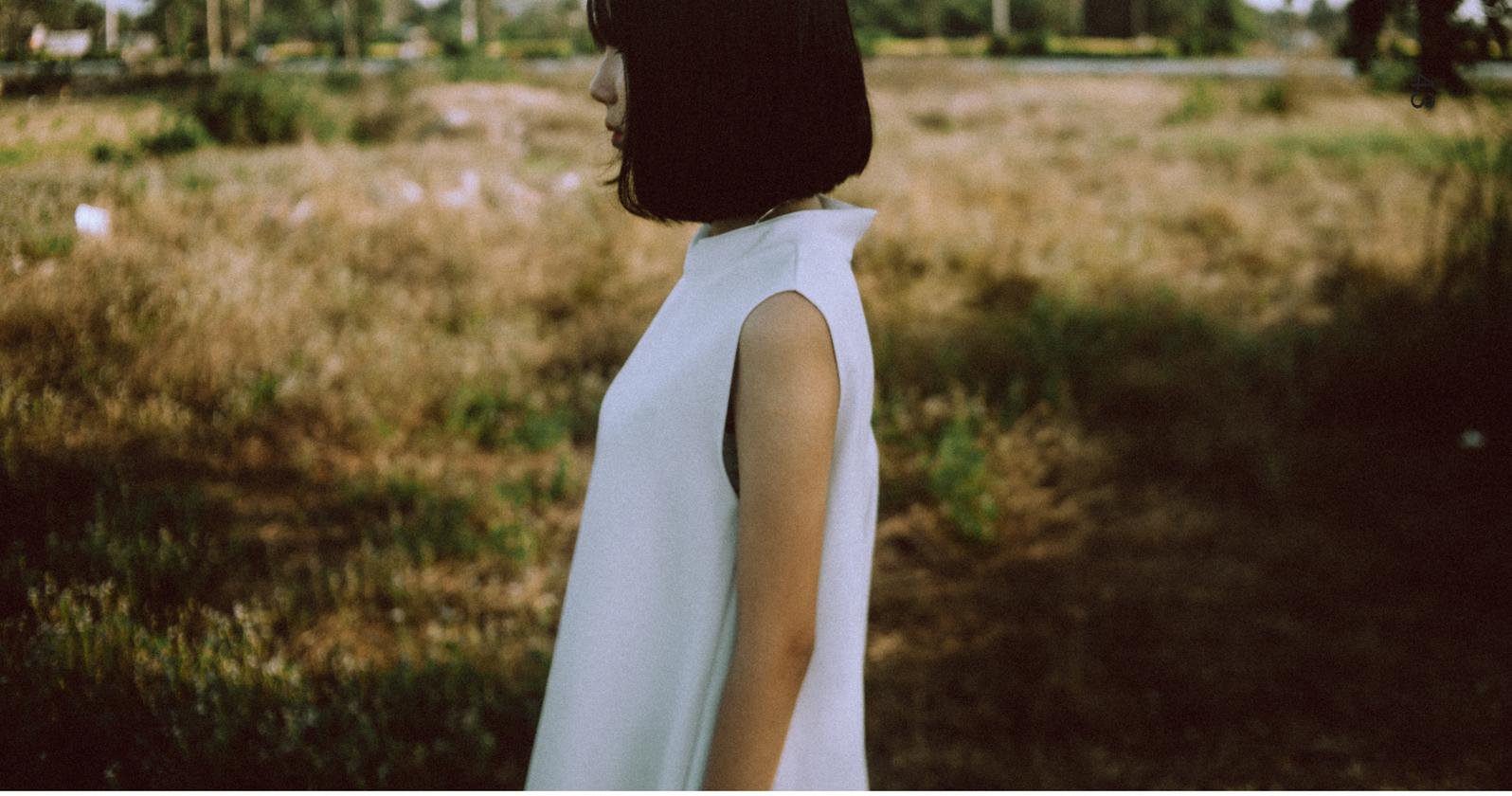
Responsibility and collaborative efforts

Companies strive to actively take responsibility to resolve the experienced challenges regarding the standardization process themselves and urge the whole industry to take on an assertive approach to ensure safe products for all menstruators worldwide

All of the consulted companies recognized that each individual MH company is responsible for the product they produce. Shaun Knights for Callaly explained that **the level of responsibility is dependent on the market one is selling in, and that in the end, it is up to the manufacturer to make sure menstrual products follow the product requirements:** *“In Europe, the base level responsibility is to adhere to the EDANA requirements and be able to prove your product is safe – although this last point is up to the manufacturer to determine what ‘safe’ actually is. My personal view is that companies also need to have a robust quality assurance system in place, but as mentioned this is not necessarily a requirement. Ultimately, it is down to the manufacturer to understand the requirements of the market they are looking to sell into and then ensure its products and practices are compliant with this.”*

Besides following national and international product standards, several companies stressed that to ensure consumer safety, they strive to move beyond the required menstrual product standards. For Einhorn, this includes not only the offset of CO2 emissions and the amount of plastic potentially used or produced during the production process but also using high-quality organic materials, fair trade principles, a transparent supply chain, and the support of local farmers. In addition, *“we stand up for a more ethical and sustainable economy and society in general and convince our partners to do the same”*, according to Elena Weidemann.

Alexis Biermann from DivaCares also stated that they go beyond national standards to consider the health and wellbeing of customers: *“As a brand, we do not settle for the status quo – in fact, we challenge it. People can speak out about what they need and what they deserve when it comes to the products they use. We ask that all companies take ownership and responsibility for the work they are doing. Move beyond average quality standards, and continually improve. Engage in research whenever feasible to ensure you are at the forefront of what’s changing, what people need, and how you can help to propel the menstrual equity movement forward.”*



Sophia Grinvalds from AFRIpads specified the additional actions that organizations distributing MH products can take to secure their product safety: *“Organizations distributing MH products as well as governments that are engaging in the distribution of MH products should emphasize and prioritize the supply of products that have been tested and certified, whenever possible. Ideally, this is a formalized procedure within the organization’s procurement process. In lieu of a national standard in the organization’s country of operation, indicated above there are options for the purchasing organization to submit products to third-party/private laboratories for testing against some of the existing standards that exist, as one way of evaluating the product. Additionally, the organization can consider running a pilot/test group to first try the product to evaluate its acceptability and appropriateness. Ideally, an inadequate product would be identified in this process, and the organization would then seek out alternatives before the project/outreach is done at scale.”*

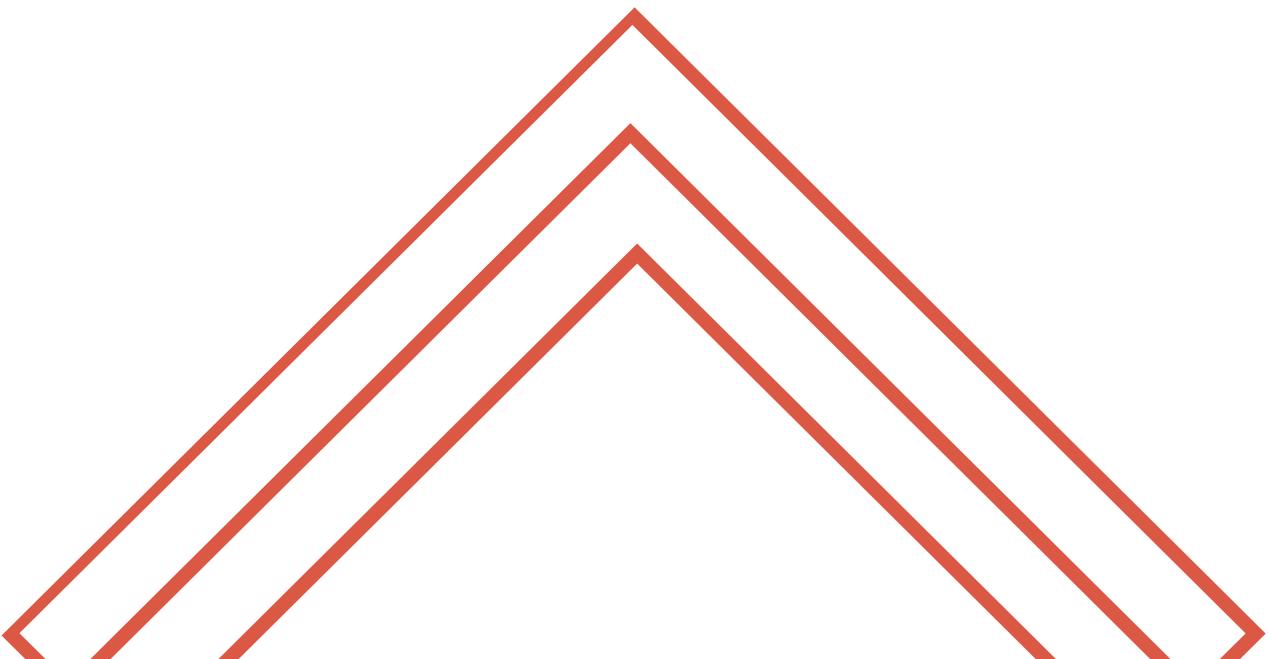
★ With regard to the role of different regulatory bodies, governments, and other stakeholders involved, Adrian Dongus suggested that it could be useful to map their responses and key areas of responsibilities in a matrix: *“Especially for large development actors, donors and multilateral institutions, there are important questions to raise on market-shaping, removing barriers to markets for innovators and development of common advocacy agenda's that should include the development of standards. Here, splitting the different stakeholders and understanding who should be involved, who should advocate for these points, and which actors are on the receiving end of this advocacy is important information to capture. This may also help the participants to formulate what their expectations are of the different actors. The role of a humanitarian agency is a very different one from that of a world bank or a foreign donor.”*

All the companies interviewed have taken on a proactive approach to finding out how standards were regulated in their region and field of activity, and based on that, each had their own strategy to ensure the safety of their products. **There is a strong sense of responsibility, and the consulted companies find it important that the whole industry takes on this approach and hope that this devotion to ensuring safety is embraced by the industry as a whole.** Several ways to accomplish this were suggested.

According to Suzanne Siemens and Madeleine Shaw from Aisle, MH companies should participate in working groups to establish 'best practices' for the sector and learn more. They state this could include engaging with external parties in order to get unbiased opinions on issues the sector faces and how to navigate them, encouraging other sectors to do the same, and educating consumers on how to decipher what is true and what is greenwashing.

They also suggest participating in policy change and encouraging local representatives or organizations to prioritize Femtech and the MH sector. Lastly, they stress the importance of sharing perspectives: *“advance the importance of social and racial justice and ensure that our systems, standards, priorities, and action are done with equity in mind. Looking at menstrual health from a white or western or privileged perspective will not bring about the important systemic changes necessary to advance an anti-racist and more equitable future. We should strive to do this in collaboration with each other or share best practices as there is a lot of knowledge to share and learning to be done.”*

Hyasintha Ntuyeko from Kasole Secrets shares this view and states: *“it's time to have one voice as key players tabling our agenda and commit to adhering to the standards and other key issues that affect us all regardless of the brands we are passionate to promote.”*



CONCLUSION

This report summarized the key findings identified per high-level topic, including shared experiences, concerns, recommendations, and calls to action. The diverse range of perspectives is to be taken into consideration by, and inspire both stakeholders in MH and regulatory bodies on how to best cater to, and facilitate social businesses engaged with menstrual product standards. These actors are not only profit-driven but pursuing social outcomes through activism and advocacy acting as a powerful ally in the broader menstrual movement.

This consultation demonstrates that there are many perspectives, challenges, and modalities being used to both discuss and regulate MH companies. As indicated, an in-depth examination of each of the distinguished key topics to determine what concrete actions should be taken regarding menstrual product standards in that context is strongly recommended as a concrete next step.

This report only scratches the surface of what is possible when social businesses advocate for regulations and safety across the industry.

We believe that moving forward the discourse on menstrual health requires concerted efforts to improve product education, transparency, and safety across the industry. Product standards and regulatory bodies play a pivotal role here, as they can help improve and mature the MH market, while stimulating consumer demand. The absence of a system or frameworks which test, regulate and respond to product safety puts all users at greater risk.

Uniform industry standards concerning product characteristics could position new products, strengthen the market and truly ensure informed choice for all menstruators. Because everyone deserves to find the right and safe product to best suit their menstrual needs.



This report demonstrates there is a strong interest and acknowledgement by social businesses that menstrual products are necessities and not luxury goods.

Consequently in a rapidly developing and innovative market identifying an appropriate product category and systems to regulate the industry as a whole is key to consumer safety and individual wellbeing. The proactiveness of the consulted MH companies who are self-regulating or driving country-level regulations goes to show that the private sector has an important role to play in changing the conversation.

As readers will note, several concerns raised around menstrual product standards are pressing and it is evident that they should be a priority for those invested in understanding and strengthening the supply and distribution of menstrual products moving forward.

While historically global corporations providing MH products have been predominantly dominated by male actors and female consumers, the growth of femtech companies and MH enterprises demonstrates a shift toward women innovating for, and with women. We believe that this trend heralds a new era for MH markets with them a means of empowering women across the supply chain as founders, workers and users of essential products.

What this report, and those of Development Solutions, Reproductive Health Supplies Chain Coalition, Mann Global Health, Nuru Capital, Next Health Accelerator and UNICEF/ UNFPA demonstrate is that MH markets require a more concerted conversation around the safety, efficacy and accessibility of the supply and demand of MH products.

Complacency and a lack of transparency will no longer be the norm in this sector. Standards are vital to the intimate health of women, girls and those who menstruate. The Technical Committee within the ISO (approved January 2022) set out to examine and chart new paths towards the standardization of menstrual products is a long awaited and much needed victory in this space.

Ensuring that menstruators have access to affordable, accessible and appropriate solutions which meet their MH needs demands a more advanced understanding of the supply and demand of menstrual products. The systematic lack of regulatory requirements or standards to guarantee the safety of menstruators everywhere is alarming, and the wish from MH companies, stakeholders and more and more users themselves to improve as a sector in order to promote the health and well-being of menstruators and the environment is evident.

We want to sincerely thank Aakar Innovations, Aisle, AFRIpads, Callaly, DivaCares / DivaCup, Einhorn, Kasole Secrets Company / Glory Sanitary napkins for sharing their precious expertise, experiences and recommendations with us.

Our gratitude also goes out to experts from the Reproductive Health Supply Coalition, The Case For Her, the Swedish Institute for Standards, and UNHCR-UNFPA for their valuable feedback and contributive perspectives on the findings presented.

ANNEX 1

Annex I Menstrual Health social entrepreneurs consulted



Jaydeep Mandal, Founder of Aakar Innovations

Aakar Innovations is on a mission to enable and empower women to produce and distribute affordable and fully compostable sanitary napkins in areas where these products would otherwise not be available. In 2013, the company launched India's first certified fully compostable sanitary napkin named 'Anandi', manufactured in a woman-supervised and woman-employed mini-factories.



Sophia Grinvalds, Co-founder and Director of AFRIpads

Committed to helping women and girls overcome the barriers that menstruation creates in their lives so they can rise to their full potential, AFRIpads has become the world's leading social enterprise manufacturing reusable sanitary pads. Recognizing that in order to drive change, menstrual products are not enough, the company works with humanitarian and development partners to provide holistic menstrual health management (MHM) solution which combines product, education, and evidence.



Suzanne Siemens & Madeleine Shaw, Co-founders of Period Aisle

Aisle, formerly known as Lunapads, has been a proud advocate of menstrual care, equity, inclusivity, sustainability, and positivity for all since they launched the first line of modern, reusable period products over 25 years ago. Among other things, they have mentored and assisted the start-up of several prominent menstrual health organizations by providing product development advice, patterns, and financial support.



Callaly®

Shaun Knights, Head of Quality & Continuous Improvement at [Callaly](#)

In a quest to reinvent period products so that they're better for our body and the rest of the world, Callaly has developed a completely new period product called the tampliner that combines an organic cotton tampon with a soft mini-liner for extra protection against leaks. Recognizing that everyone has different needs, they have expanded their product selection to include tampons, pads, and liners, all made with organic cotton and in customizable absorbencies.



Elena Weidemann, Content & Social Impact Manager at [Einhorn](#)

After their condom revolution, Einhorn's next chapter is marked by a period revolution, combining design with Fairstainability (fair & sustainable). The Berlin-based movement, community, and start-up aims to kick-start a mutual dialogue between society, culture, politics, and the economy to question today's business norms and values.



Hyasintha Ntuyeko, CEO & founder of [Kasole Secrets Company](#) and [Glory Sanitary napkins](#)

After realizing that providing quality menstrual products was not enough to improve menstrual health, Glory Sanitary Napkin has been delivering broad-based innovative MH&H solutions to African girls, women, and key influencers. Among other things, the company leads a Corporate Social Responsibility program to consult local and international NGOs on menstrual programs and runs MH&H campaigns on a national level to raise awareness among communities.



DIVACARES™
DIVA INTERNATIONAL INC.

Alexis Biermann, former [DivaCares](#) Manager & Positivity Officer & Sophie Zuvku, Communication Manager of [DivaCup](#)

Revolutionizing the period game for over 15 years now, Diva International Inc. (Diva) has been challenging the period status quo with the reusable DivaCup. With their social impact and responsibility program, DivaCares, they are committed to advancing the menstrual equity movement through key pillars of Education, Advocacy, and Access and continue to invest in improving people's period experiences around the world in various ways, all with the aim to create a world where menstruation is a fact of life, not life-limiting.

ENDNOTES

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