WOMENA SUMMARY AND APPROACH[1]

WoMena sometimes gets the question: Are menstrual cups (MCs) 'regulated' by governments? This is an important question for Government Departments, donors, NGOs and others when planning MC interventions to ensure safety and efficacy of the products. The question sometimes extends beyond MCs to other menstrual health management (MHM) products - washable and disposable pads, tampons etc.

This FAQ tries to address this question in a preliminary manner, with the main focus being MCs, but with other MHM products also mentioned for comparison. This is a complex area, and we do not claim to know the entire truth - simply that we exercise due diligence in trying to find out.

Around the world, there are no globally agreed regulatory framework for approval of MHM products in general, and MCs specifically. The classification, standards, and procedures vary by country. It complicates matters that, according to one source, there are 199 brands of MCs, marketed in 99 countries. For example, in Europe, MCs are generally categorised as "hygiene products", and expected to comply with general product safety directives for any given country, but with no requirement for further testing or regulation. In the US, in order for the Food and Drug Administration (FDA) to "clear" MCs for sale, manufacturers may need to submit a "premarket notification", but do not need to go through a more extensive process called "premarket approval", requiring clinical trials and testing. In fact, we are not aware of any country which requires 'approval', which is a term reserved for high risk products (not MHM products).

In Uganda, there is no specific set of standards for the MC. Instead, every batch of imported MCs is cleared by the Uganda National Bureau of Standards (UNBS) according to general standards. That is, at the moment there is no requirement or justification for MCs to be registered or 'approved' by the NDA, The NDA has suggested it can be handled by the UNBS, and UNBS is presently considering its follow up.

WoMena's approach: WoMena is committed to introducing products which are safe, effective, affordable and acceptable. For example, in 2016, with WoMena's advocacy, based on Uganda Revenue Authority, MCs now fall under classification 9018.90.00/CPC 478 which means only withholding tax (6%) is payable if the importer is not exempted from that. This applies to other MHM products such as menstrual pads as well, making them more *affordable*.

WoMena has examined the *safety* of both MCs and other products in terms of infections and harmful chemicals. WoMena is working with partners internationally to include MCs in their lists of products available, as well as further clarify quality standards. WoMena advocates for improved transparency on what components used in producing MCs, and what tests have been conducted. We would be delighted to contribute to a dialogue with Ugandan authorities, providing information which might be helpful for their decision on classifying MCs as medical devices. This could bring both advantages and disadvantages.

To find out the classification status of MCs in other countries, you can go to the national regulatory body (bureau of standards or medicines regulatory authority - National Medicines Regulatory Authorities (NMRA)). Search for the product or for the 'consumer product manager' or 'regulatory affairs manager'.

This is the best evidence we could find. Comments are warmly welcome!
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[1] This FAQ was researched and written by Siri Tellier, Hanna Hidenbrand, and Andisheh Jahangir. Comments by Janie Hampton, World Menstrual Network, Alfred Muli, Ruby Cup-East Africa, Zachary Gavry, and Tanya Mahajan, Development Solutions, are gratefully acknowledged.
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What is the problem?

All countries in the world face the challenge of consumer protection.

For MHM products, one concern is that they are all in close contact to the skin, and are sometimes worn internally. They may expose the body to any harmful chemicals which the products may contain, including any causing allergies. Another concern is that, if any of the products are not appropriately cleaned, they might cause reproductive tract infections.

At this point, there is little evidence to indicate dramatic risk from any one type of product or brand[2]. The only historical exception is that of one brand of tampon, which was determined to pose a risk for toxic shock syndrome, resulting in thousands of cases and a series of deaths. It was removed from the market in 1980 (Vostral, 2011). Other potential risks are periodically identified, but need further study. For example, whether bleach or the chemical glyphosate (a weed killer used to treat cotton) is present in dangerous levels in cotton pads or tampons; whether other chemicals are at dangerous levels in some brands of MCs; whether long drying times for some products may increase the risk of yeast infection; how long products should be worn. The importance of how products are handled is also becoming apparent - whether girls reuse disposable pads, their washing habits, how users insert and remove MCs. Of course, a major part of the market may still be under the radar for regulation and surveillance - homemade or cottage industry products, or (without comparison) counterfeit products sold on the market. Finally, regulation makes no sense unless surveillance is realistic (WoMena, 2019a & 2019b).

Africa is no exception - it is also faced with the issue of consumer protection, and many initiatives have been taken to regulate. In 2005, the World Health Organisation reported that only 7% of the 46 sub-Saharan African countries had National Medical Regulatory Authorities (NMRA) in place. Of the remaining countries, 63% had minimal regulation and 30% had no regulation (WHO AFRO, 2009). A number of international organisations including the African Organisation for Standardization (ARSO), the African Network for Drugs and Diagnostic Innovation (ANDI), African Union (AU) and the United Nations Economic Commission for Africa (UNECA) have been established or tasked to promote harmonisation of procedures and standards within the African continent (Lamph, 2012). The AU has set forth a treaty for the establishment of a Regulatory Authority which will be the "African Medicines Agency" (AMA). [3] Until then, 'regulatory approval' is defined by the NMRA's for MHM products. Countries with stronger NMRAs and success bringing products to market will likely be a strong foundation of the AMAs regulations in the future.

This should of course be balanced against the cost of regulation: For example, the FDA in the US notes that it is selective in identifying products which should be assessed, as resources might be better used on other issues with greater public health impact.

What are the different types of categorisation and approval?

This is a highly complex area, further complicated by the commercial interests at play, and the multitude of brands available. We will try here to analyse in a very simple, hopefully practical (and accurate) way. We focus on safety/quality assurance: what procedures are in place to check whether MHM products contain substances that might be harmful to health, or whether there are other reasons their use might be harmful (e.g. infections, allergies, bruising).[4]

[2] For further information see WoMena's reviews of whether menstrual products cause infections, toxic shock syndrome, or whether they contain harmful chemical substances: http://womena.dk/faqs/, as well as an even more recent article by van Eijk et al, 2019.
[3] Treaty for the establishment of the African Medicines Agency. February 2019. https://au.int/en/treaties/treaty-establishment-african-medicines-agency
[4] At times the term 'approval' (somewhat confusingly) is used to refer to whether a given company has gone through the correct import procedures for a given product, for a given year, paying taxation and import duties.

Different countries use somewhat different regulation regimes and categories. Since there is no universal standard, we will first briefly describe the example of the USA Federal Drug Authority standard, which is widely used as a reference.

The FDA classifies three levels of medical devices[5], based on the level of control perceived to be necessary:

- Class I: products which are perceived to pose a low risk, and are determined not to need to undergo standardised approval processes. They should conform to general consumer product standards.
- Class II: products which require *clearance* or *registration* with a national authority (the FDA) with a submission 510k, before they go to market. They are exempted from *pre-market testing*, but invite *post-market* reporting of adverse events, by consumers, medical professionals etc. If the product is as safe and effective as an already legally marketed device, an exemption from the general 510k can be made[6].
- Class III: products which are required to undergo *pre-market* tests and *approval* before being cleared for sale on the market. Thus, only Class III are required to be *'approved'.*

Other countries frequently use similar categories and requirements, although terminology varies. For example,

- 'consumer products' or 'hygiene products' often may be similar to Class I products (needing no clearance, only conformity to general consumer product standards). The standards for consumer products, however, may vary by country or geographic area.
- The term 'medical devices' is often used only for Class II (need for clearance, but not pre-market testing) or
- Class III, needing testing and approval premarket, before the product is allowed on the market.

How are menstrual products, including MCs, classified around the world?

In the following we give a few examples of classification, starting with Uganda. This is not a legal document, merely an indicative list of similarities and differences among countries, which we hope may contribute to further discussion.

In Uganda, there is no specific set of standards for MCs. Instead, all imported products, including MCs, undergo general pre-shipment inspection and are subject to examination at destination by the Uganda National Bureau of Standards (UNBS), according to general consumer standards (UNBS, 2018). All importers trading with Uganda need to comply with the requirements of the UNBS, including a certificate of confirmation for their goods to be cleared from customs (UNBS, 2016).

The National Drug Authority (NDA), which handles medical devices, suggested in December 2018 that MHM products including MCs should be handled by the UNBS, and that UNBS should develop standards. The UNBS has begun this process. This means there is no immediate requirement or justification for MCs to be registered or approved by the National Drug Authority. Although there are no standards, the manufacturers with which WoMena work voluntarily comply with additional international quality standards, e.g. from ISO. That is, **MCs are cleared for marketing and use at entry to Uganda.**

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[5] Medical devices as defined by the FDA refer to products which have an intended medical use. They range from simple tongue depressors and bedpans to complex programmable pacemakers. A medical device does '*not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.'*
https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device

[6] 510(k) Premarket Notification: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm

Further indicating that MCs are seen as mainstream MHM products, in 2017 the Government of Uganda removed VAT from the import of menstrual cups, leaving only payment of 6% withholding tax of total cost and insurance if shipped by air. The Government of Uganda deemed that MCs fall under classification 9018.90.00/CPC 478, and HS tariff code 4001.01.00 (WoMena, 2016).This applies to other MHM products such as menstrual pads as well (Parliament Watch, 2017).This followed submission by Womena and its private sector partner EcOptions to the Ministry of Finance and Uganda Revenue Authority of documentation on safety and acceptability (WoMena, 2016)[7].

Uganda is working towards harmonisation of regulations of medical devices and the classification of medical products (Lissel et al., 2016). If categorisation as a medical device is decided, then the National NDA and the UNBS will act as regulatory bodies.

In **Kenya,** the MC is included in the category of 'medical device' and apparently falls into Class IIb (medium risk) (MoMS, 2011) and need to meet post-market requirements that consist of distribution record-keeping, records of complaints, adverse event reporting (WHO AFRO, 2015). While MHM products are classified as 'hygiene products'. Both medical device products (e.g. MCs) and hygiene products (e.g. pads, tampons) are registered with the Pharmacy and Poisons Board (PPB). Kenya has a zero tax rate on hygiene products but not on medical devices (e.g. MCs)[8]. Companies are first required to register their medical device products with Kenya Revenue Authority and then register the product including shipper and manufacturer's details on the PPB website. Once the application has gone through, an invoice, payable to PPB will be received. After that, the license will be received, allowing them to import their products (e.g. MCs) into Kenya and distribute them in the country – the license is valid for one calendar year (MoH & PPB, 2017).

Indeed, in 2019, the African Union resolved to establish an African Medicines Agency, to improve and harmonise regulations for drugs and medical devices, particularly to prevent counterfeit products. This would presumably include MHM products.

In the **United States,** MCs are classified as Class IIb (special controls) medical devices. That is, manufacturers of MCs are required to submit a 510(k) *pre-market notification*, and then that brand of MC is cleared for sale after the process is completed (FDA Modernisation Act of 1997 and the 21st Century Cures Act of 2016, Kwak et al., 2019; US FDA, 2019, US FDA 2020a). It is thereby exempted from undertaking the tests and clinical trials which would be required for "*premarket approval"* if the MC were classified as a Class III product. MCs are not exempt from other general controls. MCs sold in the US are required to meet FDA standards which include being made from all medical grade[9] materials such as medical silicone, be manufactured under a quality assurance programme, be suitable for the intended use, be adequately packaged and properly labelled, and have establishment registration and device listing forms on file with the FDA (Sugathan, 2018, USA FDA, 2020a & 2020b). A large number of MCs are already registered with US FDA[10], and as long as a manufacturer can establish that it is similar in form and function to another brand, it is exempt from the full registration process. Some other MHM products (e.g. tampons and pads) are subject to the same clearance procedures as MC (US FDA, 2005).

In **Europe**, MCs are categorised as hygiene products and should comply with the general product safety directives. Any marking like Conformité Européenne (CE) marking[11] on the product is voluntary. Compared to the US, the EU currently

[7] WoMena's partners: https://womena.dk/partnerships/
[8] Countries with VAT zero-rated MHM products: https://en.wikipedia.org/wiki/Tampon_tax
[9] 'Medical grade' means that the product has been tested and found to be bio-compatible, that is, suitable for long-term insertion in the body.
[10] Establishment Registration & Device Listing
[11] CE marking is a certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area. https://ec.europa.eu/growth/single-market/ce-marking_en

has no regulations on quality assurance of MCs. MC companies themselves choose to undertake tests on their material and MCs, as consumers request for quality is high. MC companies often choose to adhere to the Restriction of Hazardous Substances Directive[12] regulations, adopted by the European Union in 2003 and the LFGB-food-contact-grade-testing standards[13]. This LFGB test is for controlling products that come in contact with food, human skin, mucous membranes or endanger human health. These tests are often done by SGS[14]; they also test for volatile organic matter. A common test is also the Consumer Product Safety Improvement Act (CPSIA), which tests for lead and phthalate.

In **Australia,** the Therapeutic Goods Administration of Australia notes that: '*prior to 1 July 2018, MCs were required to be listed on the ARTG. As a result of recent regulatory amendments, these products became exempt goods and therefore you are no longer required to have an ARTG entry for these products. MCs are required to comply with Therapeutic Goods Order No.99 - Standards for Menstrual Cups 2018 before they can be supplied in Australia. If you have a problem with a MC, please tell us about it at: Report a medical device adverse event (medical device user)' (Australia TGA, 2018).* That is, the assessed level of risk has been downgraded.

In the **Republic of Korea,** MHM products in general are classified as quasi-drugs, (Kwak et al., 2019). MHM products first must be evaluated for safety and efficacy before being issued approval and granted market authorisation (KHIDI, 2018; Fryer, 2019). The first MC was cleared for sale in 2017 (Chu, 2017). This was reported to be preceded by a number of 'sanitary pad scares' based on public claims that certain menstrual pads contained radon, various volatile organic compounds, or that they altered menstrual cycle patterns (Kyoung-Son,2018), in one case resulting in a manufacturer undertaking a lawsuit against the women's advocacy organisation which had made the statement (Eun-byel, 2017; Kyoung-Son,2018).

It should be mentioned that MC manufacturers and companies can also indicate the safety of their product by complying with the ISO 10993 set involving a series of international quality standards for evaluating biocompatibility of medical devices to manage biological risks which are voluntary standards for MCs companies to be compatible with[15].

van Eijk et al., (2019) estimate that 199 brands of MCs are sold in 99 countries, but we found no estimate of how many of those brands have been 'cleared' or 'registered'. There seems to be no country where MCs are deemed to be 'high risk' and therefore require 'approval'. Some have registered or cleared as medical devices, but also many classify as consumer goods. We know of no country in the world where sale of MCs in general has been disallowed.

How does one find the classification status in a given country?

To find out the classification status of MCs or other MHM products in any given country, you can go to the national regulatory body (bureau of standards or medicines regulatory authority - NMRA). Search for the product or for the 'consumer product manager' or 'regulatory affairs manager.'

[12] Restriction of Hazardous Substances Directive restricts the use of ten substances, including Lead, Mercury, Cadmium, Hexavalent chromium, Polybrominated biphenyls, Polybrominated diphenyl ether, Bis(2-ethylhexyl) phthalate, Butyl benzyl phthalate, Dibutyl phthalate, and Diisobutyl phthalate. https://en.wikipedia.org/wiki/Restriction_of_Hazardous_Substances_Directive
[13] LFGB Food Contact Grade Testing: Even Though, it is a food-contact-materials testing, it also provides testing for all materials including menstrual products. https://www.tuv.com/world/en/lfgb-food-contact-grade-testing.html
[14] SGS is a multinational company headquartered in Geneva, Switzerland which provides inspection, verification, testing and certification services. https://www.sgs.com/
[15] ISO 10993: https://en.wikipedia.org/wiki/ISO_10993

WoMena's approach: WoMena is committed to introducing MHM products which are safe, effective, affordable, and acceptable. As mentioned above this includes advocacy work (2016 tax removal). We would be pleased to support UNBS further in the development of standards, particularly on the issues where we have most experience, namely education to ensure safe and effective use. We will also advocate for (1) manufacturers to include labelling of the packages, (2) these standards, no matter how the MCs will be classified in future. This is both to safeguard the health of women and girls, to reduce the cumbersome and somewhat unclear procedures presently in place, as well as to help form the tools for control of counterfeit or other sub-standard products.

Transparency: Many advocacy groups, including WoMena, have advocated for clear labelling providing information on the components of products and results of any tests conducted by the manufacturer. The possibility of including this in consumer product standards should be explored.

Clarity on status: As noted, it is time consuming to find the classification of any particular product. The ongoing processes for clarifying and harmonising classification of products globally in particular Africa should be supported. It would seem positive if each national authority would not need to test e.g. the chemical components in pads, MCs etc. Classification as a medical device rather than a consumer product may be helpful, but would probably also entail higher cost. It could be examined whether global standards (e.g. ISO) may help. The type of approval determines future supply chain and management efforts to best reach the intended population. If seeking approval, waiting time is often a hassle. Medical devices will likely take longer to approve than a MHM product. It may entail more cost for both consumers (e.g. if this classification will lead to a need for a doctor's prescription), governments (both establishment of standards and surveillance), and manufacturers (if processes are cumbersome and time consuming).

Many African countries import most or all MHM products. However, a country such as Uganda is at times reported to be the most entrepreneurial in the world, and it can be expected that local production will develop. In this case, import control will be insufficient.

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