

## Reproductive health supplies: a question of availability, quality and affordability. Be-cause health Seminar on access to quality medicines and supplies for sexual reproductive health and rights – SRHR, Wednesday 8<sup>th</sup> Nov., Brussels

Insights and recommendations based on notes from the Seminar and presentations. *Presentations and recording of the session are available in a dedicated space on the Be-cause health webpage (<https://www.be-causehealth.be/nl/bch-events/reproductive-health-supplies-a-question-of-availability-and-affordability/>)*

### Insights

Achieving Universal Health Coverage includes providing **access to quality reproductive health supplies to all** those in need, and it implies financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

### Quality of Reproductive health supplies

- ✓ The globalization of pharmaceutical production has not been accompanied by the strengthening and harmonization of the regulatory systems worldwide, and the global market is characterized by a situation of multiple standards, with patients in low- and middle-income countries especially at the **risk of receiving poor-quality medicines<sup>1</sup>**. Medical products for Reproductive Health (RH) products are not an exception to this;
- ✓ The **WHO Prequalification Programme** (<https://extranet.who.int/prequal/>), established in 2001, to guide UN agencies and other international organisations with respect to the quality of antiretroviral medicines for supply to low-income countries, now covers a wider range of therapeutic fields, including reproductive health<sup>2</sup>. Nonetheless, there is need of more pre-qualified products for reproductive health. For instance, to date there are no pre-qualified sources of Benzathine penicillin, despite its key-importance in prevention and treatment of syphilis;
- ✓ The WHO *Survey of the quality of medicines identified by the UN Commission on life saving commodities for women and children*, published in 2015, showed that **23% of samples<sup>3</sup> failed** one or more tests when tested “against pharmacopoeial specifications rather than the manufacturers’ specifications”. The highest proportion of non-compliance found for oxytocin injection (64%), and relatively high failure rates were recorded for gentamicin, ampicillin and dexamethasone phosphate injections. The authors note that “more intensive cooperation and exchange of information among regulators would help to eliminate poor quality medicines. Regulatory cooperation, harmonization of regulatory requirements and procedures can also help to improve regulatory efficiency and incentivize manufacturers to register more UNCoLSC-relevant medicines in the respective countries”. The full report is available at [https://extranet.who.int/prequal/sites/default/files/documents/UNCoLSC\\_2015.pdf](https://extranet.who.int/prequal/sites/default/files/documents/UNCoLSC_2015.pdf)

<sup>1</sup> In 2017, the World Health Assembly reached a new agreement on substandard and falsified medical products. The new definitions are as follows:

- The new name of “substandard and falsified” (SF) medical products will be used for what had previously been known as “substandard/spurious/falsely-labelled/falsified/counterfeit medical products.
- “Substandard” medical products (also called “out of specification”): authorized by national regulatory authorities, but fail to meet either national or international quality standards or specifications – or in some cases, both.
- “Falsified” medical products: deliberately or fraudulently misrepresent their identity, composition or source.
- “Unregistered or unlicensed medical products”: have not been assessed or approved by the relevant national or regional regulatory authority for the market in which they are marketed, distributed or used.

<sup>2</sup> See list of prequalified products for reproductive health at this link : [https://extranet.who.int/prequal/content/prequalified-lists/medicines?label=&field\\_medicine\\_applicant=&field\\_medicine\\_fpp\\_site\\_value=&search\\_api\\_aggregation\\_1=&field\\_medicine\\_pq\\_date%5Bdate%5D=&field\\_medicine\\_pq\\_date\\_1%5Bdate%5D=&field\\_therapeutic\\_area=18&field\\_medicine\\_status=&field\\_basis\\_of\\_listing=All&Apply](https://extranet.who.int/prequal/content/prequalified-lists/medicines?label=&field_medicine_applicant=&field_medicine_fpp_site_value=&search_api_aggregation_1=&field_medicine_pq_date%5Bdate%5D=&field_medicine_pq_date_1%5Bdate%5D=&field_therapeutic_area=18&field_medicine_status=&field_basis_of_listing=All&Apply)

<sup>3</sup> A total of 204 samples produced by 106 manufacturers were collected and tested in Burkina Faso, Kenya, Madagascar, Nepal, Nigeria, Tajikistan, Tanzania, Uganda, Vietnam and Zimbabwe: oxytocin injection, magnesium sulfate injection, gentamicin injection, procaine benzylpenicillin injection, ampicillin injection, ceftriaxone injection, dexamethasone phosphate injection, amoxicillin dispersible tablets, zinc sulfate dispersible tablets/syrup, levonorgestrel tablets, and mifepristone tablets.

### Availability of Reproductive health supplies

- ✓ **Supply planning and monitoring is critical** to improve access to medical products for family planning to all those in need in low- and middle-income countries;
- ✓ Shortages of reproductive health supplies (stock-outs) continues to be a concern. UNFPA estimates that in the 46 FP2020 focus countries in which the UNFPA Supplies programme operates, on average, only 50 per cent of service delivery points have three or more lifesaving maternal health medicines available. The probability of stock-outs was higher at primary level than at secondary and tertiary level<sup>4</sup>;
- ✓ The pilot experience by MSD for Mothers in Senegal suggests that moving from a pull supply chain to an **'informed push chain'**, that integrates private sector logistics providers into public health supply chains and delivers commodities directly to the peripheral health facilities, may strengthen commodity, data, and financial flows across the public health supply chain, and help solving stock-out problems (<http://msdformothers.com/docs/senegal-informed-push-model.pdf>);
- ✓ There is a **need for increased national capacity building**, in particular in case of transition from externally funded programmes to services and regulation funded with domestic resources;
- ✓ There is a **need for accurate and public information on the global needs**. Generic manufacturers need this information as a “market incentive”: without accurate figures of the possible market size, it is unlikely that they will invest in quality-assured products for family planning for the market of low- and middle-income countries.

### Affordability

- ✓ Prices were reduced for 94% of contraceptives procured in 2016 by the UNFPA Supplies program. UNFPA Supplies contributed over 40% of all donated health commodities and reduced prices via long-term agreements, volume guarantee mechanisms<sup>5</sup>;
- ✓ Transition from international development assistance to a reliance on national (public) financial resources needs to avoid increased **out-of-pocket payments (OOPs)** by the population – users of health services. Reproductive health needs to be affordable to all<sup>6</sup> without carrying the risk of catastrophic expenditure;
- ✓ Affordability can be enhanced by risk pooling (through social security systems), as well as including a **benefit margin for distributors in the reimbursement of costs** can reduce out-of-pocket payments. In addition, third party payments of pharmaceuticals after delivery of products can reduce direct payment and avoid out-of-pocket payment.

<sup>4</sup> UNFPA Supplies Annual report 2016, <http://www.unfpa.org/featured-publication/unfpa-supplies-annual-report-2016>

<sup>5</sup> UNFPA Supplies Annual report 2016, IDEM

<sup>6</sup> WHO [Raising revenues for health in support of UHC: strategic issues for policy makers](#);

Public funds are compulsory and pre-paid (i.e. taxes) whereas voluntary payments are considered private. There is a concern in total available funding for health available. Several (WHO) evidence shows that when countries rely predominantly on private sources (OOPs), many households forgo care or face serious financial problems. However, even at low levels of public spending, countries can make significant steps towards UHC. Strategies that countries use to reduce OOP include “target and exempt maternal and child care from official payments and deliver them free of charge”

## Recommendations

### The Belgian government incl. DGD, Ministry of Foreign Affairs should

- Continue to champion universal access to quality-assured products for SRH at public fora, and add/include a call for a sustained/increased focus on quality of Reproductive Health products, including possible prioritization of products for RH in pre-qualification;
- Based on continued Belgian core-funding to WHO, inquire publicly / plead within WHO governance (Executive Board, ...) for a sustained budget allocation for the pre-qualification team, including for reproductive health products;
- Continue to facilitate equal partnership between public and private actors, with the aim of benefiting and sharing of knowledge & skills transfer; for example in setting up high performance supply chains, and/or in providing technology transfer to local manufacturers;
- Facilitate / foster strengthening of national regulatory authorities in partner countries.

### Belgian implementing development actors, NGOs and researches, should

- Ensure that products they supply for RH are quality-assured (ref. to the Quality Engagement) and when possible support national procurement centres to strengthen their supply and quality systems;
- Timely report to the national regulatory authorities and to the WHO Alert System any cases of substandard/falsified medicines;
- As research members take advantage of the Be-cause health platform to jointly generate and analyse reliable data on their needs and consumption of products for RH. These could be regularly communicated to the WHO PQ team to suggest priorities, and published in the international press to foster advocacy;
- Continue to invest in research on quality of medicines, by defining the priority research questions together with concerned counterparts (e.g. WHO PQ Team).

### International Development Actors / Agencies should

- Ensure quality assurance of developed and marketed pharmaceutical products, set-up monitoring systems, and actively fight substandard and falsified medicines in collaboration with public authorities;
- Avoid (indirectly) weakening the National Procurement Centres by setting up parallel procurement systems for medical products; strengthen where possible capacity building of (national/local) regulatory authorities and national procurement centre(s);
- Invest in 'information sharing systems'; Invest in joint WHO – country monitoring systems; improve data visibility; Improve 'visibility' by tracking the quality in country of RH Supplies procured or managed by International agencies such as UNFPA, UNICEF, GFATM;
- Maintain efforts to guarantee access and affordability of RH Supplies by avoiding out-of-pocket payments by users; keep the equal access in mind when addressing the need to develop (local) market share to tackle a commodity gap;
- Assist national authorities to strengthen local production and control of medical products.

### National (Regulatory) Authorities should

- ✓ Strengthen regulatory supervision on products for RH. For instance, ensure the appropriate choice of the pharmacopoeial specifications, ensure an adequate check on bio-equivalence studies, stability studies, related substances (impurities), etc.;
- ✓ Coordinate demand aggregation, establish/share market information and market controls.
- ✓ Align national and partner organisations' procurement policies;
- ✓ Improve logistics management information systems (LMIS).