



NEWSLETTER

ACQUISITION OF SEXUAL AND REPRODUCTIVE HEALTH SUPPLIES

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REPRODUCTIVE PLANNING AND HUMAN RIGHTS

By Jaime Nadal, Representant of the United Nations Population Fund (UNFPA) in Brazil

Guaranteeing the sexual health and reproductive planning is guaranteeing the compliance of the human rights. Every year, thousands of girls and women get unplanned pregnancies, most of them in situations of extreme poverty and inequality. When this unintentional pregnancy happens in teenagers and young people, a cycle of commitment of the present and the future is fed, in different spheres.

When a teenager or a young woman can plan her reproductive life, her options in life are multiplied. She is able then to finish the studies without the risk of a pregnancy, she can develop life projects: the job perspectives increase and the vulnerabilities are diminished. The chances that this young girl remains in the poverty and at the margin of the society are considerably diminished, as of her children to get stuck in this situation and to multiply it in the next generations. The reproductive planning can be a fundamental framework in the fight against poverty and its social detterminants.

We live today in a situation where the most demands for services and supplies of family planning are in the most poor classes of the

population and in the developing countries.

Since 1994, governments of 179 countries agreed with the Action program of International Conference of Population and Development (ICPD) and are committed to supply the means so that women and girls exercise their reproductive rights. This is the commitment that guides the work of UNFPA. And it is with this commitment that UNFPA Brazil starts to bring the liability to the supplying companies of reproductive health commodities.

In June of 2017, we started a process in Brazil of prequalification of sexual and reproductive health supplies. With this initiative, in a partnership with the Health Ministry of Brazil and the The Pan American Health Organization (PAHO/WHO), we want not only to include supplies produced in Brazil in the world catalog of UNFPA, with quality and competitive prices. We want the Brazilian companies to join us in this strategy to guarantee that women have access to quality supplies and qualified professionals over a human rights perspective.

WORKSHOP PROMOTED BY UNFPA AND PAHO/WHO BRINGS NEW HORIZONS TO BRAZILIAN COMPANIES

Brazil can have a strategic role in the attendance of global demands for supplies of reproductive health

In face of the difficulties of access to modern and quality contraceptive supplies, in special by poor populations, the United Nations Population Fund (UNFPA) in Brazil gathered strengths with the Pan American Health Organization (PAHO/WHO) and with the Health Ministry of Brazil for the Workshop “The Industrial Complex of Health towards the opportunity of participation in the external market through International Bodies”. During three days of meeting, realized in Brasília in August, laboratories and companies of the pharmaceutical industry knew the parameters used by UNFPA and by the World Health Organization (WHO) for the process of prequalification of supplies for the international market.

The Representative of UNFPA in Brazil, Jaime Nadal, brought numbers that get the attention by the need to strength the Latin American market: in 2016, UN counted with 214 vendors from 59 developed and transitioning countries, from which only four were companies of Latin America and Caribbean. On the other side, the region is between the main applicants of sexual and reproductive health supplies. The UNFPA supplies that come to the Latin America and to the Caribbean are produced in other continents, because of this, end up having expenses with transportation and require more delivery time.

“We believe that, with the workshop, we are able to contribute with the Brazilian Government to walk in new paths in the guarantee of supplying

of these basic commodities in the international scope and so that the Brazilian companies can be added to us in the supplying of commodities for other countries. It is a strategic moment for our efforts to make that women have access to supplies of quality and qualified professional services under a human rights’ perspective that we need to strength in our future suppliers,” reiterated.

For the agents of the international headquarters of WHO and UNFPA, the event was historical. For the first time there was the meet of United Nations and WHO with the sectors of a local government (represented by the Brazilian Health Ministry), the pharmaceutical companies and the Brazilian Health Regulatory Agency (Anvisa), responsible for the regulation of the products in the country.

“As from this meeting, we realized that we are not the only ones to see the strategic role that Brazil can have at an international level. But in order to make this workshop really efficient, we must assume the commitment of realizing other meetings in the search of better quality and fair prices for the regions that need our job. Because as long as we take long in this process and we yield to bureaucracies that prevent our advancements, we have women and children that cannot wait for our attendance and need it with urgency”, highlighted the technical specialist in Procurement Services Branch in UNFPA in Copenhagen, Seloï Mogatle.

In the workshop, representatives of the headquarter-

THE UNFPA MARKET IN 2015

In 2015, the contraceptives, commodities, equipment, medical devices and pharmaceutical products of



112 million

pharmaceutical products distributed all over the world



69 million

contraceptive drugs distributed



520 million

Male and female condoms distributed



Companies from all over Brazil participated in lectures and debates with instructions about pre-qualification of products and commodities

ter of PAHO/WHO guides the participants due to the perspectives of the market and products of interest for the organization. Specialists of UNFPA presented the main criteria of previous qualification of sexual and reproductive health supplies, while technicians and managers of Anvisa showing the work developed by the agency, point celebrated in the workshop thanks to the proximity of the processes with the protocol established by the UN.

The director of the The Science, Technology and Strategic Inputs Secretariat of the Health Ministry (SCTIE/MS), Rodrigo Silvestre, believes that the valuation of the Brazilian regulatory process must be placed in evidence in the political articulation processes with the international bodies, since it is a quality guarantee. "We have a permanent action

with Anvisa that aims to establish a standard of the Brazilian requirements of sanitary vigilance of internationalized way. In these moments of external articulation, we can show the strategies of our industrial complex of health as from the way the rules of Anvisa strengths the rigorousness that guarantees the quality."

As from the workshop, there will be an evaluation of the products of the companies that are interested in participating in the Prequalification Programmes. The expectation is that up to three products receive the accompaniment in this process by UNFPA and other three by PAHO/WHO. The Ministry of Health also signaled the possibility of a credit line so that the interested companies invest in the qualification.

United Nations Population Fund allowed the reproductive planning of millions of people all over the world



20,9 million
people reached with
modern contraceptives



12,2 million
of unplanned
pregnancies avoided



34,2 thousand
maternal deaths
avoided

TO PREQUALIFICATION, PRODUCTS NEED TO ATTEND THE CRITERIA OF QUALITY AND COMPETITIVENESS

To enter in catalog, the products need to favor also the acquisition by transitioning countries

Since 2005, the United Nations Population Fund (UNFPA) is responsible to realize the management of the strategies of evaluation of reproductive health in the global system of supply in the United Nations. Under the liability of UNFPA are, among other expenses, male latex condoms, female condoms and copper intrauterine devices (IUD). The biggest concern is to guarantee that the products arrive to the regions where the access to quality reproductive health still faces a lot of challenges.

To favor the distribution and have more competitive products, the Technical Specialist in Procurement Services Branch in UNFPA in Copenhagen, Seloj Mogatle, defends that more companies, in special transitioning countries, qualify their products. In this process, it is essential that the governments of the countries are allied - it is the case of Brazil.

"It is necessary to gather a jointly force between PAHO/WHO, UNFPA, the Government and the other responsible authorities so that we can think in ways of turning the Brazilian production one of the main suppliers of Latin America, because it attend technical standards that are already aligned with a good part of the international requirements to attend other countries", observed.

The prequalification of products is not a final process: after being apt by having the qualification, the suppliers need to be submitted to international bidding processes.

According to the leader of the Acquisition of UNFPA in Copenhagen, Lídia Porto, the prequalified manufacturer must realize the free enrollment in the website of the United Nations Global Marketplace (UNGM). Based on the supplied code by the user, the website automatically links the products with the UN organizations responsible for the selective process for the commercial supply. The process realized by UNFPA follows the rigorous procedures (see the board).

In the evaluation of the specialists, the criteria adopted for the authorization of the health products in Brazil serve as a great direction for the international qualification. "Brazil has a great know-how about attending popula-

tions with large socioeconomic problems, a humanitarian side developed thanks to a policy of generics that counts with accessible prices, but that do not stop being competitive", affirms the Regulatory Technical coordinator of the National Pharmaceutical Laboratories Association, Fernando Marcussi.

In the shopping portal, the UNFPA publishes the selective processes, open to all the manufacturers, authorized representatives and other suppliers. Once enrolled, they receive alerts of proposals by the own platform. The interested parties must answer all the evaluation criteria and general condition of the contact of each bidding process.

The proposals are evaluated in up to ninety days, and, once approved, receive a contract or Long Term Agreements (LTAs) valid for three years. LTAs also ensure that orders can be placed without clients undergoing lengthy bidding processes, leading to significant time savings.

Selection process of suppliers

Registration: The suppliers can register themselves in the United Nations Global Marketplace (UNGM), at www.ungm.org, in a free form. UNGM will automatically combine enrolled suppliers with UN organizations that buy their products and services.

Publication of proposals: All proposals of UNFPA will be published at UNGM.

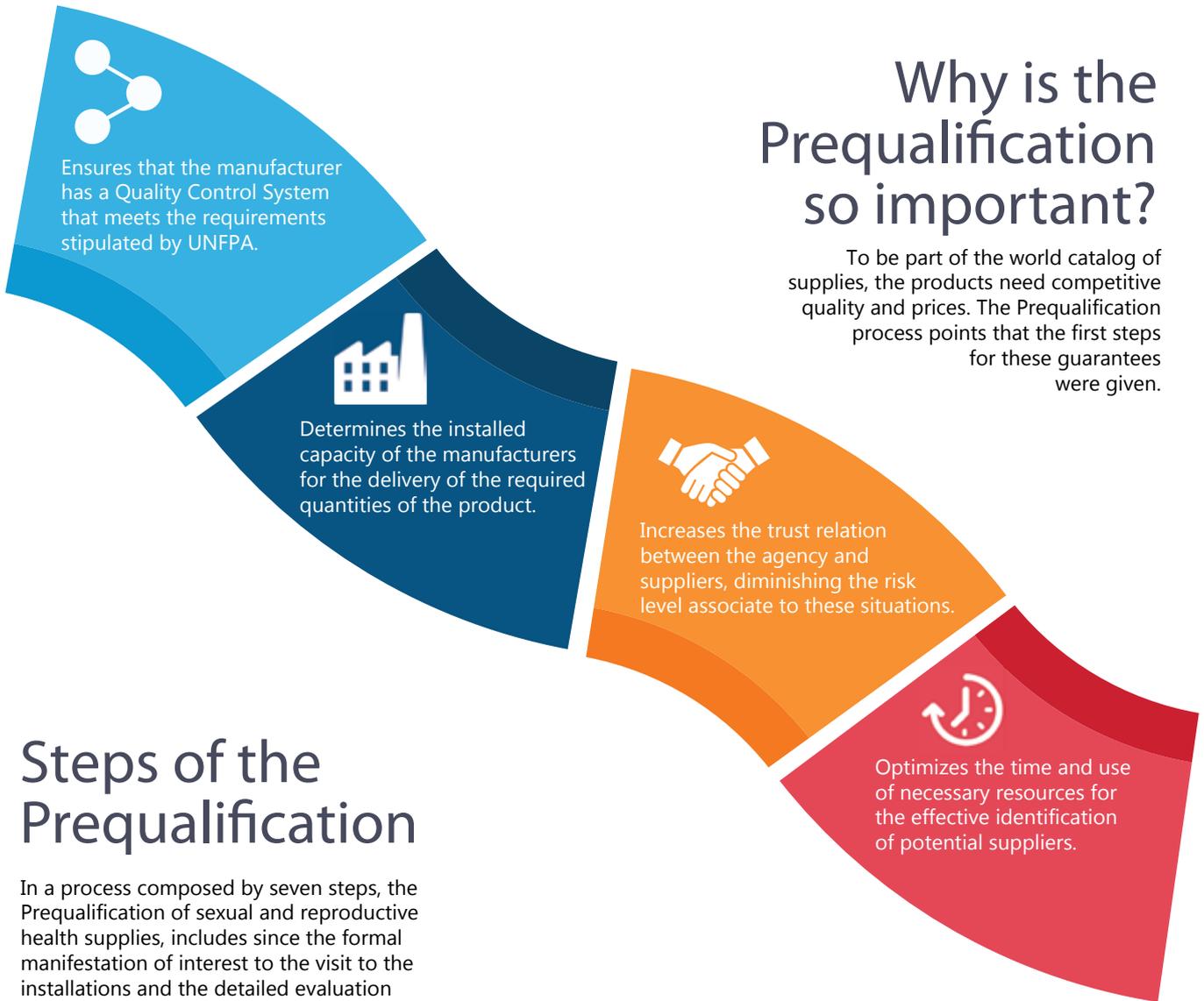
Responses of the suppliers: Interested suppliers can answer to the notices of UNGM. Evaluation criteria and general conditions of contract are specified in the bid documents. The suppliers must guarantee that the shipments follow the specific format, are complete and are sent at time.

Evaluation: The UNFPA realizes the detailed evaluation of the offers. In this phase, an emphasis is given to the quality of the products, manufacturing capacity, production time and country register.

Results: The contracts or Long Term Agreements (LTAs) are valid for up to 3 years. LTA serves as a structured agreement upon the purchase requests. It is important that the suppliers keep the quality of the products presented in the bid documents.

Why is the Prequalification so important?

To be part of the world catalog of supplies, the products need competitive quality and prices. The Prequalification process points that the first steps for these guarantees were given.



Steps of the Prequalification

In a process composed by seven steps, the Prequalification of sexual and reproductive health supplies, includes since the formal manifestation of interest to the visit to the installations and the detailed evaluation of the quality of products.

Step 1

Manufacturers manifest interest for sending the documentation

Step 3

Detailed evaluation and technique of the documents sent by the manufacturers

Step 5

Sampling and testing

Step 7

Maintenance (new qualification at each 3 years and continuous conformity test)

Step 2

Initial trial for the integrity of the documents

Step 4

Inspection of the local/factory

Step 6

Inspection report of the factory and corrective and preventive actions



CONDOMS MANUFACTURED IN ACRE CAN INSERT SOUTH AMERICA IN THE GLOBAL LIST OF SUPPLIERS

Factory uses latex taken from Amazônia and pursuits promotion of the workforce in local economies

©Alexandre Noronha/Agência de Notícias do Acre



With a factory installed in Xapuri (AC), NATEX has a capacity to produce 100 million male condoms per year

In August of 2017, a team formed by representatives of the United Nations Population Fund (UNFPA) and the Health Ministry of Brazil were in the Factory of Natex Condoms in Xapuri (AC) to determine the possibilities of entrance in the company to the Prequalification Program of the UNFPA/WHO. If the process of Prequalification is concluded, the factory will be the first of the South America to compose the list of global suppliers.

During the visit, the inspectors reveal that Natex is in good conditions. "The technical people of the industry seem to have conscience of what they are doing and are familiarized with the activities, but some failures exist that must be evaluated", affirms the analyst of UNFPA, Bill Porter. The specialists also seem to be impressed with all the production process of the male condom, since the removal of the latex of the rubber trees and traceability control of the received material up to the production and storage process.

Inaugurated in 2008 as from a partnership between the Federal Government and the State Government of Acre, Natex was created to develop an industrial park as from the products of the Amazon forest. The objective was to make the competitive product for the local and regional market and contribute for the sustainable development in the amazon region.

Currently, the company is responsible for supplying 15% of the male condoms distributed by the Health Ministry. Is also the only factory of the world in this segment that uses a native rubber in the industrial process with the raw material, guaranteeing the maintenance of the forest, at the same time that generates income, job and life quality for families of extraction workers of the region. Today, Natex generates more than 120 direct jobs and has 700 families enrolled and involved in the supplying of latex for the production line.

Overall, the installed capacity in Xapuri guarantees the annual production of 100 million of condoms, with the annual medium consumption of 50.000 liters of latex in natura. With the Prequalification of the commodities, Natex can increase the industrial park, at the same time that would increase the income of the extractor workers and would foment the local economy.

For the technical director of Natex, Silvia Basso, the visit of the delegation to the factory was essential for the company to show and explain with more details the plans it has to improve products and process aiming the international market. "The visit of the inspectors of UNFPA in conjunction with the Health Ministry was of great importance

so that the beauty of our project would be better understood", affirms. "When I say beauty, I broad for the social and economic aspect of all the chain, exceptionally to the latex chain. We are really confident that we will gather the objectives of UNFPA and consequently we will be lined for the Prequalification process."

In order for Natex to reach the international market, some adaptations will be necessary: it must be adequate to the international rules of ISO 13.485 (recognized as the Management System of Quality for the Industry of Medical Devices). This rule evaluates mainly the conditions of the product to avoid an unintended pregnancy or the propagation of sexually transmitted infections (STIs).



18 BILLION

is the estimated number of male condoms necessary to attend the global demand



98%

is the efficiency rate of the male condom when used in the correct way



1 MILLION

of people get a sexually transmissible infection per day in the world, according to WHO



3 YEARS

is the time that the products keep the prequalified status up to the new inspection



70 COMPANIES

applied to receive a prequalification of any of its products by UNFPA between 2001 and 2014



ONLY 14

companies had male condoms prequalified by UNFPA until the end of 2014



18 TYPES

of condoms are offered in the online catalog, varying in sizes, colors, textures, smells, flavours and formats



35%

of the factories that pass their condoms through a rigorous process of prequalification were approved, since 2001



118 COUNTRIES

and about 56 million couples received, only in 2013, male condoms of the UNFPA catalog

Testimonies

REPRESENTATIVES OF ORGANIZATIONS AND INDUSTRY OF HEALTH SUPPLIES TALK ABOUT THE PREQUALIFICATION



“The Workshop is a historical landmark because allowed to deepen our relation with the WHO and with the UNFPA, involving actors of the third sector of the private sector.”
- **Rodrigo Silvestre**, director of the Industrial Complex Department of Innovation in Health of the Health Ministry of Brazil



“We do not work with the sale idea: for us, each manufacturer or country is a partner with whom we are going to form a team in all the steps of the prequalification process.”
- **Seloj Mogatle**, technical specialist in Procurement Services Branch in UNFPA in Copenhagen



“When the suppliers assume the necessity to enter in the international market, they are committed to keep the quality of the services and prices that represent the health potential of the country”.
- **Vimal Sachdeva**, technical officer/Inspector of Prequalification Team - Medicines in WHO/ Geneva



“There is a preoccupation to guarantee continuous improvements and be aligned to the international interests.”
- **Monique Stávale**, advisor of the Vice-Presidency of Quality of the Technology Institute in Immune Biologics Bio-Manguinhos/FioCruz



“We work just at a national level and we have a lot of interest in expanding the business internationally. We already attend the requirements of Anvisa and some details are pending, we want to discuss about it with UNFPA.”
- **Jean Carlos Campos**, representative of the União Química Nacional



“It is important that the approximation of the companies also happen with ministries connected to the commerce, with the MDIC, so we can identify together how to act in this market.”
- **Ana Paula Azevedo**, technological manager of INMETRO



Fundo de População das Nações Unidas

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