Generics: Impact of WHO prequalification and UNFPA Expert Review Panel

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The landscape of quality generic Reproductive Health (RH) medicines has changed significantly in the past 6 years. In figure 1 below, it can be appreciated that the number of WHO prequalified medicines has been multiplied by 7, moving from 4 WHO prequalified medicines in 2009 to 29 in 2015. Increasing not only quantitative but also qualitative in terms of expanding to cover the different categories.

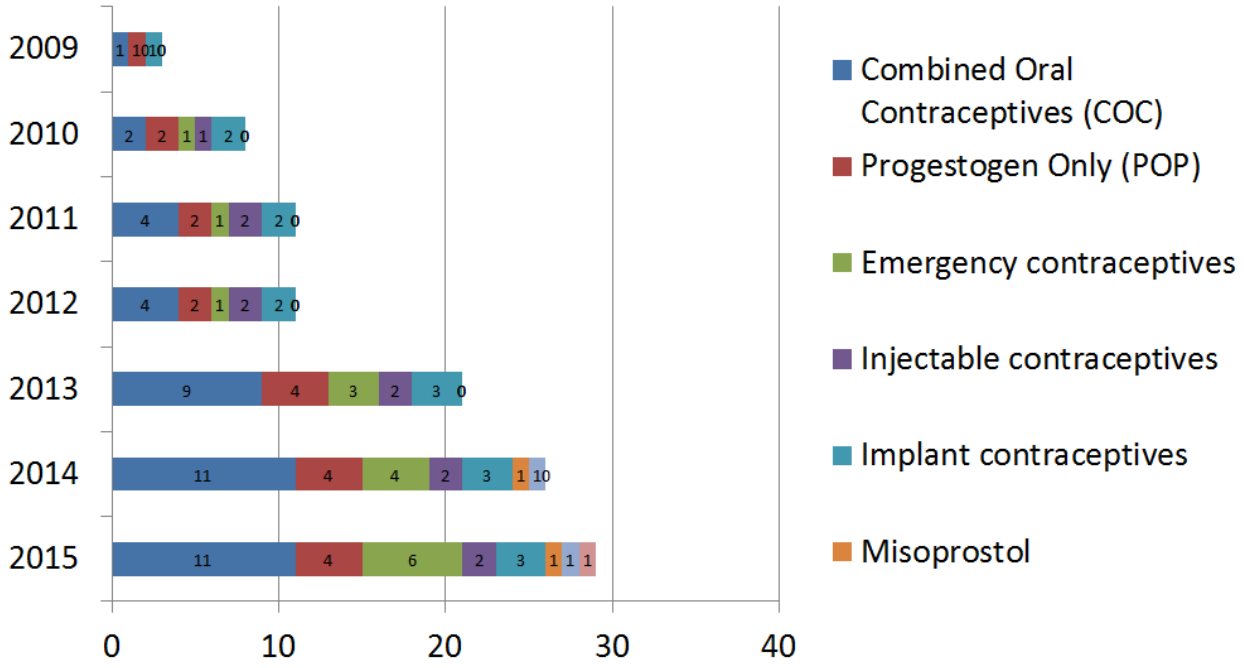

Figure 1

The UNFPA Expert Review Panel has played a paramount role in the development of the WHO prequalified base of RH medicines. Having acknowledged the lack of a solid supplier base in this area, the UNFPA ERP was first implemented in 2011 following The Global Funds model, in order to yield for options for procurement in the meantime medicines achieved WHO prequalified status.

Figure 2 below shows the progress from UNFPA positive ERP recommendation to WHO PQ or Stringent Regulatory Authorities approval (SRA) -which is considered at the same level in terms of quality standards-. In the graph it can be appreciated the evolution from ERP products to WHO PQ products, the orange colour representing ERP products was higher in the beginning, however as time passes by these products transition into WHO PQ or SRA approved. In figure 3, it can be seen that the average time that an RH medicine takes to get WHO prequalified has been notably decreased, being currently **13.4 months**, considerably lower than some years back, when the ERP was not in place and a product could be in the WHO PQ pipeline during 2-3 years.

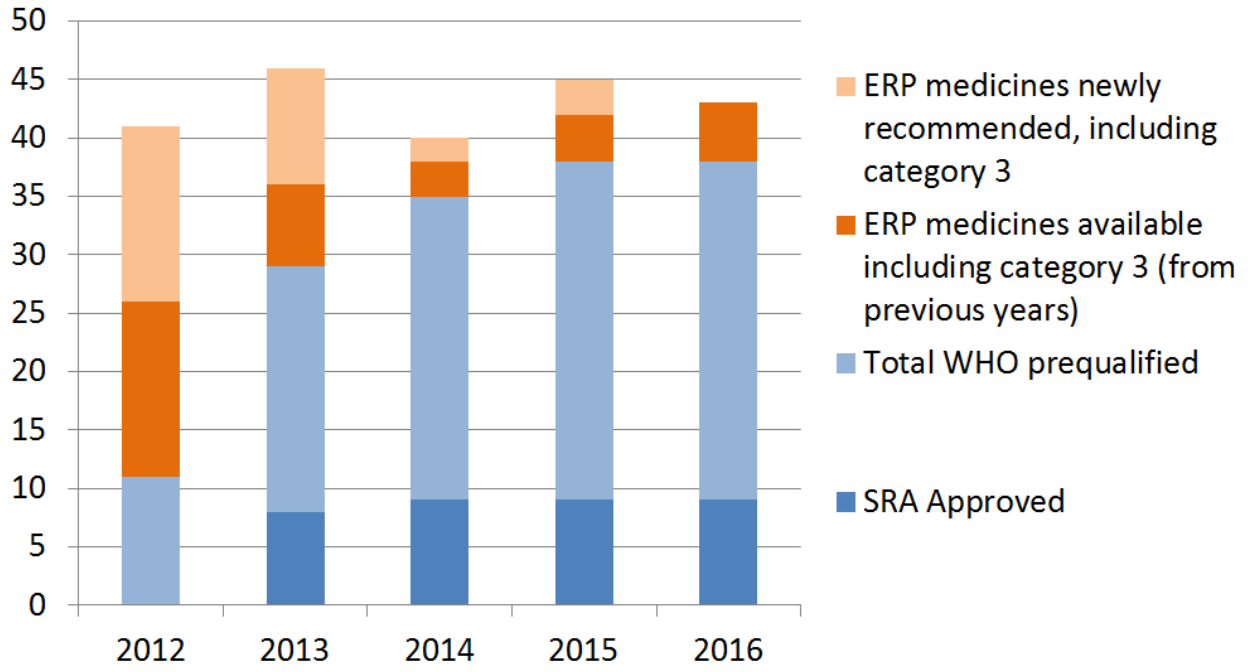

Figure 2

No	Manfuacturer	INN	Formulation and strength	Risk Cat	ERP EOI	ERP date	WHO PQ	Time (months)
1	Jai Pharma	Ethinylestradiol + Desogestrel	Tablet, 30 micrograms + 150 micrograms	1/2	2	Jun-12	Aug-13	14
2	Chemo	Ethinylestradiol + Desogestrel	Tablet, 30 micrograms + 150 micrograms	1/2	2	Jun-12	SRA, EU	NA
3	Novastlabs	Ethinylestradiol + Desogestrel	Tablet, 0.03mg + 0.15mg	1/2	2	Aug-12	USFDA	NA
4	Jai Pharma	Ethinylestradiol + Levonorgestrel	Tablet, 30 micrograms + 150 micrograms + placebo	1/2	2	Jun-12	Oct-13	16
5	Novastlabs	Ethinylestradiol + Levonorgestrel	Tablet, 30 micrograms + 150 micrograms	1/2	2	Jun-12	USFDA	NA
6	Novastlabs	Norethisterone	Tablet, 350 micrograms	1/2	2	Jun-12	USFDA	NA
7	Chemo	Levonorgestrel	Tablet, 1.5mg	1/2	2	Aug-12	SRA, EU	NA
8	Jai Pharma	Levonorgestrel	Tablet, 0.75mg	1/2	2	Aug-12	Jun-13	10
9	Chemo	Ethinylestradiol +Levonorgestrel	Tablet, 0.03mg + 0.15mg	1/2	2	Aug-12	SRA, EU	NA
10	Exelgyn	Misoprostol	Tablet, 200 micrograms	1/2	2	Aug-12	SRA?	NA
11	Chemo	Levonorgestrel	Tablet, 0.75mg	1/2	2	Oct-12	SRA, EU	NA
12	Jai Pharma	Levonorgestrel	Tablet, 1.5mg	1/2	2	Oct-12	Oct-13	12
13	Cipla	Levonorgestrel	Tablet, 1.5mg	1/2	3	Sep-13	Jul-15	22
14	Cipla	Misoprostol	Tablet, 200mcg	1/2	3	Sep-13	Apr-14	7
15	Cipla	Levonorgestrel	Tablet, 0.75mg	1/2	3	Jul-13	Apr-14	9
16	Jai Pharma	Ethinylestradiol + Levonorgestrel + ferrous fumarate	Tablet, 30 micrograms + 150 micrograms + placebo	1/2	3	Aug-13	Mar-14	7
17	Lupin	Levonorgestrel	Tablet, 1.5mg	1/2	4	Dec-13	Dec-15	24

Figure 3

Figure 4 below shows that the number of submissions indeed has been reduced based on the fact that the medicines that were in the pipeline for prequalification have successfully moved along this line and the number of manufacturers producing generic RH medicines is restricted. However, the submissions received for the ERP are turning into more solid ones, receiving a lower number of them but still getting a high proportion of positive results. This is the outcome of the number of initiatives that UNFPA is undertaking in order to prepare the suppliers, some of the ones are mentioned below:

- UNFPA ERP Workshops – conducted in 2013 and 2014 in collaboration with WHO, targeting Indian manufacturers.
- Joint UNFPA/UNICEF/WHO Meeting with Suppliers – conducted yearly from 2013 up to date, where not only plenary sessions are delivered with special focus on RH medicines and the mechanisms to assure their quality, but also individual meetings are scheduled between the manufacturers and the different teams, including the UNFPA one.

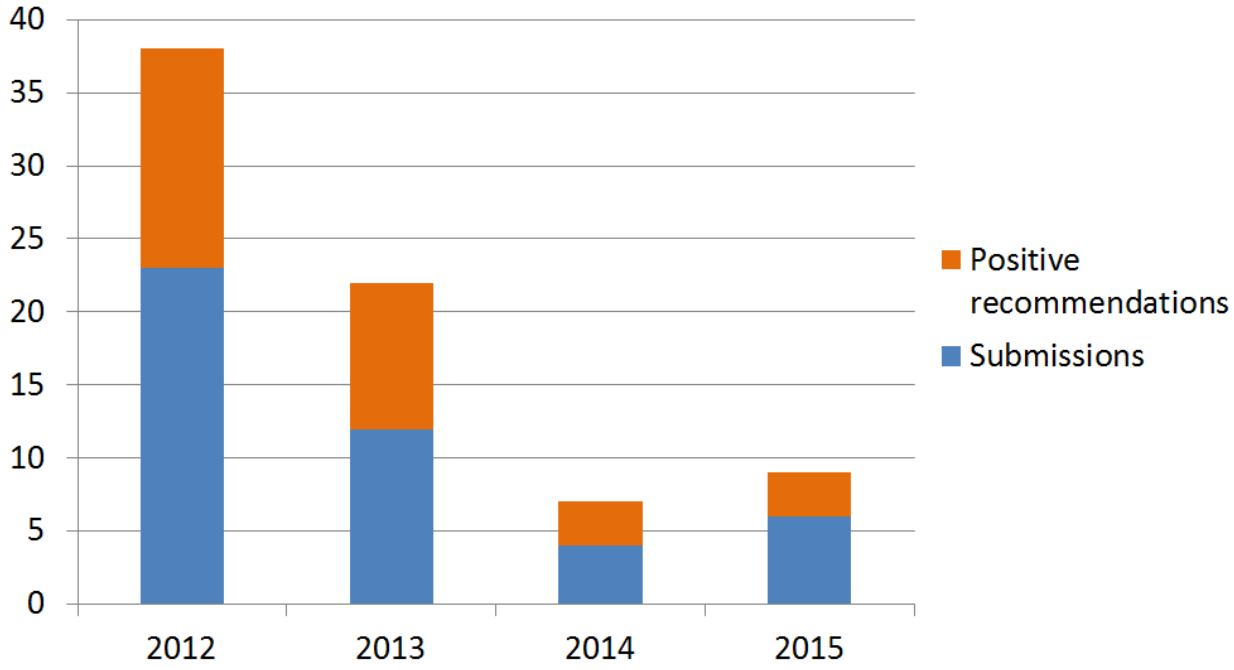

Figure 4

The increase on the number of generic RH medicines complying with the internationally recognized quality standards applied by UNFPA has a positive impact on prices. In figures 5 and 6 below, it can be appreciated the savings (in USD) achieved by UNFPA only during 2015 based on the increased number of quality generics available. In figure 5 the savings made by purchasing of generics combined oral contraceptives are shown in comparison to the potential expenditure incurred on if the innovator would have been procured. Figure 6 shows the total value of the orders placed with generic emergency contraceptives compared to the value incurred in if the innovator would have been procured.

This can also be interpreted from the perspective of value for money: with the same amount of money, more cycles of quality contraceptives will be accessible for the women.

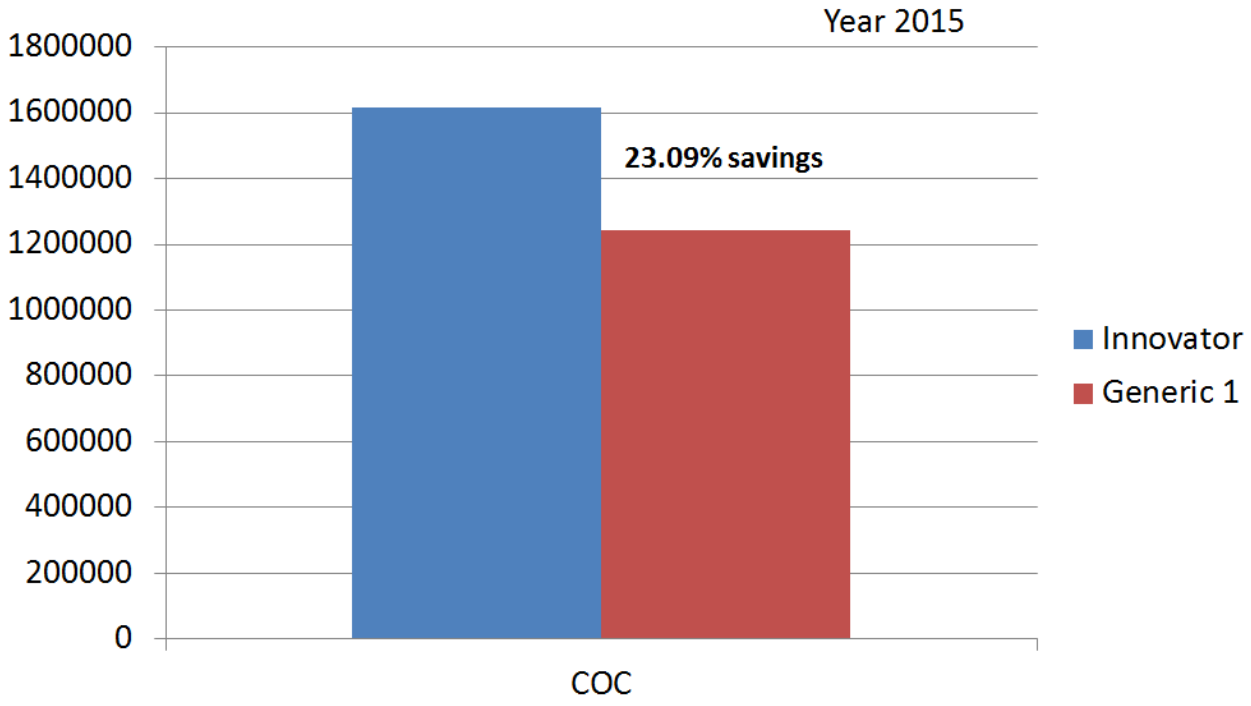

Figure 5

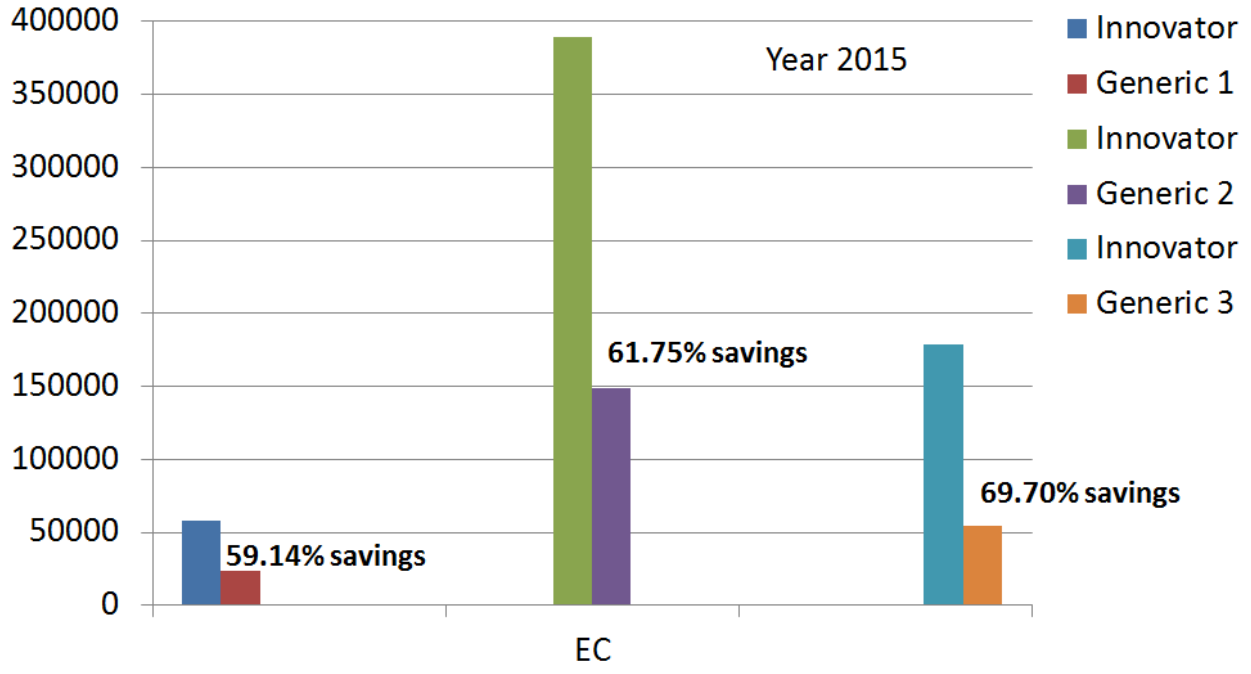

Figure 6

In 2016, UNFPA plans to continue advocating for the use of generics in order to increase access to RH medicines. Some of the activities planned are: switching to a generic catalogue, conducting webinars and individual sessions tailor made, etc.