

# Questions–Answers: Scaling up preventive malaria treatment in pregnancy by enhancing African manufacturing capacity



Malaria infection during pregnancy (MiP) is a major public health problem. Each year, MiP is responsible for 20% of stillbirths and 11% of all newborn deaths in sub-Saharan Africa, and 10,000 maternal deaths globally.<sup>1</sup> These deaths can be prevented with a simple and cost-effective intervention known as intermittent preventive treatment in pregnancy (IPTp) with sulfadoxine-pyrimethamine (SP), but barriers impede IPTp-SP uptake in many countries across sub-Saharan Africa. Medicines for Malaria Venture (MMV) is working with partners to address supply-side barriers by enhancing the capacity of African manufacturers to improve the availability and administration of quality-assured SP.

## Q Why is it important to increase coverage of IPTp-SP in sub-Saharan Africa?

A Malaria infection during pregnancy brings substantial risks for the mother, unborn baby and newborn. Even when death is averted, MiP can cause maternal anaemia, premature labour and low birthweight, all of which are associated with a negative impact on early childhood development.<sup>2</sup> In 2018, about 11 million pregnancies in sub-Saharan African countries were at risk of malaria infection and 872 000 children were born with low birthweight.<sup>3</sup>

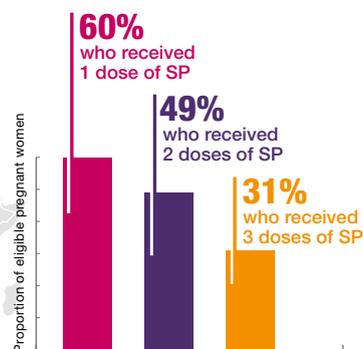
The World Health Organization (WHO) recommends that pregnant women in areas of moderate to high malaria transmission in Africa receive quality-assured SP for IPTp-SP at routine antenatal care visits.<sup>4</sup> Women should receive at least three doses of SP throughout pregnancy, starting as early as possible in the second trimester.<sup>5</sup> IPTp-SP has proven to be effective in reducing maternal malaria episodes, neonatal mortality, maternal and fetal anaemia, placental parasitemia, and low birthweight.<sup>6</sup>

1. World Health Organization. Implementing Malaria in Pregnancy Programs in the Context of World Health Organization Recommendations on Antenatal Care for a Positive Pregnancy Experience. 2018.
2. Schantz-Dunn J & Nour NM. "Malaria and Pregnancy: a global health perspective". *Rev Obstet Gynecol*; 2(3):186–192 (2009).
3. World Health Organization.
4. World Health Organization. *Guidelines for the treatment of malaria*. Third edition. April 2015. analysis were those estimated for 2015 as shown in this source.
5. *ibid.*
6. World Health Organization. Intermittent preventive treatment in pregnancy (IPTp). 21 October 2019. *Intermittent preventive treatment in pregnancy (IPTp)*, 21 October 2019.
7. World Health Organization.
8. *ibid.*

In 2018, across the 36 African countries that adopted IPTp-SP as a policy, at least 69% of eligible women did not receive the complete three doses, and 18% did not receive any SP at all.<sup>7</sup> This represents a huge missed opportunity to prevent malaria and other negative health outcomes among pregnant women and their unborn babies.<sup>8</sup>

## 2018

In **36**  
African countries



Source: World Malaria Report 2019

“ An estimated 30% of SP across Africa is procured through donor sources which require quality assurance.



**Q** What prevents eligible pregnant women from accessing IPTp-SP?

**A** A broad range of barriers impede access to IPTp-SP in sub-Saharan Africa. These include gaps in coordination, policy, human resources, supply chain and service delivery.<sup>9</sup>

On the supply-side, producers of quality-assured SP are limited.<sup>10</sup> Manufacturers are reluctant to invest in this product due to its low sale price and limited market size that result from low IPTp coverage.<sup>11</sup> Stockouts of SP have been observed in many countries in sub-Saharan Africa.<sup>12</sup>

Furthermore, countries do not always prioritize procurement of quality-assured SP. An estimated

30% of SP across Africa is procured through donor sources which require quality assurance; the rest is nationally procured through a mix of domestic and international manufacturers, and quality is not always assured.<sup>13</sup>

Misuse of SP has also been documented across sub-Saharan Africa. WHO recommends SP only as a preventive intervention for pregnant women and infants in areas with moderate to high malaria transmission in Africa.<sup>14</sup> Despite current guidance, SP is still distributed in the private sector for the treatment of malaria, rather than restricted to use for prevention.<sup>15</sup> ■

9. Roman et al. 'Determinants of uptake of intermittent preventive treatment during pregnancy: a review.' *Malaria Journal*. 2019; 18:372  
 10. Unitaid. Malaria Disease Narrative. December 2019.  
 11. Ibid.  
 12. Ibid.  
 13. MMV. 'Market Research Project Proposal: Prevention of malaria in pregnancy – SP Forecast.' 2019.  
 14. World Health Organization. Guidelines for the treatment of malaria. Third edition. April 2015.  
 15. ACTwatch. 'SP availability and (mis) use in sub-Saharan Africa: Antimalarial market data from 8 countries.' (Poster). 64th Annual Society of Tropical Medicine and Hygiene Conference, 2015.

## Q How is MMV working to address these supply-side barriers?

A To help address supply-side barriers and as part of its effort to support global capacity for quality-assured antimalarial manufacturing, MMV is leading a project, funded by Unitaid, which aims to strengthen the capacity of African manufacturers to produce quality-assured SP for prevention.

As part of this initiative, MMV entered into an agreement with a Kenyan manufacturer, Universal Corporation Ltd, in January 2019 and SWIPHA, Nigeria in 2020, to produce WHO-prequalified SP for IPTp. MMV is also in negotiation with one additional African drug manufacturer. In addition to providing a quality-assured product, these manufacturers will ensure that the packaging and labels carry clear instructions to use SP only for

IPTp or intermittent preventive treatment in infants (IPTi). Low-quality versions of SP often lack this important information which can lead to misuse of the product.

MMV has worked closely with the United Nations Industrial Development Organization (UNIDO), WHO and other international stakeholders to ensure alignment and complementarity of this initiative with global malaria strategies and related activities. These include the African Union's Pharmaceutical Manufacturing Plan for Africa<sup>16</sup> and its effort to establish the African Medicines Agency (AMA), which aims to strengthen regulatory systems for quality-assured, essential medicines and facilitate their production.<sup>17</sup> ■

16. Third session of the African Union Conference of Ministers of Health. [Pharmaceutical Manufacturing Plan for Africa](#). 9-13 April 2007.

17. African Union. [Treaty for the Establishment of the African Medicines Agency](#). February 2019.

## Q What are the expected benefits of strengthening African manufacturing for SP?

A Enhancing the capacity of African manufacturers to produce quality-assured SP, thus ensuring proximity of manufacturing to the point of use, could have many benefits including:

- *Mitigating risks that the supply of quality-assured SP is interrupted on the continent.* In Africa, between 70 and 90 percent of pharmaceuticals are imported.<sup>18</sup> African countries' dependence on imported quality-assured SP, antimalarials and many other essential medicines makes them vulnerable to the potential interruption of supply. International procurement agencies such as the Global Fund to Fight AIDS, Tuberculosis and Malaria must procure medicines that meet stringent quality standards,<sup>19</sup> such as WHO pre-qualification. The limited number of African manufacturers that have received WHO pre-qualification for malaria medicines mean that, until now, drugs purchased through the Global Fund

and WHO and distributed in Africa have been mostly imported from pre-qualified manufacturers outside the continent. Already, the COVID-19 pandemic has caused disruptions to global supply chains.<sup>20</sup> This has resulted in countries facing constraints such as lengthy lead times for the supply of essential medicines.

- *Increasing the global supply of quality-assured SP.* MMV will help expand the limited number of African antimalarial manufacturers that have received WHO pre-qualification for malaria medicines from two to five. This may also increase demand for SP beyond the domestic market to other countries. The availability of locally produced, quality-assured SP could also help displace product of sub-standard or unknown quality. ■

18. Council on Foreign Relations. [Scaling Up African Pharmaceutical Manufacturing in a Time of COVID-19](#). Blog Post. 22 May 2020.

19. Global Fund grant funds may only be used to procure antimalarials that are prequalified by WHO, authorized for use by a Stringent Drug Regulatory Authority (SDRA) or recommended for use by an Expert Review Panel (ERP). [Global fund quality assurance policy for pharmaceutical products as amended and restated on 14 December 2010](#).

20. Council on Foreign Relations. [Scaling Up African Pharmaceutical Manufacturing in a Time of COVID-19](#). Blog Post. 22 May 2020.



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MMV is helping expand the number of African antimalarial manufacturers to receive pre-qualification for malaria medicines from two to five, and thus contribute towards an increase in global supplies of quality-assured SP.



## Q What can countries do to improve uptake of IPTp-SP?

A To help policy makers prioritize their activities and maximize their impact, MMV commissioned a forecast model that simulates the impact of key changes on the uptake of IPTp-SP over a 10-year period.<sup>21</sup>

Developed by the William Davidson Institute at the University of Michigan (WDI),<sup>22</sup> the model predicts, *inter alia*, that increasing the number of women attending antenatal care and the number of visits attended will lead to increases in demand for SP.<sup>23</sup>

In the context of Global Fund-supported programmes, a minimum of 15% co-financing is required from domestic sources.<sup>24</sup> If SP is to be purchased using domestic funds, it is essential that it be quality-approved; procurement from local manufacturers compliant with WHO Good Manufacturing Practices could also help ensure this.

Governments can also help create a favorable and competitive environment for manufacturers of quality-approved essential medicines by removing import tariffs on the needed starting materials. ■

21. William Davidson Institute at the University of Michigan, Intermittent Preventive Treatment in Pregnancy with Sulfadoxine Pyrimethamine Forecast Model, January 2020 (document non publié).

22. *ibid.*

23. *ibid.*

24. The Global Fund. Focus on Domestic Financing for Health. August 2019.

## Conclusion

Now more than ever, governments across the globe are realizing there is strategic merit in having sources of drug production closer to home. It is critical for African countries and their development partners to invest in supporting manufacturers from the continent to produce quality-assured SP, while taking action to increase

coverage with IPTp-SP. In Africa, where the burden of disease is greatest, this will help contribute towards the survival and better health prospects for pregnant women and their babies, as well as better health outcomes and economic progress for their communities.