Quality Medicines for Malawi

PMRA STATEMENT ON THE STUDY CLAIMING MALAWI HAS HIGHEST PREVALENCE OF SUBSTANDARD AND FALSIFIED MEDICINES

Lilongwe, Tuesday, 20th August, 2024: The Pharmacy and Medicines Regulatory Authority (PMRA) wishes to inform stakeholders and the general public that it is aware of the article published in *The Guardian* newspaper of 4th August, 2024, titled ***"Fifth of medicines in Africa may be sub-par or fake, research finds."*** The article cites a study by researchers at Ethiopia's Bahir Dar University, which suggests that Malawi has one of the highest prevalence of substandard and falsified medicines in Africa.

The Bahir Dar University review, which analyzed studies published between 2014 and 2024 from different countries in Africa, referenced a 2015 study by a Malawian researcher at University of Ghana who in his study reported that Malawi had 88.4% prevalence of poor-quality anti-malarial medicines.

Accordingly, the Authority examined the referenced 2015 Malawi study which is the sole source of the claims in question and would like to state as follows:

1. The study which the article quoted only examined the quality of anti-malaria medicines which were: LA, Quinine, SP, DHA/SP, DHA/Pp, ATS/SmP, and ATS/SP. This means that the findings of the study cannot be used to generalize the **quality of all medicines** in Malawi as portrayed by the Bahir Dar University review.

2. Based on the design of the referenced 2015 Malawi study, the samples were drawn from the retail pharmacies, private clinics, and medicine stores. The study did not include samples from the government health facilities which constitute the largest proportion of anti-malarial medicines consumed in the country and whose medicine brands are not found in the private sector. This study, therefore, cannot be used to generalize the **quality of all anti-malarial medicines** used in the country.

3. The laboratory analytical method used for assessing LA in the 2015 reference study was modified from a published well validated method.

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However, the extent of the modification was quite significant and resulted into inferior validation parameters, rendering the method unsuitable for assessing quality of LA. For example, samples from the same batch of LA gave significantly different results, which is not normal in medicines analysis especially considering that the samples were collected from regulated facilities.

4. Therefore, the failure rate of LA (95%), which had the highest number of samples (41 out of 112), in the 2015 study was largely due to analytical method problems. Had the analysis been as per the reference analytical method (Arun 2011), the failure rate could have been much different from the 88.4% that was reported in the 2015 Malawi study.

5. Additionally, 36% of all sample results were outside the validated linear range and, therefore, should not have been used to establish the quality of anti-malarial medicines in this study. This is because results that fall outside a validated linear range are inaccurate, imprecise and unreliable.

Furthermore, PMRA would like to inform the public that its Medicine Quality Control Laboratory is ISO 17025 accredited. The accreditation means that Malawi has the requisite capacity and international recognition to test and assure the quality of medicines which are consumed in the country. Using this ISO 17025 accredited laboratory, PMRA tests medicine samples, among others, prior to distribution and also those samples collected through routine quality surveillance activities.

Results from routine quality surveillance activities over the past four years indicate that the prevalence of substandard medicines in the country is currently at around 4%. The World Health Organisation (WHO) estimates that on average, 10.5% of all medicines in low and middle-income countries are substandard or falsified. Recent studies in the country have reported findings consistent with this WHO estimate.

It must also be pointed out that the prevalence of substandard and falsified products (SSF) in any country is related to the strength of the regulation of the supply chain pipeline of medicines.

In Malawi, regulation of the medicine supply chain pipeline, starting from where the medicines are manufactured to a point where they are consumed by the client is clearly within the scope of PMRA's mandate.

It is a regulatory requirement under the PMRA Act, 2019 for any medicine that gets imported into the country to be produced by a manufacturing company that has been inspected and licensed for compliance to WHO Good Manufacturing Practice (GMP) standard. The medicines coming from the licensed manufacturers

have to be quality-assessed and registered on a list of registered products for Malawi before they are authorized for use on the market.

Only registered pharmaceutical wholesalers, for example, Central Medical Stores Trust (CMST) and private wholesalers, are allowed to import medicines directly from pharmaceutical manufacturers through a PMRA issued import permit that is used by customs for clearance at port of entry.

In March 2023, WHO conducted the regulatory benchmarking assessment for the medicines regulatory system in Malawi. The results of the assessment in relation to medicine supply chain security indicated that PMRA has documented procedures necessary to grant authorizations for medicine importation and distribution activities that are well implemented. The assessment also indicated that a rapid alert system for managing the threats by SSF medical products and for recalling these products from the market is implemented too.

Finally, the Authority acknowledges the importance of studies conducted by institutions of higher learning whose recommendations inform both public health policy and medicines regulatory practice.

However, the Authority calls on adherence to best research practices as incorrectly done studies may raise alarm and grossly mislead the public to lose confidence in the health sector. Further, such studies undermine the efforts by government institutions, partners and stakeholders in the health sector in ensuring access to quality health services.

To this end, the Authority will continue to engage with research institutions to harness collective expertise, drive research-informed regulatory decisions, and ultimately ensure the safety, efficacy, and quality of medicines for the benefit of all Malawians.

The Authority assures stakeholders and the general public that the country has the capacity to undertake medicine quality assessment for product registration and also monitor quality of medicines on the market.

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