

Online Consultation on the SECURE Initiative Draft Business Model and GARDP License for cefiderocol (Fetroja) with the Antibiotic Resistance Coalition (ARC) and Partners

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The WHO released its **SECURE initiative Draft Business Model**. PHM's AMR representative, **Nafis Faizi (Email: nafisfaizi@gmail.com)**, attended the consultation meeting through Skype and made an intervention on Enabling a transparent and representative process along with other ARC colleagues.

First

We acknowledge the efforts of the WHO as well as GARDP for today's consultation about the SECURE initiative. While we welcome the initiative, we are concerned with the lack of stringency in terms of the wide ranging stakeholders in the initiative. The stakeholders include the industry as well as certain organizations funded by the industry. We are yet to understand the operational processes through which the initiative can be resilient against all such conflicts of interests. We are also concerned about how SECURE can optimally harness the potential of not-for-profit civil society organizations.

Second

The second point is on the overlooking of diagnostics. When all of us agree on the vital role of diagnostics in antimicrobial stewardship, how can we afford to overlook them while discussing new antibiotics. The ARC has been concerned about the Access-Excess challenge, which needs a good diagnostic support for stewardship and optimal use of antimicrobials.

Third

The document in section three is rightly concerned with low quality and high prices. However, we disagree that low quality is restricted to LMICs. The WHO's global surveillance and monitoring report mentions that all WHO regions report substandard and falsified drugs with 21% of such drugs in American and European regions. The report on substandard drugs also clearly mentions that constrained access is one of the main reason for poor quality. Constrained access is not limited to the reserve antibiotics. Covid 19 exposed the fragility of supply of essential medications especially generics as well as drugs for intravenous infusion in the US. The solution to constrained access is local production. Experiences such as the Kerala State Drugs & Pharmaceuticals Ltd., a Public Sector Undertaking as well as many local generic companies is vital in this regard. Local production is important for fair access, which in turn also reduces the substandard products which find their place due to constrained access.

Fourth

The fourth point runs in continuation with the low quality and high prices concern. The document is concerned with therapeutic and structural access but not quite a lot on financial access (completing a rational course). The argument for fair financing is based on the assumption that fair financing for the private manufacturers is the best way to solve the availability and shortage. It continues to create the old unfair debate in the name of fairness where Fair financing is pitted against fair access or affordability. Affordability of antibiotics is a concern for many resistant infections including TB and also affects stewardship, optimal dosage as well as duration, which are vital for antibiotic resistance. We believe that affordability concerns can help us bring a more optimal solution to the AMR crisis.

Fifth

The document correctly identifies that "The data required to sufficiently understand local AMR conditions and to develop strategies to foster improvements are incomplete." Forecasting mechanisms and procurement mechanisms such as pooled procurement are essential for rational access to antimicrobials. The SECURE initiative seeks operational costs of SECURE portfolio from participating countries (including L and MICs). However, given the wide stakeholders network, we are concerned with surveillance and forecasting roles within this model. Clearly, manufacturers, industries and their sponsored organizations cannot be allowed to play a part in such roles as it could mean a direct conflict of interest. With the operational costs from participating countries, SECURE should help in strengthening the forecasting and procurement mechanisms without any involvement of stakeholders with conflicts of interest.