EDITORIAL

THE NEED FOR LOCALLY DEVELOPED FORMULATIONS

The 1994 malaria epidemic in the lake (Victoria) basin created a crisis of unprecedent proportions in the Gusii highlands, which outstretched healthcare resources beyond their capacity. Such transmission upsurges often coincide with the long rains thus triggering characteristic epidemics in the highlands surrounding Lake Victoria. The scenes in public healthcare facilities were heart wrenching, a sad display of suffering and frustration for both overworked healthcare workers and desperate patients. Several patients including children developed malaria complications and many deaths were recorded. At the time, the first line drug for case management was chloroquine, but due to resistance quinine was frequently used as an IV infusion followed by oral dosage upon discharge of the patients. However, oral quinine was only available as tablets of 300 mg strength which presented a problem in the management of paediatric patients. During the crisis, doctors of course looked up to pharmacists to provide solutions. They faithfully prescribed quinine by body weight according to guidelines. As a pharmacy student on attachment, I had first-hand experience in providing innovative solutions to address the issues at hand. Naturally, extemporaneous preparation of quinine suspension using tablets in suitable base was the only way out. In the absence of sugar syrup, we resorted to multivitamin syrup as base. The formulation was carefully calculated to produce the prescribed dose (mg of quinine base) per 5 ml which was then conveniently administered eight-hourly. To my knowledge, that period heralded the origin of quinine liquid forms whose stability is still controversial.

Three articles in this issue of the journal focusing on specialty preparations are reminiscent of the 1994 story above. It is encouraging that efforts are being made in our universities towards development of home-grown solutions to unique dosage form requirements. Several formulations for paediatrics, geriatrics, dental, dermatology and palliative care do not have commercial off-the-shelf brands thus making extemporaneous compounding the most practical source. This scarcity is elicited by low consumption volumes which makes commercial production unprofitable. Yet these products are vital in the management of the target patients. Formulations for children and aged persons are designed to achieve ease of swallowing, acceptable palatability and convenience of administration. Liquids such as syrups and suspensions remain the formulation of choice for these cohorts but suffer the drawbacks of bulkiness and instability. Therefore, more convenient dosage forms such as orally disintegrating tablets may be preferable. With respect to dental products for periodontal disease and prophylactic post-dental procedures, local action is often desirable. A wide range of dosage forms have been applied including rinses, pastes, gels, ointments, chips and fibres. Dermatological products on the hand, present a challenge in cases where unique mixtures of drugs from diverse therapeutic classes are indicated for individual clients. In all these scenarios, extemporaneous production of the required specialty products may not be feasible due to unfavourable cost-effectiveness which makes institutions prefer commercial products. In addition, the stringent cGMP requirements for pharmaceuticals are not achievable in a typical dispensing pharmacy, due to high costs and complex process requirements. Therefore, specialty commercial manufacturers, remain the most reliable source of these products.

About 70% of pharmaceutical products in the Kenyan market are imported. This means that foreign production is unlikely to be responsive to the local market needs. Manufacturing companies usually focus on high volume products with an established market demand. Hence, the domestic industry needs to perform market research to elucidate and respond to local pharmaceutical needs despite the limited market. Incidentally, the research and development (R&D) capacity for local pharma is weak due to low investment, poor innovation capability and shortage of the necessary expertise. This in effect undermines the potential for development of products by local manufacturers. Conversely, it also presents an opportunity for the establishment of academia-industry collaborations to forge synergistic partnerships which are the *sine qua non* for a robust local industry.

To promote local manufacturing, the regulatory regime is expected to stimulate the requisite investment through establishment of a supportive framework. It is imperative to build and nurture local manufacturing capacity to meet domestic pharmaceutical needs. This calls for deliberate establishment of comprehensive, sustained and suitable programs for product development in support of the government's big four agenda, with manufacturing as a major pillar. Further, government support through economic incentives, such as reduction of costs of industrial hardware, labour, taxation and energy are also required. Additionally, devolved governments should strategize on how to promote industrialization, cottage industries and innovation hubs in their individual counties.

For a long time, academia has been accused of not advancing research findings beyond journal papers. To achieve discernible positive impacts, research outputs should be relevant and applicable in solving societal problems. The focus should therefore be directed towards existing industry needs and gaps. If this agenda is consistently advanced, developing countries will gradually utilize their intellectual property resources towards self-sufficiency thus ending the current dependence on imports. It is my hope that the formulations described in the relevant articles in this journal will someday enter the market.

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