EDITORIAL

SELF-SUFFICIENCY IN PHARMACEUTICAL MANUFACTURING

The terms, 'self-sufficient', 'self-reliant', 'autarkic' are used interchangeably to describe a scenario whereby an industry or economy satiates its regional requirements without the need for imports. Though ideal, autarky may not be readily tenable due to the complexity and interplay of various factors involved in industrial production. Nonetheless, aiming for 'self-sufficiency' is the aspiration of many economies around the world.

With focus on the pharmaceutical industry, consider a nation with the capability to locally manufacture all pharmaceutical products for its entire population. These products would comprise a wide range of dosage forms including but not limited to tablets, capsules, injectables, suspensions, creams, ointments and possess diverse pharmacological actives such as analgesics, anti-infectives, anti-diabetics, anti-hypertensives, and cytotoxics. Manufacture of such a vast array of products would require significant industrial investment in terms of personnel, training, energy and equipment. Furthermore, unique requirements such as dedicated production facilities for hazardous/sensitizing drugs and controlled environments for the production of light, oxygen or temperature sensitive drugs would need to be considered.

For a nation with a 'self-sufficient' pharmaceutical industry, key advantages would include a more efficient supply chain by eliminating delivery delays, customs embargoes occasioned by importation and better pricing control. Notably, the economy of such a nation would be bolstered by the generation of employment opportunities through local production.

The current issue of this journal features an article by Vugigi et al., that analyzes the production capacity of the Kenyan pharmaceutical industry and forecasts the year 2043 for full manufacturing capacity utilization, an important prerequisite for autarky. The results obtained reveal that in 2014 the nation's utilized production capacity was only 27.4%. The underutilized production capacity was occasioned by low demand for local products due to importation of cheaper pharmaceutical equivalents, high costs of electricity, staff shortages and insufficient government incentives. There is an urgency to address these challenges and offer appropriate stimuli to strengthen the local pharmaceutical industry. In relation to this, Kenya's Vision 2030 aims to develop a robust and competitive local manufacturing sector.

With regard to pharmaceutical dosage forms, the available production capacity was highest for tablets at 29.3 billion units based on analysis of two shift operations. Notably, these tablet lines had an idle capacity of over 70%. Despite this unutilized production capacity, the nation still relies heavily on importation of some tablet products (antiretrovirals, anti-malarials and antituberculars) due to prequalification requirements, highlighting an area which could immediately be advanced to improve the local production capacity and near 'self-sufficiency' of this critical industry.

Tablet formulation entails careful selection of excipients, unit operations such as blending, granulation, compression and coating (optional). The complexity of the formulation process depends on the type of tablet, with modified release tablets requiring more expertise. The quality of delayed release tablets is largely dependent on the integrity of the enteric coating in the acidic media of the stomach, whilst that of extended release tablets is dependent on the success of the control-release matrix or coating. These drug release modifying coatings and matrixes are often polymeric in nature, indicating the input of various specialities in the formulation process.

Quality evaluation of tablets involves various pharmacopeial tests such as weight uniformity, uniformity of content, friability, hardness, disintegration, assay and dissolution. Whilst for immediate release tablets these tests may be rapid and straightforward, for modified release tablets the disintegration and dissolution tests may involve utilisation of different test media and markedly longer test durations. Despite this diversity of quality tests, it is imperative that individual manufacturers establish functional quality control laboratories to support production.

Another complexity encountered in tablet formulation entails the development of fixed-dose-combinations comprising different active pharmaceutical ingredients. Several antiretroviral and

antitubercular tablets fall in this category, understandably to reduce pill burden and improve patient compliance. The entire formulation process must take into account the properties and stability of the individual active pharmaceutical ingredients therein.

Furthermore, generic tablets are expected to comply with ICH guidelines with regards to pharmaceutical and therapeutic equivalence. This is particularly critical for antiretroviral, anti-malarial and antitubercular drugs owing to the risk of anti-microbial resistance if the generic products do not meet the desirable drug concentrations *in vivo*.

Against this backdrop, focus of Kenya's available industrial resources and technical expertise in the formulation of tablets is prudent. The local manufacture of pharmaceutical tablet products among others would ensure 'self-sufficiency' in this frequently used dosage form.

Dr. Lucy J. Tirop (PhD)

Formulation specialist/Editor