

The Seed, Tree and Fruits of Sri Lankan Drug Policy

The story of Prof Senaka Bibile, State Pharmaceuticals Corporation, Students Involved in Rational Health Activities and the National Medicines Regulatory Authority

It started with him! He was the seed. And the seed was strong! Prof Senaka William Bibile graduated from Ceylon Medical College with a First-Class Honours and two Gold Medals in Surgery and Medicine. After acquiring his PhD from University of Edinburgh in 1952, Prof Bibile became the first Professor of Pharmacology in Sri Lanka. He extended his service to the entire world through the United Nations Conference on Trade and Development by preparing drug policies for several countries, until his untimely death at 57 years on 29th September 1977 in Georgetown, Guyana.

Prof Bibile's contribution to pharmaceutical reforms in Sri Lanka started in 1957; he rationalised the medicines that were being procured by the government Medical Supplies Department and was instrumental in publishing the Ceylon Hospital Formulary which provided information on the medicines. Due to the shortage of foreign currency in the 1970s, imports were cut down. Prof Bibile used this opportunity to rationalise drug procurement for the whole country, decrease the cost and still make sufficient quality assured medicines available to the healthcare system of Sri Lanka. The historical 'Bibile-Wickramasinghe Report' titled 'Pharmaceuticals Management in Ceylon', was submitted to then Prime Minister, and featured in the British Medical Journal along with an editorial. This was the tree he planted. There were 5 key recommendations in this historical report that bore fruit!

1. **A State Buying Agency** for import, distribution, storage, and quality control of drugs. This was achieved by implementing the State Pharmaceuticals Corporation (SPC) on 22nd September 1971. Prof Bibile was the first Chairman of SPC.
2. **Rational use of drugs.** This was accomplished by having a defined list of effective medicines relevant to healthcare needs being purchased for the country. It saved a huge amount of foreign exchange by stopping the import of unnecessary drugs. Later, the Sri Lankan experience provided the groundwork in the WHO Essential Drugs Concept in 1975 and its implementation of the Essential Drugs List in 1977 (now known as the WHO Model List of Essential Medicines). The initiative in Ceylon achieved global results in 1975.
3. **Independent drug information for doctors.** This was achieved by publishing regular bulletins of "Formulary Notes", which later became the "The Prescriber". Now, it is named as "The Sri Lanka Prescriber" and is published by the SPC with complete editorial independence of the Editors from the SPC.
4. **Pharmaceutical formulation and manufacturing in the country.** This was attained by establishing the State Pharmaceuticals Manufacturing Corporation (SPMC) in 1987, which manufactures essential medicines by the generic name, all of which are quality assured for the Sri Lankan healthcare system for both the public and private sector.
5. **Training of pharmacists and improving the profession and conditions of pharmacies.** To improve the conditions of pharmacies, 'model pharmacies' were established, named "Rajya Osu Sala" ("State Pharmacy"), which enabled the SPC to provide medicines at affordable prices to patients in the private sector.

Prof Bibile also took several steps to ensure quality by evaluating the manufacturers wherever and whenever possible. Later, a drug quality control laboratory was implemented and named as National Drug Quality Assurance Laboratory (NDQAL).

Prof Bibile once said, "I do not want loyalty towards myself. I want loyalty to my ideas". Inspired by Prof Senaka Bibile's ideas and work, Students Involved in Rational Health Action (SIRHA) was founded in July 1992 at Faculty of Medicine, University of Colombo. The objective of SIRHA was to give Sri Lankan medical students the opportunity to question the current state of health care in Sri Lanka, increase awareness for rational health care, and find solutions to challenges faced by the system. The group achieved national and international recognition within a matter of few years. SIRHA changed the attitudes of medical students towards rational health care. For example, students of Colombo Medical Faculty decided not to obtain sponsorships from Pharmaceutical Companies for events organized

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by the faculty. With current medical students, SIRHA is continuing to do its part for improvement of the public health of Sri Lanka, with a broader area of concern. SIRHA is now involved in activities against substance abuse and illicit trafficking as well.

Medical students of Sri Lanka usually check the prices of the drugs that are mentioned in the lectures/wards to get an idea of the cost. What we always find is that SPC price is lower than everything else, with quality assured! In other words, even after 43 years from Prof Bibile's untimely death, the policy is still working! For example, SPC price for one Paracetamol 500mg tablet is LKR 0.91, while brand prices range from LKR 2.25 - 2.50 in the private sector. This is the same for the rest of the medicines.

Sri Lanka has a state health sector (from the 1940s), which is FREE at the point of care and the cost is borne completely by the government. However, a parallel private sector also plays a role in providing health care in Sri Lanka due to excess demand on the government sector. Therefore, affordable maximum retail prices should be there for each and every drug as cost is an important determinant for patients when prescribing medicines. As medical students, we are trained to use generic names only. We are trained not to use trade names by the Sri Lankan MBBS degree programme.

Extending Prof Bibile's work, a new chapter started in the medicines registration system of Sri Lanka when the National Medicines Regulatory Authority (NMRA) was established in 2015. The primary objective of NMRA is to increase patient access to quality-assured, efficacious, safe, cost effective medicinal products. This includes drugs as well as cosmetics. This initiative was a novel solution for low- and middle-income countries and broke away from considering only the three pillars (quality, safety, efficacy) of medicines registration, by adding a fourth; 'cost effectiveness'.

Before NMRA (1977 – 2015), the registration system had failures. For example, 172 brands were registered for the generic name atorvastatin. But NMRA was given powers to prevent such unnecessary registrations. NMRA is strict about the price regulation also. Recently the NMRA issued notices of cancellation of registration to 10 medicines belonging to 5 pharmaceutical companies for violating pricing regulations.

Before concluding, it must be noted that, rational use of quality-assured, cost effective drugs is a war! A war between 'patient-friendly drug policy advocates' and Big Pharma'. From the very first day Prof Senaka Bibile initiated his pharmaceutical reforms, up to the very present moment, Big Pharma has been continuously taking every possible step to make sure 'patient-friendly drug policy' does not happen! However, whatever they do, how powerful they are, effective Drug Policy will stand strong as long as compassionate and caring doctors are produced.

In conclusion, to enforce patient-friendly drug policy and ensure GMP, local manufacturing of more drugs by SPMC should be encouraged. If the government can again think about SPC as the ONLY buying agency of drugs for Sri Lanka, as Prof Senaka Bibile wished, money wastage will be reduced. NMRA and NDQAL should also inform the public about their test result and actions taken for quality assurance via newspaper notices.

In summary, Prof Bibile's initiative has come a long way. NMRA has been ensuring the quality-assured, cost effective drug supply to the patients of Sri Lanka, against the odds created by the Big Pharma. As medical students, as SIRHA, we support the actions taken by the NMRA of Sri Lanka to regulate drugs within the country in an independent manner, for the improvement of the public health of Sri Lanka.

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