

Brief Report

Outlook for the Pharmacy Profession at the Dawn of the Decade 2020s

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Abstract

Pharmacy profession operated at elementary level in Sri Lanka well up to the beginning of the 21st century. Their training programs were limited to certificate level, with courses of 1-2 years duration. With the introduction of the four-year university degree programs, pharmacy profession now carry the prospects of making good for the lost time. However, they still appear to be professionally somewhat timid hindering the realization of their full potential. There are many encouraging developments which are bound to promote a bright future. The positive, negative and many other areas related to pharmacy profession are discussed.

Keywords: Professional organizations, Covid vaccine, Last gate, Pharmacy Council

Introduction

The author had spent over a quarter of a century as a lone active pharmacy graduate in Sri Lanka. He was perplexed as to why there wasn't a single personality in the country that had any idea about the pharmacy profession valued at multibillion dollars. It was the S. A. Wickremasinghe – Senaka Bibile report in 1971 that had well thought out strategies, each taking over one decade to implement [1-2]. It is expected that this article will open up a wide range of professional pathways available to the contenders. After a long anxious wait, a spurt of developments all around the pharmacy profession is now taking effect. Notable among the positive developments are the successful establishment of the pharmacy degree programs in a number of universities, expansion of the pharmaceutical industry, the introduction of the National Medicines Regulatory Authority Act No 5 of 2015, improved standing of the Pharmaceutical Journal of Sri Lanka which is the scientific journal of the Pharmaceutical Society of Sri Lanka (PSSL) with online accessibility [3] and our pharmacy graduates serving the industry productively at

various levels. Apart from being academics in our universities, they also hold academic positions in a number of universities in advanced countries.

There are other negative developments though probably done in good faith, are not quite keeping in line with the stringent practices and ethical standards of the pharmacy profession. These events in turn tend to erode the standards and the image of the profession. This brief report is presented in a lucid reader friendly sectional format for easy deciphering. It is hoped that the article will generate a renewed vigorous dialogue among the members of the health sciences professionals. The traditional artefacts should be speedily phased out.

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Received: 05 December 2020; Accepted: 18 December 2020

How to cite this article:

Pathirana, W. Outlook for the Pharmacy Profession at the Dawn of the Decade 2020s. Journal of Health Sciences and Innovative Research, 2020;1(1):55-63.

The facts are presented to the best of the author's knowledge and any omissions are regretted. Other allied health sciences professionals will be able to analyze their situation in relation to each section.

The progress of the pharmacy profession is on a two-pronged drag down, one from within and the other from without. From within is the attitude of the professionals themselves, "I have graduated, succeeded in obtaining a job, career hurdles will be cleared automatically in a system that lacks rigorous assessment where there is none to take one to task, secured for the rest of the life and shall live happily ever after". In a vibrant relentless global pharmacy advancement, to be stagnant is to lose grounds. From without, it is mainly the administrative authorities of the healthcare system. It is essential to undertake the responsibilities of pharmacy profession by a Pharmacy Council.

The allied health sciences training standards and the professional outlook remained stagnant at an elementary level in Sri Lanka right up to the dawn of the 21st century. Many of them were not under the control of appropriate professional bodies. With the introduction of the four-year university degree programs in nursing, medical laboratory science, physiotherapy, radiography and pharmacy in line with the international norms, it is time that we start making headway with our own inherent professional strengths.

The current Covid-19 pandemic has brought to light unending demand for nursing care, complex of medical laboratory tests, physiotherapy and the deadly consequences of non-availability of an effective pharmaceutical against the disease. It should be an inspiration to the pharmacy professionals to witness how the best of the brains, pharmaceutical firms, cutting edge technologies of the world are pooled together in the discovery of an effective vaccine for the

pandemic, more accurately the pestilence. This should be an eye opener to the pharmacy professionals about the fact that no other profession offers such an array of diverse scientific pursuits. The current predicament of the humankind in the absence of an effective pharmaceutical, vaccine or otherwise, could be quoted by pharmacy professionals for years to come. It shows the significance of what is said to be the "last gate", the administration of the appropriate drug (s) after a series of "gates" to be cleared, the examination, testing, screening, diagnosis and prescribing. One should not take what is available for granted and should strive to keep the pharmaceutical products and services supplied continuously for 24 hours, 365 days.

One must be thinking, "How on earth we can undertake such intricate expensive research work like new vaccine production"? You can undertake less expensive research like the American specialist doctors who treated their country's president with a cocktail of six regular drugs, only special item being the monoclonal antibodies [4]. In this part of the world, a simple salt and sugar formulation, the Oral Rehydration Salts introduced by Bangladeshi doctors was selected as the outstanding medical advancement of the last century [5]. One can also use these two examples as awareness spot checks to find out if you are an informed pharmacy professional or not.

Historical hindsight

Separation of medical and pharmacy professions took effect over seven centuries back in Europe [6]. This was due to realization about the unique needs and the competencies in the two professions. The very term 'medical' profession denotes the significance of medicines meaning the drugs or the pharmaceuticals, thereby that of pharmacy profession in the management of patients. Not only for the sick, the pharmaceuticals are used on healthy populations

too as prophylactic measures with vaccines, post-operative hormone replacement, performance enhances and in oral contraception. It is this separation and the resulting freedom that had led to the fully blossomed profession of pharmacy for the greater benefit of mankind, not forgetting the animal kingdom. Preparations in the indigenous medicines date back to well over 2000 years.

The landmark developments related to the modern pharmacy profession in Sri Lanka are listed here.

1. Up to 1940s: Earliest pharmacy practitioners were the apothecaries and dispensers, hands on training through father to son. Extemporaneous preparations, imperial measures and Latin terms were in common use.
2. 1940s: The first formal apprentice pharmacists training program in Sri Lanka took effect leading to Certificate of Efficiency in Pharmacy. Few years later, they were offered registration under the provisions of the Medical Ordinance.
3. 1950s: Certificate of Proficiency in Pharmacy introduced for the Government service but was not eligible for registration.
4. 1950s: The Licentiate in Medicine and Surgery (LMS) training program in medicine upgraded to Bachelor of Medicine, Bachelor of Surgery (MBBS) degree but no parallel development in pharmacy. This disadvantage lasted for the next 50 years with far reaching consequences in general for healthcare delivery and in particular to the pharmacy profession.
5. 1980s: Cosmetics, Devices and Drugs Act No. 27 of 1980 came in to force. Enactment of three sets of Regulations for cosmetics, devices and drugs took effect in 1984. Until then, drugs were governed by Food and Drugs Act 1949.
6. In 1981, recommendations were made to commence a degree program in pharmacy by a World Health Organization (WHO) consultant Professor P. F. D'Arcy, Queen's University of Belfast. Then in 1987 by Professor Gita Fernando,

Faculty of Medicine, University of Colombo and in 1994 by Norwegian consultants Jan Karlsen, University of Oslo, Norway, Kare Oydvin, Norwegian Medical Depot and Hanne Hjorth Tonnesen, University of Oslo [7, 8, 9]. It took 20 years since the first recommendation to commence the B.Sc. Special Degree in Pharmacy at the University of Colombo in 2000.

7. In 1985, pharmacy registration was offered to those engaged in Government service qualified in the Certificate of Proficiency in Pharmacy.

8. In the year 1987, the formulation center of the State Pharmaceuticals Corporation (SPC) Ratmalana, was established with the aid of Japan International Corporation Agency. Since the large investment disrupted costing, it was separated within one year as the State Pharmaceuticals Manufacturing Corporation (SPMC).

9. In 1993, the Diploma in Pharmacy program was commenced at the University of Colombo, terminated in 2002, a total of only 110 passed out, with a pass rate of 25%. This was the first pharmacy qualification awarded by a university in Sri Lanka. It was an after hour 6.00-8.00 p.m. extension course for want of facilities, not in keeping with the policy that healthcare programs should be conducted only during regular hours.

10. In the year 2000, with the collaboration of Science and Medical Faculties, B.Sc. Pharmacy degree program was commenced at the University of Colombo with a batch of 10 students, the first ever pharmacy degree program in the Sri Lankan university system.

11. In the year 2005, the policy matters given in a series of semi-official and well written drug policy documents during 1960s, 1970s and 1990s were consolidated into a single document, the National Medicinal Drug Policy for Sri Lanka (NMDP) [10]. This is the most important basic document that had given directions to most of the developments we witness today. With the early setting up of a National Standing Committee, many of these policy matters have been implemented, particularly those related to the

pharmacy profession.

12. In 2006, under the World Health Organisation (WHO) consultant Dr. Susan Walters of Australia, a comprehensive report was framed on establishing a new regulatory authority following a series of meetings [11].

13. In 2006, an application was received from a foreign student from Kenya to join the University of Colombo, B. Sc. Pharmacy program (it was turned down).

14. In 2006 B. Pharm programs were commenced at the Universities of Peradeniya, Sri Jayewardenepura, Ruhuna and Jaffna. In 2011 the Open University of Sri Lanka started recruiting registered pharmacists for their B. Pharm degree program. About the same time B. Pharm degree program was commenced at the General Sir John Kotelawala Defence University, Ratmalana, established under an Act of Parliament.

15. In 2015, established the National Medicines Regulatory Authority Act No. 5 of 2015.

16. In 2018, the University of Vocational Technology, Ratmalana, in liaison with selected manufacturers initiated a program for prospective pharmaceutical factory operators for the award of National Vocational Qualifications (NVQ) grade V claimed to be equivalent to a master's degree. National Apprentice and Industrial Training Authority (NAITA) in liaison with the Pharmaceutical Traders Association and freelance external pharmacy trainers started awarding NVQ grade IV certification as pharmacy technicians. This may lead to a conflict with future plans for internationally recognized pharmacy technician program under proposed Pharmacy Council Act (The Pharmaceutical Society of Sri Lanka is working tirelessly on the Pharmacy Council for the last 30 years).

It is self-evident how hard and long were the efforts taken to bring the profession to this point. It is poised for a bright future more so if decisions are made collectively through representative associations. The feedback is that

the graduates who had taken up challenging carriers are making a good impression in their respective institutes and also with the medical profession with whom the affairs of our profession are closely linked.

Stakeholders in pharmacy

Regular and irregular categories appear in the list below.

1. Pharmacists registered with the Sri Lanka Medical Council in active community practice or hospital pharmacy practice.
2. Pharmacists registered with the Sri Lanka Medical Council not in active practice. Some of them happen to be in other regular employment, reportedly sell the registration certificate to run pharmacies without the presence of a pharmacist. This is the "autoimmune disease of the pharmacy profession".
3. Community pharmacy support staff, usually family members and unemployed youth.
4. Academic staff of pharmacy degree programs with regard to pharmacy undergraduate education.
5. Staff involved in Certificate of Efficiency and Certificate of Proficiency programs in Pharmacy in the universities and the National Institute of Health Sciences, Kalutara and those serving the Ceylon Medical College Council.
6. Master Pharmacists in training apprentice pharmacists for the Certificate of Efficiency in Pharmacy.
7. Private tutors engaged in training candidates for the Certificate of Efficiency in Pharmacy.
8. Quality assurance personnel under National Medicines Quality Assurance Laboratory (NMQUAL), Medical Research Institute (vaccines), Industrial Technology Institute and the Government Analyst Department.
9. Authorized Officers engaged in inspection.
10. Manufactures, importers, wholesalers and distributors.
11. Medical representatives.
12. Practitioners of Alternative Medical Systems.

13. Veterinary Drugs Control Authority that regulate veterinary drugs.

Non-practicing registered pharmacists slowly erode the integrity of the profession. There is a dire need to strike off registration when not in active practice. There is evidence regarding the poor application of master pharmacists in the training of apprentice pharmacists by treating them as mere helping hands. It is time that only graduate pharmacists become drugs inspectors since inspection on many aspects of both hardware and software of current Good Manufacturing Practice (cGMP) are wanting. These include the manufacturing facilities, production, quality control, documentation, analytical procedures, instrument validation and the environmental concerns.

It is the responsible work voluntarily done by the pharmaceutical industry that holds it in high esteem year after year with no adverse issues. The Sri Lanka pharmaceutical manufacturing industry operates under a strict disciplinary and ethical code mostly unwritten. Over the years a number of persons out of step with the system were weeded out from the industry. The currently emerging new industries must be taken in to this fold as early as possible.

Threats

1. Inadequate representation of pharmacists at all levels in the Government healthcare administration set up. The Medical Supplies Division was headed by a graduate pharmacist Mr. D. A. Munasinghe until early 1990s.
2. Inadequate corporation between different trade unions and professional organisations in the healthcare system.
3. Monopoly on veterinary drugs.
4. Ad hoc training and award of pharmacy related qualifications outside established norms and not recognized by the Medical Ordinance.
5. Practitioners of other medical systems using

modern drugs having no regard for laws and regulations. No prescription drug should be available to them according to the Sections 105 and 119 of the National Medicines (Registration and Licensing) Regulations, 2019.

6. Practicing and senior pharmacist's failure to keep up pace with modern advances in the pharmacy profession and the resistance to update. Extremely poor reading habits prevent any expansion of the wider subject knowledge.

7. Absence of a Pharmacy Council so that everyone is left to his/her own devices and profession left rudderless.

8. Prospects of unauthorized foreign pharmacists in Sri Lanka.

9. Prospects of unauthorized foreigners engaging in the pharmaceutical industry.

10. A culture in which the authentic pharmacy profession is in total isolation from pharmacy industrial and business houses. This has resulted in a dearth of funds coming in the way of sponsorship of professional activities, research and development work. However, one private manufacturer offers a scholarship and a gold medal annually to an academically deserving undergraduate at the University of Colombo and an annual scholarship for the University of Peradeniya.

11. Absence of any central authority in regulating pharmacy education and training.

12. Pharmacy graduates' reluctance in opening up to the wide world of careers available to them in the pharmacy profession and bring to bear their full capacities.

The current spurt in the expansion of the pharmaceutical industry and in the academic sectors must be guarded carefully. It has the potential to disrupt the time old traditions and ethical norms in the event raw recruits are absorbed without due diligence. It is said that the entire progress in pharmacy depends on professional ethics [12]. In the United State of America, a pharmacist was sentenced to 30 years

imprisonment including US \$ 100 million settlements to the victims for adulteration of anticancer capsules [13]. The highest-ranking officer in charge of pharmaceuticals in a major country was sentenced to death on an adulteration fraud [14].

Lost control by the Pharmacists

1. Some retail pharmacies are not owned by pharmacists.
2. A new trend in stocking excessive amounts of drugs by persons not authorized to do so.
3. No due attention paid to devices, controlled cosmetics and border-line substances. A very large number of medical devices are in use at present, many are expensive.
4. Very few pharmacists are engaged in import, wholesale, distribution and transport of drugs including highly sensitive biologicals and diagnostics.
5. Inadequate involvement of pharmacists in Blood banks.
6. Use of radiopharmaceuticals.
7. Absence of ward pharmacists in major hospitals.

It was reported that in Australia, over 90% of pharmacies are owned by pharmacists themselves. Drug import business is a trade in excess of billion rupees and pharmacists remain shy in claiming the share due to them.

Pharmacy related organizations

1. Pharmaceutical Society of Sri Lanka (PSSL)
2. The Society of Government Pharmacists.
3. Sri Lanka Chamber of Pharmaceutical Industries.
4. Pharmaceutical Traders Association of Sri Lanka.
5. Student forum of the Pharmaceutical Society of Sri Lanka (PSSL-SF) which will be the Sri Lanka chapter of the International Pharmaceutical Students Federation (IPSF) being coordinated by the Pharmaceutical Society of Sri Lanka.

Undergraduates of almost all pharmacy degree programs have already signed up. The new generation pharmacy graduates must take an interest in making representations through associations.

Educational and training institutes

1. University of Colombo, B.Sc. Special Degree in Pharmacy.
2. University of Peradeniya, University of Sri Jayewardenepura, University of Ruhuna, and University of Jaffna, the Bachelor of Pharmacy degree.
3. General Sir John Kotelawala Defence University, established by an Act of parliament outside the Universities Act, the Bachelor of Pharmacy degree.
4. Open University of Sri Lanka, Bachelor of Pharmacy degree under distant education mode for registered non-graduate pharmacists.
5. National Institute of Health Sciences (NIHS), Kalutara, trains candidates for Certificate of Proficiency in Pharmacy.
6. National Apprentice and Industrial Training Authority, commenced awarding NVQ Level 1V certificate for pharmacy assistants.
7. University of Vocational Technology, Ratmalana, intends awarding NVQ Level V certificates for new trainees on pharmaceutical manufacturing technology. Claims to be equivalent to a master's degree.
8. Several private institutions. The quality of the academic programmes offered by the private institutions need to be evaluated appropriately.
9. Mooted idea in setting up a School of Pharmacy affiliated to a university by the Government. The purpose is to award Diploma in Pharmacy for the proposed category of registered Pharmacy Technicians in line with international norms.

Absence of a Pharmacy Council has led to four types of pharmacy degrees. Just as seven universities commenced pharmacy degree

programs on the one hand, it was dragged down to apprentice and vocational training levels on the other hand. There is an uncontrolled proliferation of all shades of pharmacy training programs. Absence of foreign students deprives wider exposure of our graduates during university life and denies income to the universities.

Governing bodies related to pharmacy profession

1. University Grants Commission.
2. National Medicines Regulatory Authority.
3. Sri Lanka Medical Council.
4. Ceylon Medical College Council.
5. Ministry of Health.
6. Pharmacy Council, yet to be established.

A well-established pharmacy profession will ease the unnecessary burden on the medical profession.

International organizations

1. World Health Organization.
2. International Pharmaceutical Federation (FIP).
3. Commonwealth Pharmacists Association (CPA).
4. Federation of Asian Pharmaceutical Association (FAPA).
5. South East Asian FIP-WHO Forum of Pharmaceutical Associations (SEARPharm Forum).

Many of these organizations offer scholarships, participation in seminars, generally at graduate level. In some years the offers go unfulfilled for not having graduate applicants. There are many other organizations where institutional membership is offered.

Law and ethics

1. Failure to establish the Pharmacy Council despite continuous efforts spanning over 30 years by the PSSL.

2. Failure to establish the PSSL Incorporation Act despite continuous efforts spanning over 30 years.

3. Little or no contribution by pharmacy professionals in framing new Acts and Regulations.

4. Lack of awareness of pharmacy laws and regulations of foreign countries having involvements in drug trade with Sri Lanka.

In the absence of a Pharmacy Council, many institutions, authorities and groups of people have undertaken conducting various types of pharmacy training programs. It is said that the extent of laws, regulations and specifications governing pharmacy profession is only second to that of nuclear power generation plants. Ours is an extremely sensitive profession as evident by the worldwide reaction to one single adverse reaction during the current Covid-19 vaccine clinical trials. All adverse events in this profession are remembered for decades.

Emerging trends

1. Increasing number of pharmacy graduates earning post-graduate qualifications including doctorates.

2. Increasing number of research publications and filing some patents by pharmacy professionals.

3. Commercializing some of the findings such as Orange Flavored Jeevani (oral re-hydration solution), Triposha Vitamin Premix, Povidone iodine and Bioclean.

4. Publication of books locally and three B.Sc. Pharmacy, University of Colombo research projects abroad.

5. Many undergraduates earning postgraduate positions in foreign universities.

6. Demand for pharmacy graduates in the industry.

7. Proposal for setting up a School of Pharmacy by the Ministry of Health.

8. Prospects in specialist pharmacists (organ

transplant, oncology, total parenteral nutrition, pediatric, anticoagulant, other) including prescriber pharmacists.

9. Need to harmonize private community pharmacies for an elegant professional reflection with appropriate pharmacist's attire, pharmacy name boards, pharmacist's name, qualification, registration number and working hours. Pharmacies must be shut down when the pharmacist is out. It enhances the concept that the pharmacist is the custodian of drugs.

10. Immediate measures must be taken to institute an oath taking ceremony for all newly registered pharmacists in line with medicine and nursing.

11. Many countries recognize five-year basic pharmacy degree for registration purpose [16]. Others require the six-year qualification, Doctor of Pharmacy (Pharm D).

12. Need to implement charging a "Consultancy Based Retail Pricing" scheme for pharmaceuticals mooted 25 years back.

13. Initiation of postgraduate study programs in State universities

Current "profit markup" scheme is unfair by the generic drugs and common citizens where the pharmacy earns little compared to the equivalent brand. This scheme has eliminated some of the time-tested preparations like chlorthalidone tablets and an expensive brand has taken its place. The consultancy earning scheme will encourage pharmacists to professionally empower themselves which they do half-heartedly at present. Under this scheme brands or generics earning will be the same while practicing under the image of a consultant.

Newly qualifying pharmacists must venture in to commercializing of preparations. Once the School of Pharmacy is set up, all shades of non-degree courses can be consolidated into an internationally acceptable Pharmacy Technician qualification. It carries the prospects for earning

degrees with additional training. Postgraduate studies could be undertaken in line with the specialist pharmacist streams. The new norm is that the doctors are disease specialists and the pharmacists are the drug specialists.

Lost opportunities of the pharmacy profession

1. Poor representation in drug administrative set up of the Ministry of Health.

2. Ownership in import and distribution sector neglected. Need to strive towards high profile entrepreneurship.

3. Export of pharmaceuticals remains a trickle so far.

4. Implementation of new manufacturing facilities

5. Failure to diversify and expand the use of extemporaneous preparations in therapy. There are reports that 30% of all prescriptions in the UK are extemporaneous including pediatric and total parenteral compositions.

6. Insufficient attention to medicinal plantations, herbal and indigenous preparations.

7. Non participation in social healthcare programs such as cessation of smoking, prevention of drug addiction, birth control programs, preventive medicine measures against non-communicable diseases and obesity.

Export of pharmaceuticals should be encouraged in order to facilitate growth of the local pharmaceutical industry. International herbal medicine trade is a multibillion rupee worth business that has good prospects to develop. The professionals themselves must be the driving force.

Acknowledgement

Contribution by Ms Chinta Abaywardana particularly in improving the accuracy on chronology and details of institutions is highly appreciated.

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