JOINT SELECT COMMITTEE ON LOCAL AUTHORITIES, SERVICE COMMISSIONS AND STATUTORY AUTHORITIES (INCLUDING THE THA)

An Inquiry into the Current Systems and Procedures for Regulating the operations of Pharmacists and the practice of Pharmacy in Trinidad and Tobago

Written response on the 15th Report of the JSC on Local Authorities, Service Commissions and Statutory Authorities (including the THA)

Objective 1: To examine the trends in the local Pharmacy Industry.

Recommendations

1. **The Committee strongly recommends that the three main health stakeholders namely the MOH, the School of Pharmacy and the Pharmacy Board engage in discussions with a view to investigating the feasibility of expanding pharmacy education to include post-graduate programmes culminating at the Doctoral level.**

   The Ministry of Health will continue to work with key stakeholders, namely; the Pharmacy Board and the School of Pharmacy to investigate the feasibility of expanding pharmacy education to include post-graduate programmes culminating at the Doctoral level.

   This has been conveyed to the University of the West Indies, School of Pharmacy, St. Augustine, which has agreed to engage in discussions over the next few months, in order to determine the feasibility of expanding pharmacy education in Trinidad and Tobago by the possible inclusion of post-graduate and PhD programmes in pharmaceutical sciences.

2. **A manpower assessment should to be performed prior to the issuance/consideration of work permits. Additionally, it should be mandated that unemployed registered Pharmacists submit their information to the Ministry of Labour and Small Enterprise Development as a means of recording the real time quantity of local pharmacists available to address local demands.**

   During the 1st quarter of 2021, the Ministry of Health should undertake the manpower assessment of Pharmacists to determine the need, use and deployment into Pharmacies.

   In addition, the Pharmacy Board of Trinidad and Tobago (PBTT) can either submit to the Ministry of Health or directly to the Ministry of Labour and Small Enterprise Development, the Register of all Pharmacists and notify registered Pharmacists to inform the Ministry of Labour and Small Enterprise Development of their registration status.

3. **The Committee recommends that there be legislative amendments which provide that Pharmacists engage in continuing education on an annual basis in order to maintain and increase the competence of Pharmacists as is practiced in Canada.The Committee strongly recommends that the Pharmacy Board and the MOH engage in a public awareness campaign with the aim of educating the public on the legitimate steps to becoming a Pharmacist. A list of the accredited schools through which this may be achieved should be provided. This is in an effort to reduce cases where citizens are unable to register as Pharmacists due to the pursuance of an illegitimate course.**

   All key stakeholders will be engaged to determine the feasibility and plan to incorporate continuous education within the system with the intention to support these continued initiatives in order to produce more competent pharmacists for the benefit of public health.

The Ministry of Health will engage the Pharmaceutical Society of Trinidad and Tobago and the University of the West Indies in completing this task of public awareness.

4. **The MoH must work with NIPDEC to continue to explore strategies for minimizing the wastage of drugs. While the redistribution of drugs nearing expiration is one existing method, we recommend that a database that captures the inventory of all pharmacies be implemented to assist with the management of stock. Given the relatively small size of our pharmacy industry such a database should be feasible.**

   The Ministry of Health and NIPDEC is currently developing and implementing a Logistics Management Information System. One of the objectives of this project is that the Regional Health Authorities (RHAs) will have end-to-end access to redirect stocks within the RHAs. Using this system, NIPDEC will have greater capacity to monitor and manage at the warehouse level and the Ministry of Health will have a complete overview of stock availability and distribution from point of procurement to point of dispensing to patient.

5. **Notwithstanding the ability to rely on foreign based testing of drugs (i.e. Regulatory reliance), state-run Labs should be equipped to handle an acceptable level of testing. To start, the MoH may aim to develop the capacity to test samples of plant-based substances that are locally produced and sold in pharmacies.**

   The contaminants and residue levels (microbiological and heavy metals contaminants and pesticides residues) can be facilitated utilizing the World Health Organization Guidelines for assessing the quality of herbal medicines.

Further, the Ministry of Health can explore engagement with The National Herbarium of Trinidad and Tobago, the Caribbean Industrial Research Institute (CARIRI) and the Trinidad Public Health Laboratory.

6. **A robust system of evaluating international drug sources and drug distribution channels should also be developed and maintained. Full participation in multilateral bodies such as the International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) may be beneficial.**

The current drug registration process as stipulated in the Food and Drugs Act Chapter 30:01 provides for a system of verification, quality, efficacy and safety of drugs. Trinidad and Tobago does participate with international bodies such as the Pan American Network for Drug Regulatory Harmonization (PANDRH) for the advancement of its regulatory mandate.

Currently, the Ministry of Health utilizes the Pan American Health Organization/World Health Organization (PAHO/WHO) listing of approved Laboratories to evaluate international drug sources.

Drug distribution channels are closely monitored as our existing procurement system must obtain pertinent information required to be submitted to the Customs and Excise Division for approval to enter the country.

Most International Regulatory Bodies are members of the ICH and since Trinidad and Tobago is engaging in the concept of Reliance by using the PAHO/WHO list of Regulatory Agencies for Regional reference, it can be inferred that ICH guidelines are adopted with respect to pharmaceuticals.

7. **There must be greater transparency and accountability by the state regarding the decision to approve and or reject drugs that are placed on the National Formulary. The rationale for approving/rejection of imported and locally manufactured pharmaceuticals by the Minister of Health and or the Drug Advisory Committee should be published in an annual report which by the end of the first quarter of the following year. With regard to imported drugs, the public should be informed of the quality assurance body that evaluated the drug.**

   The Ministry of Health will continue to implement measures aimed at greater transparency and accountability regarding the decision to approve and/or reject drugs that are placed on the National Formulary (NF). There is an established process for drugs to be placed on the NF. The NF is a list of medicines used within the Public Health System, which is a subset of the list of medicines registered for use in Trinidad and Tobago.

   The Drug Advisory Committee (DAC) is the responsible body for registered drugs in Trinidad and Tobago. A listing of the drugs registered by the Chemistry Food and Drugs Division is available on the Ministry of Health's website and has been gazetted.

   The quality assurance certificate is a document generated upon manufacture of each batch of medicines and is a requirement for all batches of medicine imported.

8. **The Committee endorses the following recommendation contained in a 2019 Pan American Network for Drug Regulatory Harmonisation Concept Note that it encourages member states to** ***"...use reliance to increase efficiencies and in particular, states with limited resources which are seeking fast improvements in regulatory capacities..."***

The Ministry of Health, in addition to, adhering to the standard process in the registration of drugs, also engages in the concept of reliance contained in the Pan American Network for Drug Regulatory Harmonisation.

9. **The MOH should also seek to make its approval and registration process for drugs more efficient. A review of the process should be examined with a view to eliminating efficiencies. This concern was also highlighted by another Joint Select Committee in its report on the efficacy of traditional medicine.**

The Ministry of Health continues to strengthen its approval and registration process for drugs. In February 2020, a Consultant was contracted, through the British High Commission, to review the registration process. The report was delayed due the COVID-19 pandemic and is currently being finalised through the British High Commission.

The Ministry of Health is currently implementing some of the recommendations made by the Consultant to enhance the classification of the registration process in order to reduce the time taken for registration.

10. **The Committee strongly recommends that the MOH and NIPDEC institute a mystery customer as a means of identifying the errant pharmacies which engage in this practice. Furthermore, the MOH should seek to create a public awareness campaign with a view to educating the public on the dangers of obtaining illegally imported drugs.**

NIPDEC is the procurement agency of the Ministry of Health and only procures for the Public Health Sector. Inspections of the Pharmacies in the public sector are conducted and all Pharmacists/Regional Managers are held responsible by regular audit checks.

In the private sector, the Chemistry, Food and Drugs Division and the Drug Inspectorate, Ministry of Health also conducts inspections and where possible, the Private Pharmacist/Owner is made aware of the registered items and seizures are conducted immediately. They are also held accountable for any possible breaches.

It should be noted that through product recalls, consumers are consistently advised on medicines from unreliable sources. It is noteworthy that public may not be aware of the sources and therefore, it is the responsibility of the Pharmacists in the Private Sector in the first instance, to ensure reliable sources are used for the procurement of their items and secondly, the Chemistry, Food and Drugs Division, Ministry of Health to conduct inspections for compliance with the list of items being offered for sale with its registered list.

The Chemistry, Food and Drugs Division and the Drug Inspectorate, Ministry of Health will determine the feasibility and implementation plan to effect the above recommendation of the mystery customer and the public awareness campaign.

11. **There is further need for advancement in the Pharmacy Industry to incorporate more online and electronic access methods to improve efficiency and increase accountability by the relevant oversight bodies.**

The advancement and use of online and electronic access has to be a joint effort between local distributors and the Regulatory body. Presently, all local distributors of Narcotics and Antibiotics are mandated to submit sales reports, which provide direct oversight related to import details. Inspections done subsequently are able to identify inefficiencies/inconsistencies/illegalities. This ensures proper accountability and efficiency in the process.

Objective 2: To evaluate the efficiency and effectiveness of the Pharmacy Board/Council in executing its mandate.

Recommendations

A. **As mandated by Section 19 of the Act, the Committee strongly recommends that there be strict penalties for failure to publish an updated list of Pharmacies and Pharmacists. The present danger of the dispensing of medication by an unregistered Pharmacist presents a great risk to public health. Therefore, the Board/Council should move with alacrity as it pertains to the publishing of this list.**

   The Ministry of Health is in agreement with having a strict penalty applied for failure to comply with Section 19 of the Act, and the amendment of Act No. 25 of 2003, 5 (6) which require publication of all persons and pharmacies in the registers, with their addresses.

B. **It is recommended that a formal complaints system be created to facilitate the submission of complaints by members of the public. Persons may be more inclined to submit complaints if there is guaranteed anonymity and clear actions to follow. This system must be transparent and adhere to the principles of Natural Justice.**

   The Ministry of Health will continue to work with the relevant institutions to implement a complaints system. Currently, anonymous submissions are made to the Ministry of Health's offices and its website (Principal Pharmacist and the Chief Medical Officer) and subsequently, letters are dispatched to the relevant Pharmacists requesting a response. Letters are also sent to the Pharmacy Board Secretary Registrar for their action. Notably, pharmacists are penalized by termination of employment.

C. **Subject to the necessary consultations with stakeholders, the Committee recommends that legislative reform occur to address the following issues;**

- **lack of formal oversight of the Pharmacy Board;**
- **increase membership fees; and**
- **imposing a restriction on the number of pharmacies within a geographical area;**
- **Permit ministerial intervention where the council of the Board has collapsed or is unable to convene meetings after a reasonable period (to be prescribed) has elapsed.**

It should be noted that the Minister of Health has appointed two (2) members to the Pharmacy Board to ensure oversight and greater management of the operations.

While these activities are primarily undertaken by the Pharmacy Board, this recommendation will be further pursued with the two (2) members.

D. **Pursuant to Sections 11 (2) and 16 (1) (c) of the Act, we recommend that the Board/Council work assiduously to develop a Code of Conduct for Pharmacists in Trinidad and Tobago.**

During the 2nd quarter of fiscal year 2021, the Ministry of Health, will collaborate with the PBTT, to update the existing Code of Conduct for Pharmacists in Trinidad and Tobago.

E. **The Committee recommends that the MoH consult with the Pharmacy Board in order to provide the Parliament with a status update on the "legal document" (legal opinion) on the legality of the sale of wholesale drugs to patients. Furthermore, the Minister of Health should consider issuing regulations to treat with this matter as it appears that moral suasion may not be adequate in treating with this issue.**

During the 2nd quarter of fiscal year 2021, the Ministry of Health, will consult with the PBTT to update and produce the legal document on the legality of the sale of wholesale drugs to patients and any regulations required.

F. **The Committee strongly recommends that measures be taken to strengthen the capacity of the Drug Inspectorate. In this regard, a short to medium objective should be to provide additional training to the current cohort of Inspectors in order to increase their competence in detecting and correcting issues within Pharmacies. Additionally, this training should be aligned with international standards utilized in the UK.**

The Ministry of Health has undertaken a review of the existing structure of the Drug Inspectorate and is in discussions with the Service Commissions Department to strengthen the capacity of the staff.

In the interim, the option of short-term recruitment has been utilised with supported training opportunities available to the Inspectors.

G. **The MOH should determine the cost of implementing online or electronic access to drug information from pharmacies in real time. The practice of e-prescriptions should be an adopted practice to allow for greater accountability through the use of electronic record keeping, particularly within a post Covid19 scenario.**

E-Prescriptions for ease of accountability is a robust method but there must be a robust inventory management system to ensure data protection, reliability and credibility of information given the nature of the industry. To effect E-prescribing, legislative amendments are required, which the Ministry of Health will be considering.

H. **The MoH must act as a mediator between the President of the Board/Council and its members to arrange for the urgent holding of free and fair elections for membership of the Council.**

In keeping with the principle of professional self-regulation, neither the Ministry of Health nor the Minister of Health have any jurisdiction in relation to the conduct of the elections by the Pharmacy Board for their six (6) Pharmacists to serve as Members of the Council of the Pharmacy Board.

As such, it is the responsibility of the registered Pharmacists of the Pharmacy Board to arrange for the urgent holding of free and fair elections for membership to their Council.

Objective 3: To determine whether the Resources, Systems and Procedures of the Pharmacy Council are sufficient to allow it to operate efficiently.

i **The Committee strongly recommends the Board/Council make efforts to strengthen its procedural arrangements through the drafting and circulation of documents which simplify or supplement the provisions of the act and its regulations.**

The Ministry of Health has informed the PBTT of this recommendation and still awaiting a response.

ii **The Pharmacy Council must address its inability to produce financial reports and or statements. This is a core requirement under the principles of transparency and accountability. The Pharmacy Council should seek to collaborate with the MOH with a view to obtaining assistance from the Audit staff of the MOH and or external service provider.**

The Ministry of Health has informed the PBTT of this recommendation and is still awaiting the financial reports.

iii **There should be a mechanism whereby a vote of no confidence in the members of the council including the President can be initiated and executed.**

The Ministry of Health has informed the PBTT of this recommendation and still awaiting a response.

iv **Furthermore, a list of rules and procedures must be formulated to clearly stipulate the consequences for hindering the objectives of AGMS. This should be forwarded to all members.**

The Ministry of Health has informed the PBTT of this recommendation and still awaiting a response.