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Developing Pharmaceutical Legislation in the Federated States of Micronesia

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In the Federated States of Micronesia (FSM),[1] pharmacies are largely unregulated, giving rise to a lack of quality control over medicines and potentially exposing the public to harmful consequences. A joint state and national response was to adopt the FSM Medicine Policy in 2012 which served as guidance for the pharmaceutical industry (DHSA 2012).[2] A 2017 review of the sector found that a legislative and regulatory regime is urgently required to assure quality control and thus increase the public's confidence in the medicines available (DHSA 2017). Assistance from the World Health Organization (WHO) and Australia was provided to collaborate with the Department of Health and Social Affairs for the purposes of creating the legislative framework. This In Brief provides an overview of the existing pharmaceutical legal regime and the legislative framework that has been proposed to replace it.

The Federated States of Micronesia is a group of over 600 coral and volcanic islands, home to over 113,000 people. FSM is located east of the Philippines, bordering Papua New Guinea just north of the equator. FSM became an independent nation in 1986 after centuries of colonisation by four different powers: Spain, Germany, Japan, and the United States after World War Two. A democratic nation based upon the US model, it has three levels of government within those states — national, state and local (municipalities). The federal constitution demarcates jurisdictional powers between itself and the states as well as the division of power between the states and municipalities. For example, the states and the municipalities have their own constitutions. However, there are areas which have concurrent jurisdiction, such as the health sector, where the state and national governments need to collaborate.

Quality control of medicines has been an underdeveloped area in FSM's health sector for many decades. Medicines continue to be imported into FSM without assurance as to their quality for public consumption. Medicines and other pharmaceutical products continue to be distributed on the open market and sold by unlicensed pharmacists and retail outlets giving rise to major concerns about prescription procedures, administration processes, adequacy of storage facilities, and harmful side effects to the public (DHSA 2017). Health authorities do not have adequate statistical data to fully identify the negative impacts arising from the lack of regulation in this sector and the impacts on the public: the data is incomplete.

In 2017, a consultant was hired to study the FSM Constitution, the FSM Code, regulations, and policies in relation to the conduct of pharmacies and retail outlets in the marketplace. The ensuing report was provided to the Department of Health and Social Affairs (DHSA) to assist in the establishment of national legislation to regulate the sector (DHSA 2017). The aim of the proposed legislation is to control and manage the importation, storage, distribution, dispensing, disposal, selling, and manufacturing of pharmaceutical medicines and controlled substances, including traditional medicines. The proposed legislation also provides for the creation of a regulatory body to monitor pharmaceutical outlets and apply penalties, including loss of licence, to pharmacists who fail to adhere to specific practices required in the dispensing of medicines and related pharmaceutical products. The legislation also seeks to clarify the duties of pharmacists in informing the public about harmful effects of medicines or drugs that they dispense.

Collaborative reform efforts

More than a decade ago it was recognised by the DHSA and its state counterparts that coordination and harmonisation was required in the pharmaceutical sector. A series of meetings between the various levels of governments ensued, which culminated in the creation of the FSM Medicine Policy Manual (DHSA 2012). This manual has since been used as a general guide for the pharmaceutical sector. However, the manual does not have the effect of law. Enforcement of the guidelines was seen to be necessary and prompted the DHSA to propose pharmaceutical legislation.

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Meetings and consultations with relevant stakeholders were crucial to the development of the framework for the proposed legislation. A schedule was drawn up to engage the states and the private sector. The consultation process began with the secretary of DHSA, national government advisers, and legal staff to share essential information with their state counterparts.

Further consultation with the states and the private sector continued, involving a review of existing literature, production of reports, further consultation with the states for their input as well as meetings with public representatives to ascertain their level of support. Upon the completion of the consultation process, a pharmaceutical bill was drafted. The DHSA, being the regulatory body for pharmacies in FSM, is working collaboratively with the FSM Congress to pass the legislation as soon as possible.

The bill also focuses on the establishment of a statutory body for regulatory measures such as the creation of different categories and classes of licences; duties and obligations of inspectors; quality control, and penalties for violations of the legislation. The World Health Organization (WHO) was involved in the review of the draft legislation to ensure it met international standards. The proposed legislation has been endorsed by the executive branch of the FSM government and is now with FSM's Congressional Health Committee, which has held public hearings. The proposed legislation, however, has not been declared law due to budgetary constraints involved in the creation of a new regulatory regime required under this legislation to carry out its functions.

Ensuring quality control

The proposed legislation was drafted incorporating pharmaceutical practices from Pacific nations such as Fiji (Pharmacy and Poisons Act (Cap. 115) Rev. 1985) and Samoa (Pharmacy Act 2007) as well as Australia and New Zealand. In anticipation of implementing the quality control provisions of the legislation, the DHSA sought assistance from the Australian Government's Therapeutic Goods Administration. In September 2017, a memorandum of understanding (MOU) between FSM and the Australian Government was signed, the purpose of which is to 'provide medicine quality laboratory testing services to the Pacific Islands countries … through the Therapeutic Goods Administration (TGA), Australia's regulator medicines and medical devices'. In July 2021, phase two of the program commenced with all costs of laboratory testing paid by the Australian Government.

Under the agreement, the Australian Government will assist FSM by conducting some testing of therapeutic goods that include antibiotics, medicines treating diabetes and medicines treating cardiovascular diseases.[3] This is part of a pilot program that will give the FSM access to quality assurance testing services in Australia. Access to laboratory testing for the FSM government will focus on those medications that treat non-communicable diseases.

Conclusion

The FSM Congress has requested that appropriate infrastructure be put in place before it can adopt the legislation. The bill is under intense scrutiny before it becomes law. Public hearings have provided an opportunity for the harms posed by an unregulated pharmaceutical system to become more widely known and have demonstrated the need for stringent pharmaceutical laws to protect the public.

Australia is playing a major role in assisting FSM to increase its capacity in monitoring the quality of imported pharmaceutical medicines and associated products. According to the secretary of DHSA, a team from FSM is expected to travel to Canberra when the restrictions relating to the COVID-19 pandemic have sufficiently relaxed[4] to increase their knowledge about policy issues surrounding pharmaceutical drugs, the process of quality testing of medicines, and how that knowledge could be applied and transferred to FSM.

Author notes

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Endnotes

1. FSM is comprised of four states: Yap, Chuuk, Pohnpei and Kosrae.
2. Personal communication with the FSM Department of Health and Social Affairs (DHSA) pharmacist, Resel Elias.
3. Personal communication with the acting secretary of DHSA.
4. Personal communication with the acting secretary of DHSA.

References

DHSA (FSM Department of Health and Social Affairs) 2012. The FSM Medicine Policy Manual 2012, Palikir, Pohnpei. Unpublished document in the possession of the author.

DHSA 2017. Technical Report for FSM's Proposed Pharmacy Legislation for WHO, Palikir, Pohnpei, FSM, May. Unpublished report in the possession of the author.

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