Pharmaceutical Sciences Asia

Pharm Sci Asia 2022; 49(5), 498-505

DOI:10.29090/psa.2022.05.22.174

Research Article

Regulatory landscape analysis of Myanmar Food and Drug Administration based on the World Health Organization Global benchmarking tool

Ei Ei Chaw[1,2], Leena Suntornsuk[1*]

[1] Department of Pharmaceutical Chemistry, Faculty of Pharmacy, Mahidol University, Bangkok, Thailand
[2] Department of Food and Drug Administration, Ministry of Health, Nay Pyi Taw, Myanmar

ABSTRACT

Regulatory authorities play significant roles for ensuring quality, safety, and efficacy of pharmaceutical and health products. However, most of the national regulatory authorities in low- and middle-income countries encounter many challenges such as over workload and under-staff/resources to maintain the efficiency in regulatory process. To alleviate the problem, the World Health Organization (WHO) supports its member states and implements the WHO-Global Benchmarking Tool (GBT) to strengthen the capacity of the national regulatory system. In this study, the regulatory system of Myanmar was investigated using the WHO-GBT based questionnaire survey. The study aimed to assess the national regulatory system and regulatory activities with WHO-GBT indicators and sub-indicators and to provide recommendations for the future progress of Myanmar Food and Drug Administration (MFDA). The results shows that MFDA has a well-structured legal foundation for the regulatory system and regulatory activities. Interestingly, the National regulatory system is the first priority and most challenging item to be achieved. Human resource capacity is below the standard requirements to operate efficient regulatory activities. It is recommended that the MFDA should implement the guideline on complaints and appeals to regulatory decisions and published documents or channels for laboratory activities within a short to medium period (1-12 months). As a medium to long-term plan (6-12 months and above), a human resource development plan and capacity building should be immediately established to accelerate the regulatory functions. Besides, transparency and public confidence must be promoted in regulatory activities.

Keywords:
National regulatory system, Global benchmarking tool (GBT), Myanmar Food and Drug Administration (MFDA), Regulatory
*GMP-Good manufacturing practice, GDP-Good distribution practice, GSP-Good storage practice, GPP-Good pharmacy practice

1. INTRODUCTION

Regulatory authority (RA) is an organization to operate an administrative and enforcement system, to carry out legislations and regulations for ensuring safety, efficacy, and quality and to manage marketing and promotion of medicinal products[1]. National regulatory system (NRS) is the regulatory body that is responsible for ensuring the safety, efficacy, and quality of medical products throughout their lifecycle including manufacturing, storage, distribution, and dispensing[2-3]. In addition, this system is also a combination of institutions, regulatory processes, and government regulatory control for specific regulatory activities[4]. The World Health Organization (WHO) recognizes that the effective regulatory systems are an important portion in health system strengthening, which can promote better healthcare outcome. Besides, capable regulators are crucial resources for the healthcare workforce. Inefficient regulatory system can limit easy access of quality, safety and efficacious pharmaceutical products[5]. As reported by the WHO, drug quality assurance systems are insufficient in many countries due to the absence of adequate drug legislation, regulations, and well-functioning drug regulatory authority with sufficient resources[6].

***Corresponding author:**
*Leena Suntornsuk Email: leena.sun@mahidol.ac.th

Moreover, the over workload and under-staff/ resources of national regulatory authority (NRA) can be barriers for strengthening the regulatory system in many low- and middle-income countries[1-2].

The WHO mentioned that only 30 percent of the NRAs of its member states have the efficient and effective capacity for medical regulations[7]. Consequently, the WHO supports its member states and implements a five-step approach of the Regulatory System Strengthening (RSS) programme to strengthen the capacity of regional, sub-regional and national regulatory system with priority in developing countries. The five-step model for strengthening regulatory systems includes (1) implementation and maintenance of a global benchmarking tool (GBT) for national regulatory system evaluation, (2) regulatory system benchmarking, (3) implementation of an institutional development plan for progressive improvement, (4) capacity building by technical support, training and networking and (5) continuous monitoring and documentation of programme impact and outcomes[8]. The WHO-GBT assessment of national regulatory authority is among these approaches to strengthen the regulatory system[8]. The WHO-GBT is a standardized tool for the evaluation of national regulatory system and functions. The assessment can identify strengths and gaps of the regulatory system performance. The tool is structured into four levels: (1) national regulatory system and regulatory functions, (2) indicators, (3) sub-indicators, and (4) fact sheets including questionnaires for other products and activities. It consists of 268 sub-indicators for the evaluation of the regulatory frameworks, which involve the following indicators; national regulatory system (RS) (GBT 01) with eight regulatory functions, registration and marketing authorization (MA) (GBT 02), pharmacovigilance (VL) (GBT 03), market surveillance and control (MC) (GBT 04), licensing establishment (LI) (GBT 05), regulatory inspection (RI) (GBT 06), laboratory testing (LT) (GBT 07), clinical trials oversight (CT) (GBT 08) and lot release of vaccine (LR) (GBT 09). The GBT indicators and sub-indicators are categorized into nine categories related to (1) legal provisions, regulations, and guidelines (2) organization and governance (3) policy and strategic planning (4) leadership and crisis management (5) transparency, accountability, and communication (6) quality and risk management system (7) regulatory process (8) resources and (9) monitoring progress and assessing impact. The GBT evaluates the regulatory system and functions using "Maturity Level (ML)" (adapted from ISO 9004) and grades as the overall maturity level, for instance - level 1 (existence of some elements of the regulatory system), level 2 (NRS with partially performs essential regulatory functions), level 3 (NRA achieve the minimum target which can suppose as stable, well-functioning and integrated regulatory system) and level 4 (work as an advanced level performance with continuous improvement). The benchmarking steps are classified as pre-assessment, self-benchmarking, formal benchmarking and follow up and monitoring progress made by the WHO. Consequently, the GBT benchmarking evaluation can truly identify the strength and gap in NRS as well as recommendations for the better improvement on regulatory system for medicinal products[8-9].

Myanmar is among the developing countries that implements the WHO-GBT for the evaluation of its NRA. According to the national medicines policy strategy and implementation plan (2018-2021)[10], Myanmar's national regulatory authority (MFDA) is overloaded with registration applications and lacks of human resource[10]. The objective of this work was to assess the MFDA using WHO-GBT. The study was conducted to evaluate the regulatory systems and functions of MFDA. Results from this study can support the potential solutions for its improvement and highlight the gaps and challenges in the system. Last but not least, recommendations were suggested to overcome the problems and to strengthen the MFDA.

2. MATERIALS AND METHODS

2.1. Study design

This study was a quantitative questionnaire-based descriptive study. The studied questionnaire (Supplement I) was extracted from WHO-GBT indicators and sub-indicators to assess the national regulatory system and regulatory functions.

2.2. Study site and study population

We conducted a study on regulatory system and functions of Myanmar's national regulatory authority (Myanmar Food and Drug Administration, MFDA). We invited and contacted the responsible persons from MFDA by sending an e-mail and the obtained results were analyzed at the Faculty of Pharmacy, Mahidol University, Thailand.

2.2.1. Inclusion criteria for respondent

The respondents must be the authorized person or regulatory officers or high-ranking person who are currently working in the government regulatory sector of MFDA.

2.2.2. Exclusion criteria for respondent

The regulatory staff or regulatory pharmacists from non-government or private sector or those who are not working in the government regulatory authority were excluded.

2.3. Data collection

Upon the informal consultation with regulatory staff and customers, the research questionnaire was organized to evaluate the regulatory processes. It was developed based on the WHO-GBT indicators and sub-indicators. And it was structured into three sections: Section I: Background questions for benchmarking performance, Section II: Specific questions for regulatory system and activities, and Section III: Opinion questions including priority ranking and challenges on regulation. Section I intended to get the official information of benchmarking processes and to consider the progress of benchmarking activities. Section II was related to regulatory system and functions, among the nine WHO-GBT indicator tools, GBT 01 National regulatory system (RS), GBT 02 Registration and marketing authorization (MA), GBT 04 Market surveillance and control (MC), GBT 05 Licensing establishment (LI), GBT 06 Regulatory inspection (RI) and GBT 07 Laboratory testing (LT) were investigated. GBT 03 Vigilance is one of the market surveillance and control activities. For GBT 08 Clinical trial oversights, in Myanmar, clinical trials are regulated by the separate department, Department of Medical Research under the Ministry of Health. And then, GBT 09 Lot release of vaccine is a non-common regulatory function, which covers only for biological products and vaccines. Therefore, GBT 03 Vigilance (VL), GBT 08 Clinical trials oversight (CT), and GBT 09 NRA Lot release (LR) were excluded. Section III aimed to identify the challenges and gaps in benchmarking achievement. The factors of regulatory system and functions in the survey were correlated with legal provisions, regulations and guidelines, organization and governance, regulatory process and resources, accountability, transparency, and communication. The investigated 36 indicators and sub-indicators was constructed based on the recommendations from regulatory staff focusing on areas, which need to be improved in regulatory system and functions. We invited and surveyed the respondent from MFDA via e-mail. And then, we analyzed the MFDA's regulatory system and functions with 36 of 268 GBT indicators and sub-indicators.

2.4. Data analysis

The results interpretation in Sections I and II were described using narrative analysis. In Section II, the responses to each question were classified as 'Yes' (fully implemented with a proven documentation), 'Partial' (partially implemented or less than 2 years implementation), 'On-going' (showed on-going steps but not yet implemented), and 'No' (not implemented). According to the responses, the data interpretation and evaluation were described for the investigated regulatory fields. The percentages of the achievement were calculated using descriptive statistics in Microsoft excel and then reported with bar graphs and tables. Finally, we presented the challenges and proposed solutions for the better progress of MFDA.

2.5. Ethical approval

Ethical approval for this study was granted by the Faculty of Dentistry/Faculty of Pharmacy, Mahidol University Institutional Review Board (MU-DT/PY-IRB) with the certification of COE.No.MU-DT/PY-IRB 2022/007.0102 in February 2022.

3. RESULTS

3.1. Background history of WHO-GBT assessment of Myanmar national regulatory system

The first section of the research assessment is to evaluate the performance activity in benchmarking process including self-benchmarking and WHO formal benchmarking. As the result, Myanmar NRA had a background history of self-assessment with WHO-GBT for the evaluation of NRS in 2018 and completed the formal benchmarking by WHO in 2019. For both benchmarking processes, the overall maturity level was 2 out of 4 levels.

3.2. Evaluation of national regulatory system and regulatory functions

3.2.1. National regulatory system (RS)

Myanmar's national regulatory system also has the legal provisions, regulations, and guidelines for the regulatory structure of the NRS (RS 01) that conducts the WHO-recommended regulatory functions. For the consistency in regulatory activities, all regulatory authorities from central and peripheral such as states and provinces (central and decentralized authorities) partially follow non-contradictory regulations and guidelines under the direction of central FDA (RS 01.04). The regulatory and enforcement actions on recall, suspension, and withdrawal of the suspected substandard, falsified (SF), and counterfeit products are well described in the laws and notifications of MFDA (RS 01.05). Moreover, the consultation with MFDA and the representatives from specific sectors example of health professionals and industry fields are well implemented in drafting and implementation of legal provisions and regulations (RS 01.08). This response achieved the maturity level 3 of (RS 01.08). In contrast, any guidelines on complaints and appeals against the regulatory decision (RS 01.09) are not yet implemented in regulatory system. It is supposed that any guidelines for appeal process can promote the maturity level and transparency in regulatory

activities. Meetings with stakeholders and customers to evaluate their satisfaction for regulatory system development and actions taken on any complaints and claims are partially implemented (RS 05.10). Current human resources (RS 06) are below the required capacity and more recruitment plans are recommended to be effective and efficient regulatory system. The infrastructure including buildings, workspaces, and equipment (RS 08) is partially developed and this should be moved forward to support regulatory activities. In the NRS evaluation process, the MFDA has fully implemented 3 indicators, whereas the other 3 indicators have been partially implemented. One indicator has not been implemented in the NRS yet (Figure 1).

3.2.2. Registration and marketing authorization (MA)

Marketing authorization defines product registration or licensing and refers to the marketing approval process when the quality, safety, and efficacy assessment has been completed. Consequently, each NRA needs to have legal framework for marketing authorization activities. MFDA have totally organized the legal backbone for registration and marketing authorization of medical products to get the maturity level 1 of MA 01. In MFDA, the validity of product registration is defined as 5 years and the requirements for new and renewal product registration is publicly available (MA 01.04). Furthermore, specific guidelines and procedures for quality requirements of multisource generic products (MA 01.09) are described with Asean Common Technical Dossier (ACTD) format via the website of the Department of Food and Drug Administration, E-Submission System Registration Login. In recent year, the same criteria have been used for the registration application of the pharmaceutical products from local, foreign, public, or private sector (MA 04.04). But the procedures for timeline assessment of the application and internal tracking system to monitor the adherence of the targeted time frames are in on-going process (MA 04.06). As a mandatory requirement for MA, the registrant needs to submit GMP inspection report and/or certification to the authority (MA 04.09). This activity intends to reach the maturity level 3 of sub-indicator (MA 04.09). And then, the list of the already approved products (MA 05.02) can be publicly available via the website of the Department of Food and Drug Administration, Myanmar[11].

In summary, MFDA has fully implemented 5 indicators with specific maturity level. Nevertheless, one indicator has been partially implemented and the last one indicator is on-going (Figure 1).

3.2.3. Market surveillance and control (MC)

The common MC functions are the control of importation, market surveillance program for quality control of products during their supply-chain, promotion and advertising control and response activities for substandard and falsified pharmaceutical products. For these MC activities, the legislation, and regulations (MC 01) are completely implemented in MFDA. MFDA has included the legal regulations related to the unique identification number (drug registration number) on the outer packaging of the products (MC 01.05, maturity level 4). The well-defined SOPs for the discussion and agreement between MFDA and related stakeholders are existed to reach the maturity level 3 of MC 02.02, and to certain the involvement of the stakeholders in MC activities. For human resources to operate MC activities (MC 03. 01), MFDA has initiated the recruitment plan in recent years to completely conduct the MC activities. The communication for the regulatory findings and decisions of MC activities between MFDA and all national stakeholders including public (MC 06.02) has been partially initiated.

According to the outcomes in market surveillance and control activities, MFDA has completed 3 out of 5 indicators and another 2 indicators have been implemented in less than 2 years (Figure 1).

3.2.4. Licensing establishments (LI)

In MFDA, legal regulations and guidelines which provide an authority to issue, suspend, or revoke licenses for premises and establishments (LI 01), are well-described to prove that the licensing facilities in the product's supply chain is complied with good practices (GxPs). All licensing establishments in medical product's supply chain require to comply with GxPs such as GMP and GSP. Additionally, MFDA has sufficient competent staff with skills, training, education, and experience to maintain licensing activities (LI 03.01). The issuance of licensing certificates (LI 04.01) is one of the MFDA licensing activities. The certificates are valid for 3 years including drug manufacturing license and drug importation licenses. The GxPs inspection is mandatory in all cases for granting or re-granting a license and license approval of substantial modification (LI 04.02). The timeline for evaluation of license applications is 180 days (LI 04.03). Besides, the same criteria for licensing of local, private, and public establishments (LI 04.04) are used in MFDA's licensing processes to meet the maturity level 3 of (LI 04.04) according to the former WHO-recommendations in 2018 and 2019. On the other hand, the inspection reports, or summaries of licensing activities (LI 06.02) are on-going to be publicly available to increase confidence and transparency in LI activities. Results reveal that for LI activities, 6 out of 7 indicators have gained the specific maturity level of LI 01, 03.01, 04.01, 04.02, 04.03 and 04.04. One indicator is on-going, but has not implemented yet (Figure 1).

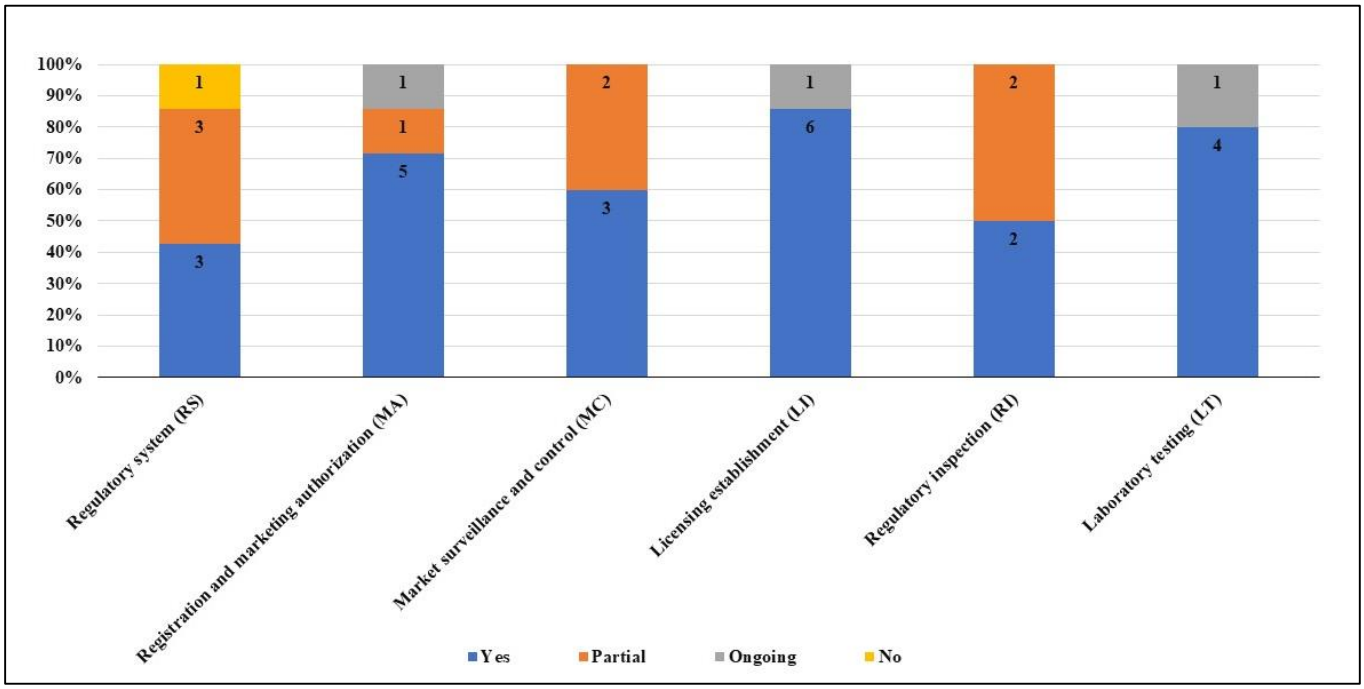

Figure 1. MFDA's implementation of WHO-GMT regulatory system and functions.

3.2.5. Regulatory inspection (RI)

To facilitate the regulatory decision-making process, legal provisions and regulations have been recently implemented to recognize and reliance on foreign NRA inspections and enforcement actions based on well-defined criteria (RI 01.05). The arrangements, including, the organization structure with well-defined responsibilities and duties, are successfully implemented. The effective organization and good governance in regulatory inspection activities meet the specific maturity level 2 of RI 02. Human resource development plan has partially started in recent years to support sufficient and competent staff in conducting regulatory inspection activities (RI 03.01). The SOPs and procedures, which conduct and monitor the GxPs inspections, inspection reports and follow-up processes, are completely described to attain the maturity level 3 of (RI 04). Among the four specific GBT criteria of regulatory inspection activities, the MFDA has implemented 2 indicators and the other two have been partially implemented in recent years (Figure 1).

3.2.6. Laboratory testing (LT)

This indicator tool intends to promote consistency and transparency of laboratory activities and increase public confidence on the regulatory activities. There are legal provisions, regulations, and guidelines for the regulatory framework of laboratory testing activities. The MFDA meet the defined maturity level 1 of LT 01. The National control laboratory (NCL) of MFDA has several divisions, including, pharmaceutical chemistry, food chemical, food microbiology, bio-standardization, cosmetic chemical, drug and cosmetic microbiology, and medical device divisions. These divisions perform the testing activities including testing and re-testing, calibration, equipment qualification and method validation under the well-established plan, policies, and quality management system (QMS) (LT 03). The NCL has adequate competent staff with required skills, training, education, and experience (LT 04.01), and has adequate laboratory facilities (LT 05.01) to conduct effective and reliable quality testing activities. Consequently, the MFDA meets the maturity level 3 of LT 04.01 and LT 05.01. However, communication between the laboratory and public community via documents or other channels (LT 07.01) are on-going, but not yet implemented.

For laboratory functions assessment, 4 out of 5 indicators have been fully implemented, and one indicator is on-going (Figure 1).

3.3. Ranking and challenges of NRS and regulatory functions

The last section of the survey aimed to identify the priority and challenges on implementing the WHO-GBT. MFDA has ranked the GBT tools, which are needed to improve from the highest (1) to the lowest (6) priority as shown in (Table 1).

The first priority is the national regulatory system and the second is registration and marketing authorization and regulatory inspection activities. Market surveillance and control, licensing establishments and laboratory testing are ranked as the same priority in the third place. Interestingly, the National regulatory system is the most difficult item to reach the higher maturity level.

Table 1. Priority ranking of MNRA requirement based on WHO-GBT.

First priority	Second priority	Third priority
National regulatory system (RS)	Registration and marketing authorization (MA) Regulatory inspection (RI)	Market surveillance and control (MC) Licensing establishments (LI) Laboratory testing (LT)

Table 2. Recommendation with timeline for future improvement of MNRA.

No.	Proposed regulatory function	Recommended solution	Action plan	Suggested timeline
1.	Guideline on complaints and appeals against regulatory decisions that is available to public	Guidelines on review, evaluation, communication of complaints and appeals against regulatory decisions	Initial meetings and SOPs with internal reviewers and experts, Agreement from the top management level	Short to medium term
2.	Human resources with a trained, experienced, and skilled workforce to perform regulatory activities	Promoting the human resource development and capacity building plan	Adequate supports from Ministry of Health, National and international assistance (e.g., Professional organizations, WHO and ASEAN regulatory network)	Medium to long term
3.	Defined timelines for the assessment of the MA applications and an internal tracking system to monitor adherence to the targeted time frames	Internal meetings and clear SOPs with reviewers and technical supports from IT professionals	Supports from top management level	Short to medium term
4.	Inspection reports or summaries (or excerpts) relevant to licensing activities are published and publicly available	Database or documentation for licensing processes, recommendation from the inspectors	Administrative approval, cooperation and collaboration between the inspectors and administrative section	Short term
5.	Published documentation or channel for laboratory activities communicated to the public community to promote transparency, consistency, public trust, and confidence in the regulatory system	Publications and social media platforms for laboratory activities	Agreements between the high administrative level and laboratory technicians	Short to medium term

*Short term: 1-6 months, medium term: 6-12 months, long term: 12 months and above

Moreover, the major challenges to achieve the maturity level of WHO-GBT are the limitation in human resources, budget supply and technical supports in regulatory activities. Lastly, this research study provided the following recommendations for the improvement in specific regulatory functions (Table 2).

4. DISCUSSION

The outcomes from the section I reveals the progress of MFDA in regulatory system assessment by self-benchmarking and formal benchmarking by WHO-GBT. Both assessments show the overall maturity level of 2 out of 4 levels.

4.1. National regulatory system (RS)

The national regulatory authority, known as MFDA, is the organization in charge for the safety, efficacy, and quality assurance of pharmaceutical products. By the WHO's definition, a national regulatory system must construct with legal basis, infrastructure, common and non-common regulatory functions. In the National Drug Law (1992) and its amendment (2014) of MFDA, it is described that the stakeholders from many sectors have participated in the foundation and amendment of laws and regulations. The MFDA has the legal basic for regulatory system to conduct various regulatory activities.

Finally, the MFDA has reached the specific maturity level of WHO-GBT RS 01, 01.05 and 01.08. Although there are well-structured legal frameworks in NRS, the performances for RS 01.04, 05.10, and 08 have been recently developed due to policy and limited resources.

As per results of the NRS, it is advised that the MFDA requires more human resource recruitment, both in terms of quantity and expertise, to increase the overall maturity level of its NRS.

4.2. Registration and marketing authorization (MA)

In MFDA, the validity of product registration is specified as 5 years and the requirements for new and renewal product registration is publicly available on the Guideline on drug registration application (Feb 2018) to promote the transparency of the registration process. Although there is a definite legal framework for MA activities, MFDA must provide clear standard operating procedures (SOPs) for MA 04.06 to facilitate the registration process.

4.3. Market surveillance and control (MC)

MFDA have implemented the regulatory function of MC 01.05. This tool is targeted to define the placement of unique identification number on the pharmaceutical product's outer packaging, to facilitate tracing and tracking of the products throughout their supply chain, to aid in the detection of substandard and falsified (SF) products.

All stakeholders not only from the various organizations (e.g., institutions and organizations) but also from other entities (e.g., laboratories, police, and customs departments) should participate in MC activities. In 2017, a national coordination mechanism between MFDA, the Ministry of Trade, customs and police was initiated to combat SF medical products [10]. It is encouraged that this mechanism should be maintained and proceeded. The regulatory findings or decisions on substandard and withdrawal products should be regularly published and communicated via website or electronic communication to all related stakeholders. In MFDA, the human resource development plan was partially implemented to completely conduct the MC activities. Therefore, it is recommended that the human resource development plan and continuous communication of high administrative levels and other stakeholders should be achieved to accelerate the maturity level of MC activities.

4.4. Licensing establishments (LI)

MFDA has a responsibility for licensing activities and supported by published legal provisions, regulations, and guidelines to ensure the compliance of licensing facilities with GxPs throughout the product's supply chain. There is a specified timelines (180 days) for licensing assessment and licensing validity are every 3 years. In licensing activities, the implementation of LI 06.02 is on-going. Therefore, the achievement of maturity level 4 of LI 06.02 can be facilitated by the policy and permission from high administrative levels and internal organizations including the regulatory inspectors.

4.5. Regulatory inspection (RI)

Currently, human resource capacity is the most challenging issue in all regulatory fields especially during the pandemic crisis. Recently, MFDA has an opening for new in-service staff to fulfill the capacity requirements at the website of the Department of Food and Drug Administration, Myanmar. For RI assessment, the human resource recruitment plan and reliable staff are critically required to efficiently operate the RI activities of good manufacturing practice, good distribution practice, good storage practice and good pharmacy practice inspections. Further, it is suggested that the continuous communication between MFDA and other regulatory authorities and international organization (e.g., WHO) can enhance the progress in regulatory functions.

4.6. Laboratory testing (LT)

For laboratory testing tool assessment, MFDA have implemented the LT 01, 03, 04.01 and LT 05.01 tools. But the documents or channels for laboratory activities LT 07.01 is on-going. Therefore, it is recommended that the MFDA should discuss with the top administrative level and its board of authority and laboratory technicians to foster the transparency of laboratory activities.

Sithole T et. al study stated that in some regulatory authorities[12], the same reviewer was assigned for reviewing quality, non-clinical and clinical submission due to the limited number of staff. On the other hand, in some authorities, one reviewer only focused on quality review and different reviewers were responsible for preclinical and clinical study[12]. NRA has an essential role in healthcare system, which can prevent consumers from medicine-related problems by the medical product evaluation, GxPs inspection and market surveillance. Importantly, the regulatory workforce requires to be skillful and sufficient to conduct regulatory purposes. Therefore, NRA's capacity building is an important activity to support the national healthcare system. Hands-on, on-site and in-service technical trainings for human resource capacity building are necessary to facilitate the MFDA regulatory functions.

5. CONCLUSION

This study aimed to evaluate the National regulatory system and regulatory functions of MFDA and to provide the recommendations for future development of its system. The assessment was based on the WHO-GBT indicators and sub-indicators. The MFDA has all necessary legal mandates to regulate medicinal products throughout their life cycle. In addition, the regulatory affair has SOPs and assessment templates in drug registration process. But, the guideline on the appeals process against regulatory decisions and published documentation or channel for laboratory activities communicated to public community are still lacking in its regulatory framework. The MFDA should accelerate the transparency in regulatory activities to promote public confidence in the regulatory system and functions. This study also identifies gaps in capacity and other regulatory functions for improvement, interventions (e.g., training and capacity building of technical persons from quality management system) and supporting the development of legal frameworks. Results enable the recommendations for specific interventions and/or continuous improvement in MFDA's regulatory system and regulatory functions. Last but not least, the outcomes of this study provided a better understanding and challenges on MFDA's regu-

latory functions.

6. ACKNOWLEDGEMENT

We would like to express our acknowledgement for the collaboration and support of Department of Food and Drug Administration, Myanmar. We are especially grateful for the technical support from Faculty of Pharmacy, Mahidol University.

Conflict of Interest
None to declare.

Funding
Faculty of Graduate Studies, Mahidol University.

Ethical approval
This study was obtained the certificate of exemption COE.No.MU-DT/PY-IRB 2022/007.0102 from Faculty of Dentistry/Faculty of Pharmacy, Mahidol University Institutional Review Board (MU-DT/PY-IRB) in February 2022.

Authors' contributions
EEC contributed to conduct research work, data collection and prepared the manuscript. LS contributed to plan, design the research methodology, supervised the project, and analyzed the data. LS also edited the manuscript. All the authors have read the final manuscript and agreed to approve the manuscript submission.

Article info:
Received May 12, 2022
Received in revised form July 7, 2022
Accepted July 26, 2022

REFERENCES

1. World Health Organization. National drug regulatory legislation: guiding principles for small drug regulatory authorities, World Health Organization Technical Report Series, No.885 [document on the Internet]. Geneva: World Health Organization; 1999 [cited 2022 Apr 23]. Available from: https://digicollections.net/medicinedocs/documents/s21964en/s21964en.pdf.
2. Khadem Broojerdi A, Baran Sillo H, Ostad Ali Dehaghi R, Ward M, Refaat M, Parry J. The World Health Organization Global Benchmarking Tool an Instrument to Strengthen Medical Products Regulation and Promote Universal Health Coverage. Front Med. 2020;7:457.
3. World Health Organization. WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems of medical products, revision VI. Geneva: World Health Organization; 2021.
4. World Health Organization. Good regulatory practices: Guidelines for national regulatory authorities for medical products. Working document QAS/16686 Draft for comment Prepared by EMP/RSS. Geneva 27, Switzerland: WHO; 2016.
5. World Health Organization. WHO guideline on the implementation of quality management systems for national regulatory authorities. WHO Drug Information. 2019;33(3):410-57.
6. World Health Organization. How to develop and implement a national drug policy. Geneva: World Health Organization; 2001.
7. World Health Organization. WHO essential medicines and health products: annual report 2017: towards access 2030. Geneva: World Health Organization; 2018.
8. World Health Organization. Manual for benchmarking of the national regulatory system of medical products and formulation of institutional development plans, Version 1. Geneva: World Health Organization; 2021.
9. Guzman J, O'Connell E, Kikule K, Hafner T. The WHO Global Benchmarking Tool: a game changer for strengthening national regulatory capacity. BMJ Glob Health. 2020;5(8):e003181.
10. Ministry of Health and Sports. National Medicines Policy Strategy and Implementation Plan (2018-2021) [document on the Internet]. Ministry of Health and Sports, The Republic of the Union of Myanmar; 2019 [cited 2022 May 5]. Available from: http://www.doms.gov.mm/wp-content/uploads/2019/12/National-Medicines-Policy-Strategy-and-Implementation-Plan.pdf.
11. Myanmar Food and Drug Administration. [cited 2022 Feb 20]. Available from: https://www.fda.gov.mm/.
12. Sithole T, Mahlangu G, Capote V, Sitoie T, Shifotoka S, Gaeseb J, et al. Evaluation of the Good Review Practices of Countries Participating in the Southern African Development Community: Alignment and Strategies for Moving Forward. Front Med. 2021;8:742181.