



# An Analysis of Pharmacy Policy Implementation in Bantul Regency, Indonesia

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## ARTICLE INFO

## ABSTRACT

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The Bantul Regency Government has arranged the implementation of pharmacy services so that a good business environment is established. This study was conducted to conduct a conceptual analysis of the establishment of pharmacies between high ratio and low ratio areas based on applicable regulations. The purpose of this study is to develop a policy of improving the effectiveness of drug supervision in pharmaceutical service facilities, and the formulation of patterns of strengthening and empowerment pharmacies. The method used is literature review on related articles from various countries. With certain filtering techniques, there are six articles meet the criteria. The results of the analysis of the article can be used to explain various patterns in the management of pharmacies implementation policies. The government needs to coordinate with associations, pharmacies provider on making policy that protect consumers. This policy is important because drug services have a broad impact on public health.

### Keywords

Pharmacies

Regulation

Public Health

Drug Services

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## **Introduction**

An individual needs health as a basic need both spiritually and physically. The development of science and technology increases people's understanding of the quality of healthy life. To achieve this health, health facilities are needed as an effort by the community to improve their health level. Pharmacies are the basic health facilities in pharmaceutical services. One form of support for the realization of the vision of "Healthy, Smart, and Prosperous Bantul" has been contained in the issuance of Bantul Regent Regulation Number 22 of 2018 concerning the implementation of pharmacies. This regulation also regulates how the location requirements for the establishment of pharmacies are based on the distribution of pharmacies in each sub-district which is divided into three criteria. The first criterion is the high ratio when the district with the number of ten pharmacies. The second criterion, when the number of pharmacies is five to ten and finally the ratio is low when the number of pharmacies is less than five. The establishment of pharmacies in locations with high ratios is required to establish pharmacies at locations with low ratios simultaneously [1].

Bantul Regency is located in the south of the province of the Special Region of Yogyakarta with an area of 506.9 Km<sup>2</sup>. The number of sub-districts in Bantul until 2021 is 17 sub-districts consisting of 75 villages. According to the Population Profile of bantul districts in 2019, there are already 6 high ratio areas. So now many pharmacy submissions cannot continue because the establishment of new pharmacies must be balanced between the high ratio and low ratio areas, while the low ratio regions have been exhausted. On the other hand, Indonesia's National Development must be supported and encouraged for the welfare of all people. The government should facilitate the provision of facilities and infrastructure through policies as a form of real efforts in economic development [2].

Regulation Pemerintah No. 51 of 2009 concerning Pharmaceutical Work Hereinafter referred to as PP 51 of 2009 regulates that pharmacies are facilities for pharmaceutical practices by Pharmacists (PP NO 51, 2009). The function of the pharmacy is as a place of pharmaceutical services to the community and at the same time a place of business that aims to seek profit. Increasing public awareness about the importance of health makes pharmacies a profitable business field without leaving other functions of pharmacies [3].

Based on Law 23 of 2014 concerning Regional Government in the Division of Government Affairs in the Health Sector, it is stated that the Regency/City Government has the authority to issue permits for pharmaceutical service facilities (including pharmacies and drug stores). In accordance with Government Regulation Number 5 of 2021 concerning the Implementation of Risk-Based Business Licensing, supervision must be carried out in the implementation of these permits. Business Licensing is the legality given to Business Actors to

start and run their business and/or activities. Risk is the potential for injury or loss from a hazard or a combination of possible and consequential hazards. Risk-Based Business Licensing is a Business Licensing based on the level of Risk of business activities. Risk-Based Business Licensing is regulated by PP 5 of 2021 concerning the Implementation of Risk-Based Business Licensing.

Along with the development of information and communication technology, there is now a system that helps in the implementation of risk-based business licensing through the Online Single Submission (OSS) system [4]. The rules for implementing OSS are in article 12 of Law Number 11 of 2020 concerning job creation in Government Regulation Number 5 of 2021. This system is intended to accelerate and increase investment and make it easier for business actors to manage or register business applications such as environmental permits, building permits and so on. The implementation of Risk-Based Business Licensing includes: regulation of Risk-Based Business Licensing; norms, standards, procedures, and criteria for Risk-Based Business Licensing; Risk-Based Business Licensing through the OSS System service; procedures for Monitoring Risk-Based Business Licensing; evaluation and reform of risk-based business licensing policies; funding risk-based business licensing; resolution of problems and obstacles to Risk-Based Business Licensing; and sanctions. In 2021 there are 1,702 business activities consisting of 1,349 standard classifications of business fields that have implemented this system. One of those who have taken advantage of this system is a business license to set up a pharmacy.

The existence of OSS can provide acceleration benefits, but on the other hand, it results in OPD not being able to see the conditions in the field, especially in the business license for organizing pharmacies in the Bantul Region. This condition also further reduces the opportunity when referring to the regulations that the establishment of new pharmacies must be balanced between the high ratio and low ratio areas. When referring to Government Regulation Number 5 of 2021, regional regulations should not be allowed to intervene in the implementation of risk bases in the regions should not be intervened. This condition had previously been discussed at the coordination meeting to discuss the draft regulation of the Bantul regent on the implementation of pharmacies that this regent's regulation was no longer relevant. However, because there are those that are not in accordance with other rules, it cannot be discussed further. Some of the things in question, such as the NSPK of the Ministry of Health PMK Number 14 of 2021, the lack of technical guidelines, plus opds that should be able to be involved in business licenses if done manually are now unable to see directly how conditions are in the field. Although the task is already there is the effectiveness of the service to supervise and formulate regulatory regulations.

Pharmacies as one of the community health facilities are increasingly in demand by the public along with the era of the National Health Insurance. In addition to being a place to carry out pharmaceutical duties for pharmacists, pharmacies are also business fields that require management techniques to generate profits and remain principled on pharmaceutical service standards. Spatial planning of health facilities can be one of the solutions for the spread of health facilities. The location factor is now an important aspect for success in addition to being associated with the distribution of numbers as well as the equitable distribution of locations. In addition, it is also related to the issuance of business licenses that must go through the OSS system.

The local government in this case is expected to be able to prepare recitations in the regions based on PP No. 6 of 2021. Local governments can strengthen pharmacy business managers in the regions. The strengthening and empowerment, among others, is carried out by means of service implementation; management of community complaints; information management; counseling to pharmacy entrepreneurs; consulting services; and legal assistance. To carry out these activities, a legal basis is needed as the basis for the pharmacy implementation program in Bantul Regency.

According to research conducted by Ref. [5] on the analysis of pharmacy distribution based on the performance of Pharmaceutical Service Standards in the City and Regency of Pekalongan, it was found that the distribution of pharmacies was uneven. Pharmacies are more clustered at a residential point near the city which can be seen based on the distribution map. This study concluded that the need for evaluasi health offices and IAI, namely the location factor, plays an important role in the licensing of pharmacies. Another study conducted by Ref. [6] also found that licensing management and adaptation to government policies are weaknesses in running a pharmacy business.

Based on the background above, researchers are interested in conducting a conceptual study of the analysis of Bantul Regent Regulation Number 22 of 2018 regarding the requirements for the establishment of pharmacies in the area of high ratios and low ratios. The purpose of this study is to conduct a conceptual study on the analysis of pharmacy establishment between high and low ratio areas based on Bantul Regent Regulation Number 22 of 2018. These results are the basis for improving the effectiveness of drug supervision in pharmaceutical service facilities through permit studies and for the formulation of patterns of strengthening and empowering pharmacies in Bantul district.

## **Method**

### **A. Inclusion Criteria**

The criteria for articles included are articles published from September 2016 to September 2021, articles in Indonesian and English, free variables, namely pharmacy guidelines and bound variables, namely the implementation of pharmacy services. The article should have a pharmacist population and discuss the regulations for the administration of pharmacies in developing countries. Exclusion criteria are opinion articles, articles that only contain abstracts and review articles.

### B. Search Outcome

In the initial stage of searching on 3 databases, 2663 articles were found and then entered into the covident application to help facilitate the selection of articles. Duplicated articles were deleted so that 2660 articles were selected. In the next stage, a selection was made based on the title and abstract so that 52 articles were selected. Articles that have been selected are then selected according to bound variables and free variables. In the next process each article is read to eliminate articles that do not fit the inclusion criteria of 22 articles. The final stage selected 6 articles that passed to the critical appraisal stage.

### C. Charting Data

The articles found are 6 articles that have been included in Table 1 of the Charting Data. The main variables included are the researcher, the origin of the country, the variables about the Regulations for the Implementation of Pharmacies in Low Middle Income Countries and the size of the sample reviewed in the article. The search results specify the article being studied as shown in Table 1.

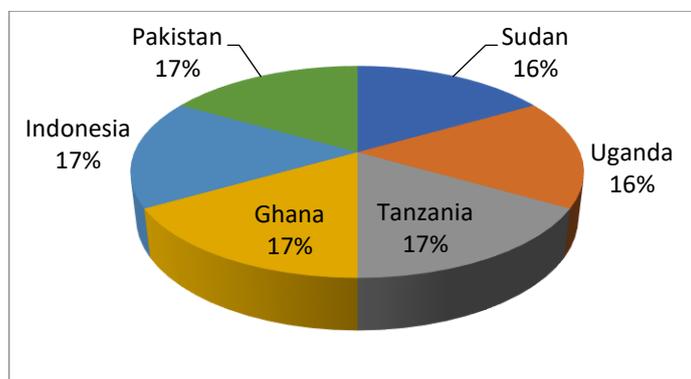
**Table 1.** Charting Data

Code	Author & Country	Design	Main Variable	Sample Size
A1	Hermansyah [7] Indonesia	<i>Qualitative</i>	Pharmaceutical Practices, Enforcement of Policies and Regulations, Increased public recognition of pharmacists	34 National Pharmaceutical stakeholders data collected with <i>Nominal Group Techniques</i> (NGT) in July 2017
A2	Omer [8] Sudan	RCT	Pharmaceutical Laws in Sudan, Drug procurement systems, Pharmacy Licensing, Types of Pharmacies	40 drug importers including pharmacists, data collected through questionnaires and interviews
A3	Trap et al. [13] Uganda	<i>Cross sectional</i>	GPP ( <i>Good Practice Pharmacy</i> ) Regulatory Evaluation using SPARS ( <i>Supervision, Performance, Assessment and Recognition Strategy</i> )	455 pharmacies measured using 10 GPP indicators

A4	Embrey et al. [10] Tanzania	<i>mixed methods</i>	Accredited Pharmacy Program (ADDO) in Tanzania	1185 households and audited 96 ADDO and 84 health facilities public/private
A5	Qadeer & Amin [9] Pakistan	<i>Qualitative</i>	Regulations on the availability of pharmacists in community-based Pharmacies	10 pharmacists using TPB-based open interviews
A6	Hamill et al. [12] Ghana	<i>Qualitative</i>	Regulation on the quality of drug dispensaries in Ghana	200 patients who were pharmacists and patients were conducted with semi-structured interviews

## Result

The articles found (Figure 2 Characteristics of Articles By Country) come from 2 continents namely Africa (Sudan, Uganda, Tanzania, Ghana) Asia (Indonesia, Pakistan).



**Fig. 1.** Characteristics of Articles by Country

Research design (Figure 3 Characteristics Based on Research Design) of all articles varies including Cross sectional, Qualitative, RCT, Mixed methods.

Of the six articles, six themes were found on the regulation of the implementation of pharmacies in Low Middle Income Countries in Table 4 of the theme.

**Table 2.** Research Topics

No	Promotion Methods	Article
1	Pharmaceutical regulation	1,2,4,5
2	Types of pharmacies	2
3	Pharmaceutical practice	1,3,5,6
4	Drug procurement	2,4,6
5	Pharmacy licensing	2,
6	Pharmacy accreditation	1,2,3,4,

## Discussion

### A. Pharmaceutical Regulation (A1, A2, A4, A5, A6)

Enforcing policies and regulations is essential to ensure good pharmaceutical practices. Policy improvements are not considered top priority recommendations. There seems to be a general satisfaction with the various policies and regulations in force in the pharmaceutical sector of the Indonesian community, and most of the discussion is about the implementation of poor regulations in practice. One of the participants noted the need for more monitoring and site visits by the authorities (example: BPOM) to minimize the absence of pharmacists. However, he also blamed the authorities for justifying the irresponsible practice considering that some BPOM staff also work in the pharmacy [7].

These policies vary at the level of practice and/or between regions demonstrating the complexity and challenges of enforcement of regulations throughout Indonesia. The problem may be exacerbated because other institutions such as the police also have the authority to investigate the supply of medicines in pharmacies. One of the participants who held an important position in a pharmaceutical organization said that a police audit was not necessary because it was a form of intervention against the profession. However, he stressed that to some extent audits may be effective in encouraging pharmacists to return to pharmacies. Instead of focusing on the role of authorities to enforce regulations, some participants highlighted the role of peer groups to support the presence of pharmacists. This effort may be more encouraging for pharmacists [7].

The regulatory and policy framework structure has provided a legal basis for community pharmacies and pharmacists in Indonesia to participate in the health sector. These findings also highlight that top down structures have not been effectively enforced leading to limitations in practice, one of which is the general absence of pharmacists [7].

The availability of medicines in Sudan is controlled on the basis of safety, quality and efficacy. Thus, the government imposes surveillance in accordance with the Pharmaceuticals, Poisons, Cosmetics, and Medical Devices Act 2001 and its devices. The Federal or State Department of Pharmacy (DOP) and directives issue orders. The main goal of the Federal and State Departments of Pharmacy is to maintain public health by ensuring all medicines and medicines in the Sudanese market meet the appropriate standards of safety, quality and efficacy. Public health protection is largely achieved through drug registration systems and licensing of pharmacy premises. The first Pharmaceutical and Poisons Act was enacted in 1939. This law has been amended three times since then. In the 2001 amendment, cosmetics and medical equipment were also included in its scope. Thus, its name was changed to the Pharmaceuticals, Poisons, Cosmetics and Medical Devices Act [8].

The law makes provisions for the publication of regulations and guidelines by the Federal Pharmacy and Poisons Board (FPPB), the pharmaceutical regulatory authority and its

executive branch - the Federal Directorate General of Pharmacy (FGDOP). FGDOP regulates mainly four aspects of drug use: safety, quality, efficacy and price. Traditionally, governments in many countries, particularly developed countries have sought to ensure the efficiency, safety, rational prescribing, and dispensing of drugs through pre-marketing registration, licensing and other regulatory requirements. When applying for registration, drug manufacturers and importers are required to complete the FGDOP with information files including drug indications, efficacy, side effects, contraindications [8].

In Tanzania, the Tanzania Food and Drugs Authority and its predecessor agents allowed retail drugstores, known as Part II stores, to sell only medicines without a prescription. With more than 5,600 stores registered in 2003, and more operating without registration, they are Tanzania's largest and most popular source of private sector medicines mainly because of their proximity, more convenient working hours, and more reliable supplies than public sector clinics. However, there are some problems with Part II stores including the illegal sale of prescription-only drugs, untrained and unqualified drug sellers, and a lack of enforcement of regulations. To solve this problem, a public-private initiative aimed at improving the quality of products and services in Part II stores was launched in 2003. The Accredited Drug Dispensing Outlet (ADDO) program takes a comprehensive approach.

The law in Pakistan has been amended and has begun to do away with the rule of the existence of pharmacists in the apothecary community encountering challenges in law enforcement. According to Pakistani law, drug dealers are responsible for visiting every pharmacy in their jurisdiction at least twice a year. It is possible that by the time of implementing the new policy, more visits will be needed. However, to achieve this, there needs to be a number of trained and competent inspectors and adequate resources for them to visit all places, in particular rural areas that have a higher level of pharmacist absenteeism [9].

The main challenge identified in law enforcement is the effort to change norms that have existed for decades. A study conducted in three cities in Pakistan found that, in 2008, half of pharmacies operated under type B licenses and the rest were evenly distributed between type A and C licenses. In addition, there is a sense of being threatened by category C cyclists who feel that the new policy will marginalize them. It would make sense to review their current numbers and give them opportunities for training and growth. For those who are unwilling or unable to improve their training, new roles and opportunities in pharmacies should be provided that do not jeopardize patient safety [9].

Ghana has a relatively well-functioning regulatory system compared to other countries in the region. However, as interviewed from the Ghana Food and Drug Authority (GFDA) told us, they remain under-resourced and lack the capacity to effectively control the supply of poor

quality medicines, especially outside major urban centres. WHO and other agencies have responded with efforts to strengthen national regulatory and reporting capacity

### **B. Pharmacy Type (A2)**

In Sudan there are two types of retail pharmacies [8]. Commercial private pharmacies are private enterprises that sell registered medicines and medical supplies with a mark-up of 18%. The source of medicines and medicines is private wholesalers. In 2002, despite the violation of the law, CMSPO began selling unregistered drugs to private pharmacies. At the end of 2004, there were 779 private pharmacies in Sudan. Public pharmacies is a quasi-public company that sells medicines and health supplies below market prices to improve access and availability of medicines. The dispensary was established in the early 1980s as a pilot study for the drug's cost recovery system. They differ from private commercial pharmacies. First, it has access to CMSPO drugs i.e. generic and large packaged products, in addition to brand products from private wholesalers. Second, people's pharmacies are owned only by community organizations (for example, hospitals, community committees, trade unions and non-governmental organizations (NGOs)). Mark-up of drug costs from CMSPO (35%), and from private drug wholesalers (profit margin 10%). However, they have been commercialized now and operate in a similar way to private pharmacies. The total number of such pharmacies is about 200 in Sudan.

### **C. Pharmaceutical Practice (A1, A3, A5, A6)**

The role of community professional pharmacists and the potential contribution of community pharmacy as a means to improve public health. However, there are concerns that frequent pharmacist absences in pharmacies are directly contrary to regulations. In addition, the current regulations that allow pharmacists to work simultaneously in up to three pharmacies became a common topic in any group discussion with some participants voicing concerns about the negative impact of these regulations that also encouraged the absence of pharmacists in pharmacies [7].

In Pakistani law, the pharmacist is responsible for narcotics in pharmacies, which are stored in bawah supervision of pharmacists and is also responsible for ensuring bahwa the storage conditions of drugs in the refrigerator are in accordance with the requirements. The presence of apoteker will allow pharmacies to comply with the laws in this area. Another reason to choose the presence of a pharmacist is tomuaskan patients who visit the pharmacy who prefer to have apoteker, especially if they want to talk to the pharmacist about certain therapeutic questions or if they want to consult a pharmacist instead of going to the doctor [9].

Pharmacy professional is very difficult to implement because pharmacies are mostly focused on selling drugs therefore the need to change the identity and layout of pharmacies as

a means to disseminate professional practice. In addition, reviewing the Standards for the place and location of pharmacies because many pharmacies are adjacent to each other and without carefully considering the safety and quality aspects. recommendations for revising building and facility standards and accreditation of pharmacy quality seem to be very important for maintaining professional ethical. The development of standards, guidelines and accreditations is highlighted as an effort to reduce variations in apoteker qualifications and pharmacy distribution across the country while pada at the same time promotes "best practices" because pharmacists and pharmacies have an important value for optimal patient care [10].

Although there was no disagreement that professional services should be performed by pharmacists, some besar participants highlighted the lack of remuneration to provide such layanan. This triggered a recommendation to settle down remuneration for pharmacists who provide professional services. While there is no disagreement that professional services should be performed by pharmacists, the study cites a lack of remuneration to provide services. Apotek perlu developed a strategy to gather evidence of the contribution of pharmacies to public health which is currently lacking because pharmacies have limited documentation capacity [7,11].

Research in Ghana by Ref. [12] explains that people choose to buy licensed pharmacy medicines because:

" Their medicines are more likely to be purchased from official manufacturers so safety is guaranteed ... I believe they will do their checks well. "

OTC drugstores and general stores are often considered to sell low-quality drugs:

' When I look at those [OTC] chemical stores, my feeling is that they may be involved in some fraudulent stuff and their drugs may be fake, '

Customers generally like established and popular outlets, arguing that such outlets do not want to risk reputational damage. Size and location are also important: interviewees generally believe that large companies located at the center will find it more difficult to sell dubious drugs than smaller and more 'hidden' ones:

'Larger shops, the probability that they will sell fake medicines is very minimal compared to those in the village. They have invested a lot – this is a sign they are thinking of doing good business. '

Some also assume that large stores have a faster stock turnover, thereby reducing the risk of spoilage of drugs. For the same reason, potential customers research the general condition and storage facilities of the drug in the store:

'These are great pharmacies and their medicines are stored in excellent condition, at the right temperature so that the potency of the drugs is not compromised'

Buyers also feel more confident in the ability of neatly dressed and professional-looking staff who speak knowledgeably in pre-sale discussions:

' You can talk to them to see that the person has been trained. If I talk to you and see that you have not been trained, I will not buy from you because it can be dangerous. I may have a headache and you give me medicine for stomach pains. You can tell from the details they enter when they talk about whether they have been trained'

#### **D. Drug Procurement (A2, A4, A6)**

The FGDOP is responsible for the assessment, and registration of all medicines and other medicines for human and veterinary use in the Sudanese market. It is also responsible for the verification of the competence of manufacturing enterprises, factories, the ability to produce high-quality substances or products before registering these companies and allowing them to apply for registration of their products in Sudan. When necessary, visits are made to those companies and their manufacturing units, to verify their compliance with the good manufacturing practices recommended by WHO. Applicants for registration of pharmaceutical products must submit all specified data and certificates required under the WHO certification scheme for pharmaceutical products that may be used in international trade [8,13].

Drug procurement system The act, for the first time in Sudan has given the responsibility of veterinary medicines to a separate committee. The Ministry of Animal Resources took the law "in hand", and began the registration of veterinary drugs and the licensing of veterinary drug premises. The conflict over the division of authority between the Ministry of Health and the chairman of the FPPB led to the suspension of the management since October 2002. FGDOP continues in the process of drug registration, inspection of pharmaceutical premises and licensing as before the establishment of the FPPB. FPPB. The law also requires state governments to take all necessary measures to ensure compliance with the marketing of drugs registered in licensed premises. However, weaknesses in the regulatory infrastructure and lack of political commitment at the state level, the leakage of unregistered low-quality medicines to those states is highly suspected. This leaves the door wide open for informal marketing of medicines particularly in distant states. State regulatory authorities should take advantage of the legal authority granted by Sudan's constitution and the Pharmaceuticals, Poisons, Cosmetics and Medical Devices Act 2001 to enforce regulations and increase the frequency of inspection visits to drug companies and retail pharmacies. Experience shows that poor drug regulation can lead to the rise of substandard, counterfeit, dangerous and ineffective drugs in national markets and international trade. Sudan's pharmaceutical legal framework is described as one of the most restrictive pharmaceutical systems in the region. One major

loophole in the system is the increasing number of unregistered medicines—government sources such as the Central Medical Supplies Public Organization (CMSPO) and non-profit non-governmental organizations (NGOs). Respondents hope the double standard of enforcement of the rules will be lifted after the new national unity government takes over.

FGDOP should establish the necessary norms, standards and specifications to ensure the safety, efficacy and quality of medicinal products. The availability, accuracy and clarity of drug information may influence drug use decisions. FGDOP does not have a good system for pre-approval of drug labels, promotional materials, and advertising. The terms and conditions under which the license to import, manufacture and distribute will be suspended, revoked or cancelled. It should be strictly applied to public, private and non-profit NGO drug supply organizations. The dominant view, which is divided among the importers of medicines is that the current pharmaceutical legislation is to some extent satisfactory and successfully prohibits the marketing of low-quality medicines. A recent post-marketing study conducted by the National Drug Quality Control Laboratories, suggests the current regulatory strength is too high. The findings of this article indicate the procedure for implementing current measures to ensure the quality of the drug should be revisited.

Research by Ref. [10] explained about the collection of data on the availability of medicines in rumah. Of the 1,185 households, 422 (36%) had drugs to be shown to the data collector, with a total of 771 samples. More than half (58%) of young medicines recommended by doctors or nurses are obtained from public health facilities, and the second from pharmacies (33%). Audits of health facilities and ADDO assess the availability of drug lists. Comparing the availability of capsules and tablets in ADDO and similar health facilities, ADDO has a much better availability of suspensions and syrups, which are usually prescribed to treat young children (70% vs. 16%,  $p < 0.001$ ). However, an average of 91% of ADDO had one or more antimalarials in stock compared to 97% of health facilities ( $p = 0.072$ ).

#### **E. Pharmacy Licensing (A2, A5)**

Licensing of pharmacy premises License is a registration exercise to provide the DOP at the state level (Federal level for local manufacturing plants) with the information necessary for the full implementation of the Act. The license is granted for a period of one year, and can be renewed at the end of December of each year (application to the relevant DOP before the expiration of the current license). To increase the effectiveness of general pharmacies, resources should be diverted to areas in need, reduce inequalities and improve better health conditions. The drugs are financed either through cost-sharing or full private. The role of private services is very significant. The current policy of the national health care system in Sudan is based on guaranteeing the welfare of the Sudanese population through increasing

national production and increasing individual productivity. The strategy of price liberalization and privatization has been implemented in Sudan over the past decade, and has had positive results on the government deficit [8,12].

#### **F. Pharmacy Accreditation (A1, A2, A4, A5)**

Pharmaceutical accreditation is also considered an important instrument for improving pharmaceutical practice. In fact, all participants agreed with the assumption that pharmacies must be accredited to ensure the continuity of good pharmaceutical practices delivered by pharmacists and pharmacies. One of the participants appreciated the initiative carried out by IAI and the Health Office to assess the quality of pharmacies in Yogyakarta [7].

Research in Uganda by Ref. [13] found Overalln, the proportion of public health facilities that obtained accreditation was 57.4%. Overall, the proportion of public health facilities that obtained accreditation was 57.4%. The percentage of certified SPARS (Erformance Assessment, And Recognition Strategy) supporting facilities and comparison facilities is 57.1 and 60.5%, respectively, this difference is not significant (Adj. OR = 0.91.95% CI 0.45-1.85.p = 0.802). The proportion of certified PNFN facilities (58.3%) is slightly higher than that of government facilities (57.1%) and the difference is insignificant (Unadj. OR = 1.07.95% CI 0.64-1.81.p = 0.792) [13]. Assessment indicators include:availability of handwashing facilities, compliance with labeling requirements, and roof and ceiling conditions. The main indicators are: storage and recording of expired drugs, Certified facilities have areas, GPP (Good Pharmacy Practices) compliance. Overall, only 57% of public facilities meet the required GPP standards and are certified for pharmaceutical practice. Our study suggests the need to supplement SPARS interventions with inspections as a regulatory strategy to continuously monitor facility progress.

Acredit through GPP strengthening strategies, such as SPARS performs more baik than comparative facilities. This is evidenced by a higher overall GPP compliance score and outperforming comparative facilities in passing major, and minor indicators. There was no difference in compliance scores for critical indicators between the two groups. One explanation is that critical indicators mainly assess structural conditions, such as walls, floors, roofs, water and sanitation whose supervisory influence is limited. Furthermore, from the indicators in which the intervention facility outperforms the comparative facility, all indicators are covered and regularly monitored by the SPARS intervention except for the cleanliness of the calculating tray which is not part of the SPARS indicator or supervision. Racks are provided as part of SPARS, and most intervention facilities can now store medicines in a more systematic and

organized manner, which underscores the considerable impact of infrastructure improvements [13].

In Ruvuma, Tanzania since 2003, the ADDO Accredited Dispensary program initiative has resulted in the creation and institutionalization of a cadre of new health providers in Tanzania's healthcare system. It is realized that from the large number of members of the public choosing to seek treatment in retail drugstores for various reasons, the Tanzanian government is precisely targeting quality problems in this arrangement rather than ignoring them. While most people still go to health facilities, mainly for the treatment of chronic diseases, most buy drugs for acute illnesses at ADDO, and DDO dispensers often refer serious cases to the public sector/NGOs. However, poor prescribing in health facilities, poor drug administration at ADDO, and improper patient demand continue to contribute to improper use of the drug. There are three main licenses in Sudan namely [8]: License A (Wholesale License), License B (Retail Pharmacy License), and License D (Manufacturer's License).

Pensale obat-medicines in Pakistan can be obtained from pharmacies, medical stores as well as community pharmacies. But unlike community pharmacies where all drugs can be sold, drugstores cannot sell drugs listed under "Schedule G" including immunological products, vaccines, biotechnology products, and narcotics.<sup>8</sup> Pharmacy licenses have been divided into three categories: type A (licenses for premises include the presence of a person with a BPharm/PharmD degree; that is, a pharmacist with full training), type B (license for the place including the existence of a person having a 2-year diploma in pharmacy) and type C (license for the place including the presence of a person who successfully completes a certified drug dispensing course)[9].

## **Conclusion**

The management of pharmacies having an impact on public health needs to be supported by clear regulations. Studies from various countries show that consumer protection, especially related to health, have an impact on the advancement of these services. In the digital era, coordination between the government, associations, and pharmacy provider make good business environment. There are many mechanisms to choose from the study results in other countries.

## **Conflict of Interest**

Authors declare that there is no conflict of interest.

## **References**

- [1] Sekretaris Daerah Kabupaten Bantul. (2018). *Peraturan Bupati Bantul Nomor 22 Tahun 2018 tentang Penyelenggaraan Apotek*. Sekertaris Daerah Kabupaten Bantul.
- [2] Puspaningrum, G. (2013). *Hukum Persaingan Usaha*. Aswaja Pressindo.

- [3] Bogadenta, A. (2012). *Manajemen Pengelolaan Apotek*. D-Medika
- [4] Kementrian Investasi. (2012). *Layanan Perijinan Berusaha OSS*. Available from: <https://oss.go.id/>
- [5] Dahbul, N. A., Yasin, N. M., & Lazuardi, L. (2021). Analisis Distribusi Apotek Berdasar Standar Pelayanan Kefarmasian Melalui Sistem Informasi Geografis. *Majalah Farmaseutik*, 17(1), 82-88. <https://doi.org/10.22146/farmaseutik.v17i1.52846>.
- [6] Sihite, T. P., & Kusumadmo, E. (2017). *PT K-24 Indonesia, EFAS, IFAS, SFAS, Strategic Audit, Strategi Bersaing*. UAJY. Availabe from: <http://e-journal.uajy.ac.id/11380/>
- [7] Hermansyah, A., Pitaloka, D., Sainsbury, E., & Krass, I. (2018). Prioritising recommendations to advance community pharmacy practice. *Research in Social and Administrative Pharmacy*, 14(12), 1147-1156. <https://doi.org/10.1016/j.sapharm.2018.02.003>
- [8] Omer, A. M. (2015). Assessment of the Substandard Drugs in Developing Countries: The Impact of the Pharmaceutical Regulations on the Quality of Medicines on the Sudanese Market Importers' Perspective. *ARC Journal of Pharmaceutical Sciences (AJPS)*, 1(2), 21-31.
- [9] Qadeer, G., & Amin, M. E. K. (2021). Perspectives on an amended law addressing pharmacists' availability in community pharmacies. *Journal of Evaluation in Clinical Practice*, 27(1), 151-157. <https://doi.org/10.1111/jep.13405>
- [10] Embrey, M., Vialle-Valentin, C., Dillip, A., Kihyo, B., Mbwas, R., Semali, I. A., Chalker, J. C., Liana, J., Lieber, R., Johnson, K., Rutta, E., Kimatta, S., Shekalaghe, E., Valimba, R., & Ross-Degnan, D. (2016). Understanding the Role of Accredited Drug Dispensing Outlets in Tanzania's Health System. *PLOS ONE*, 11(11), e0164332. <https://doi.org/10.1371/journal.pone.0164332>
- [11] Hamidi, J. (2011). Paradigma Baru Pembentukan Dan Analisis Peraturan Daerah (Studi Atas Perda Pelayanan Publik Dan Perda Keterbukaan Informasi Publik). *Jurnal Hukum Ius Quia Iustum*, 18(3), 336-362. <https://doi.org/10.20885/iustum.vol18.iss3.art3>
- [12] Hamill, H., Hampshire, K., Mariwah, S., Amoako-Sakyi, D., Kyei, A., & Castelli, M. (2019). Managing uncertainty in medicine quality in Ghana: The cognitive and affective basis of trust in a high-risk, low-regulation context. *Social Science & Medicine*, 234, 112369.
- [13] Trap, B., Kikule, K., Vialle-Valentin, C., Musoke, R., Lajul, G. O., Hoppenworth, K., & Konradson, D. (2016). First regulatory inspections measuring adherence to Good Pharmacy Practices in the public sector in Uganda: a cross-sectional comparison of performance between supervised and unsupervised facilities. *Journal of pharmaceutical policy and practice*, 9(1), 1-10. <https://doi.org/10.1186/s40545-016-0068-4>

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