

# Pharmacy Premises Licensing Policy Formulation: Experience from Ghana

Augustina Koduah (✉ [akoduah@ug.edu.gh](mailto:akoduah@ug.edu.gh))

University of Ghana School of Pharmacy <https://orcid.org/0000-0001-9915-5333>

Reginald Sekyi-Brown

University of Ghana School of Pharmacy

Joseph Kodjo Nsaiah Nyoagbe

Paddocks Company Ltd

Daniel Amaning Danquah

Ghana Pharmacy Council

Irene Kretchy

University of Ghana School of Pharmacy

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## Research

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# Abstract

**Background:** Licence to operate pharmacy premises are issued by statutory regulatory bodies. The Pharmacy Council regulated pharmacy premises until the Health Facilities Regulatory Agency (HeFRA) was mandated by Act 829 (2011) to license pharmacy premises. The Pharmacy Council under Act 857 (2013) now regulates the business of mixing, compounding, preparing, or supplying restricted medicines by retail.

**Objective:** To describe the policy actors involved, framing of narratives and decision-making processes relating to pharmacy premises licensing policy formulation.

**Methods:** A descriptive qualitative study was conducted and data gathered through interviewing eight key informants and reviewing Hansards, reports, Bills, memoranda and Acts 829 and 857. Data were analysed to map decision-making venues, processes, actors and narratives.

**Results:** The Health Institutions and Facilities Bill (2010) and the Health Professional Regulatory Bodies Bill (2010) were designed within the Ministry of Health bureaucratic system and processes with inputs and consensus from all stakeholders including the Private Hospitals and Maternity Homes Board and the Pharmacy Council. Between 28 October 2010 and 20 July 2011, the Health Institutions and Facilities Bill which established HeFRA, was subjected to legislative procedures and decisions by parliamentarians. The parliamentarians framed pharmacies as health facilities and reassigned its regulation to HeFRA. Similarly, the parliamentarians deliberated on the Health Professional Regulatory Bodies Bill which established the Pharmacy Council between 4 March 2011 and 21 December 2012. To which all content relating to licensing pharmacy premises were deleted from the Bill.

**Conclusion:** The content of these policies rested with parliamentarians (with legislative power) and was largely based on how they framed issues relating to pharmacy premises regulation. Legislative procedure limited participations although non-legislative actors had some level of influence on the initial content. As legislative processes may be similar in other LMICs, this paper can contribute to learning and the formulation of Pharmacy premises regulation.

## Background

Pharmacy premises are facilities in which pharmaceutical services are offered and a licence is needed to operate one (1). In Ghana the licence is provided by government through a statutory regulatory body. The issuance of licence to operate a pharmacy premise started with the enactment of Druggists Ordinance in 1892 where the governor issued licence to persons to carry on the business of mixing, compounding, preparing, selling, retailing or dispensing any drug or poison (2). The statutory regulatory body – Board of Examiners – was then established under the Druggists Ordinance. Since then, the name of the statutory regulatory body had evolved as laws establishing it were revised. The Board of Examiners changed to Pharmacy and Poisons Board under the Pharmacy and Poisons Ordinance 1946 (3), then to Pharmacy Board and Pharmacy Council under the Pharmacy and Drugs Act 1961 (4) and the Pharmacy Act 1994

(5) respectively. The revised laws did not create a new statutory regulatory body but expanded the administrative capabilities and responsibilities of the existing one.

In 2011, government enacted a Health Institutions and Facilities Act (Act 829) to establish a Health Facilities Regulatory Agency to license and monitor health facilities including pharmacy premises for the provision of public and private health care services. Under Act 829, the Health Facilities Regulatory Agency took over the issuance of pharmacy premise operation licence from the Pharmacy Council. A provision was therefore made in Act 829 for the Pharmacy Council to transfer any information, knowledge, materials and staff necessary for the functioning of the agency within five years after the commencement of Act 829 (6).

However, in 2013 the Pharmacy Act 1994 (Act 489) was revised and incorporated as part four in a consolidated Health Professions Regulatory Bodies Act (Act 857) (7). Part four of Act 857 established a Pharmacy Council (an existing statutory regulatory body) with added objectives among others to ensure the equitable and accessible distribution of pharmaceutical premises. Additionally, under Sect. 93 of Act 857, the Pharmacy Council was to grant licence to a body corporate or a government institution to carry on the business of mixing, compounding, preparing, or supplying restricted medicines by retail under the supervision of a superintendent pharmacist. Act 857 defined restricted medicines as prescription only medicines, pharmacy only medicines, over the counter medicines and any other classifications approved by the Minister for Health (7). Act 829 and Act 857 are different statutory policies regulating pharmacy premises and the business of mixing, compounding, preparing, or supplying restricted medicines by retail under the Health Facilities Regulatory Agency and Pharmacy Council respectively.

This paper aims to advance our understanding of policy formulation in a low and middle-income country (LMIC) setting by exploring the decision-making processes, problem definitions and the framing of narratives leading to the formulation of statutory policies for pharmacy premises and the business of mixing, compounding, preparing, or supplying restricted medicines by retail in Ghana. Decision-making process involves the steps in which choices are made or preferred option is selected at a point or series of points in time when policy makers define problems and propose solutions (8). Problem definition involves how problems are framed and how policy actors debate and interpret the issue for decision (8). Since there is no one fixed problem definition for a particular policy issue, such policy issues are subject to the interpretative manoeuvres of powerful policy actors and their ability to propose convincing solutions (9). Problem definitions are therefore shaped out of debates, rebuttals and meanings of narratives (10, 11). It is therefore important to understand who is defining the problem, pushing narratives and the context in which decisions are made. In this paper we describe the policy actors involved, how they framed regulatory issues relating to pharmacy premise and the business of mixing, compounding, preparing, or supplying restricted medicines by retail and the corresponding decision-making processes and venues. The research questions were: Which actors have been involved in the decision-making processes? How did they frame issues and what narratives did they push forward to influence decisions? Understanding how actors framed issues, advanced specific narratives and made decisions relating to regulation of pharmacy premise and the business of mixing, compounding, preparing, or supplying restricted

medicines by retail is essential to inform pharmacy policy making and learning. Additionally, there is little information available to practitioners who wish to understand how issues relating to pharmacy premises and business regulation were framed and debated in a lower-middle income setting such as Ghana.

## Methods

We conducted a descriptive qualitative study to examine the policy actors involved and how they framed issues during decision making processes in the design of Act 829 and Act 857.

## Data collection methods

Data collection methods included extensive document review and key informant interviews. Document review and analysis were used to examine the sequence of decision making, trace and map events, identify the policy actors involved in the decision-making processes and how they framed issues relating to regulation of pharmacy premises and the business of mixing, compounding, preparing, or supplying restricted medicines by retail. The documents reviewed and analysed are summarized in Table 1. The Acts were passed by the Parliament of Ghana and therefore the Parliamentary debates reports (Hansards) which are verbatim records, were a great source of information on policy actors involved and how they framed and debated issues. Hansards transcripts from 28 October 2010 when the Health Institutions and Facilities Bill was first read to 21 December 2012 when the Health Professions Regulatory Bodies Bill was passed in Parliament were obtained from the Ghana Parliament Library. Hansards transcripts are important data sources and provide a way to investigate how decisions are made (12). Other documents generated outside the Parliament such as the Parliament Select Committee on Health report and memoranda submitted to the committee were also reviewed and analysed to map up discussions and decisions outside of the Parliament. The Health Institutions and Facilities Bill and Health Professions Regulatory Bodies Bill and corresponding Act 829 and Act 857 were also reviewed to trace content changes relating to pharmacy premises and business.

Table 1  
List of documents reviewed

<b>Documents</b>	<b>Date</b>
<b>Hansards</b>	
Parliamentary Debates (Official Report) Fourth Series Vol 71 No.7 • First reading of Bills - Health Institutions and Facilities Bill, 2010	28th October 2010
Parliamentary Debates (Official Report) Fourth Series Vol 72 No.39 • Second reading of Bills- Health Institutions and Facilities Bill, 2010	22nd March 2011
Parliamentary Debates (Official Report) Fourth Series Vol 73 No.22 • Consideration stage of Bills- Health Institutions and Facilities Bill, 2010	23rd June 2011
Parliamentary Debates (Official Report) Fourth Series Vol. 73 No.37 • Third reading of Bills- Health Institutions and Facilities Bill, 2010	20th July 2011
Parliamentary Debates (Official Report) Fourth Series Vol 79 No. 3 • Second reading of Bills- Health Professions Regulatory Bodies Bill, 2010.	24th October, 2012
Parliamentary Debates (Official Report) Fourth Series Vol 79 No. 4 • Consideration stage of Bills- Health Professions Regulatory Bodies Bill, 2011	25th October, 2012
Parliamentary Debates (Official Report) Fourth Series Vol 79 No. 9 • Consideration stage of Bills- Health Professions Regulatory Bodies Bill, 2011	18th December, 2012
Parliamentary Debates (Official Report) Fourth Series Vol 79 No. 11 • Consideration stage of Bills- Health Professions Regulatory Bodies Bill, 2011	20th December, 2012
Parliamentary Debates (Official Report) Fourth Series Vol 79 No. 12 • Consideration stage of Bills- Health Professions Regulatory Bodies Bill, 2011 • Second consideration stage of Bills- Health Professions Regulatory Bodies Bill, 2011 • Third reading of Bills- Health Professions Regulatory Bodies Bill, 2011	21st December, 2012
<b>Memoranda accompanying the Bills</b>	
Health Institutions and Facilities Bill, 2010 Memorandum	2010
Health Professions Regulatory Bodies Bill, 2010 Memorandum	2010
<b>Bills</b>	
Health Institutions and Facilities Bill, 2010	July 2010
Health Professions Regulatory Bodies Bill, 2010	July 2010

<b>Documents</b>	<b>Date</b>
<b>Report &amp; Memorandum</b>	
Report of the Parliament Select Committee on Health	October 2012
Council of Elders of the Pharmaceutical Society of Ghana memorandum to the Parliamentary Select Committee on Health on the Health Institutions and Facilities Bill, 2010	1st March 2011
Review of the Pharmacy Council Component (Part Four) of the Health Professions Regulatory Bodies Bill 2012 by the Pharmaceutical Society of Ghana (PSGH)	2012
<b>Acts</b>	
Health Institutions and Facilities Act 829	2011
Health Professions Regulatory Bodies Act 857	2013

Key informant interviews were conducted to further understand the decision-making processes, policy actors' role and framing of issues as well as triangulate data from the document review and analysis. Key informants were selected based on their availability, experiences and knowledge of the decision-making processes, framing of issues and the policy actors involved. Eight respondents were interviewed between 28 November 2018 and 3 May 2019 and these included: the executive secretary of the Pharmaceutical Society of Ghana (PSGH), former chief pharmacist of the Ministry of Health and past president of the PSGH (2011–2015), two former Pharmacy Council chairpersons (1994–2009; 2009–2015), former chief medical officer of the Ministry of Health (2002–2008), head of monitoring and evaluation of the Ministry of Health (2004-date), former registrar of the Pharmacy Council (1981–1997) and the founding dean of the School of Pharmacy (University of Ghana). Five interviews were tape recorded and later transcribed. Notes were taken for three interviews and these were verified by the respondents. The interviews on average lasted 50 minutes and respondents were informed in advance of the study's purpose and their verbal consent sought. Interviews were stopped when respondents provided no new information on pharmacy premises and business regulation decision making processes, actors involved and how they framed issues. Personal identifiers were removed from the results session to ensure anonymity.

## **Data analysis**

Content on pharmacy premise and business licensing were traced from the Health Professions Regulatory Bodies and Health Institutions and Facilities Bills and Acts 829 and 857. The Bills submitted to Parliament and the amendments made overtime were highlighted, mapped and compared to Act 829 and Act 857 respectively and inclusions and deletions noted. Accompanying explanations and justifications for the deletion from the Bills and inclusions into the Acts from the Hansard transcripts, reports and memoranda were traced and documented.

Specific actors with interest in pharmacy premise and business licensing were listed and their narratives examined and categorized. Decision-making processes and venues and timelines relating to discussions on the Bills in and out of Parliament were mapped out. Interview transcripts were read, analysed and organised into retrievable sections based on the research questions. The transcriptions and document review notes were further manually coded using these themes: policy actors, framing narratives, Act 829 and Act 857. Analysis of parliamentary debates, reports, memoranda, Bills and Acts were used to further corroborate information from our key informants. Data were finally mapped out to chronological present timelines, decision making processes and venues, actors involved and the way they framed issues for pharmacy premises and business regulation.

## Study Limitation

The study relied on parliament proceedings which provided information on how decisions relating to pharmacy premises and business regulations were made in Parliament. However, these Hansards do not capture who said what and to whom during backbench discussions and these can be opportunities to influence others and create alliances. During the research period, efforts were made to interview Parliamentarians involved in direct discussions either on the floor of Parliament or as members of the Parliament Select Committee on Health to further understand their individual framing of issues, but this was unsuccessful. We acknowledge this difficulty and therefore triangulated data from multiple sources in an effort to present the decision-making processes and policy actors involved in the formulation of Act 829 and Act 857.

## Results

### 1. The Health Institutions and Facilities Act 2011, (Act 829)

The Minister for Health submitted the Health Institutions and Facilities Bill (dated 23rd July 2010) to Parliament on 28 October 2010 for first reading of the Bill (13). The Ministry of Health and its agencies and stakeholders such as the Attorney's General office (principal legal advisers) drafted the Bill.

*'The Health Institution and Facilities Bill was developed by the Ministry of Health and its agencies such as the Private Hospitals and Maternity Homes Board.'* (KI 6: 29/11/2018)

The part one of the Bill sought to provide for a Health Facilities Regulatory Agency to license facilities for the provision of public and private health care services. The Health Facilities Regulatory Agency was to replace and expand the mandate of the Private Hospitals and Maternity Homes Board under Act, 1958 (No.9) (14). The Private Hospitals and Maternity Homes Board (Act 1958) was outdated and did not adequately regulate all health care facilities.

*'The Private Hospital and Maternity Homes Board was over stretched and could not adequately regulate all private hospitals and maternity homes. The Act has not been revised since developed 1958 and a lot has happened since then within the health sector.'* (KI 4: 20/01/2019)

*'The Private Hospital and Maternity Homes Board's objectives were outdated, and its regulation excluded other facilities such as eye care clinics, geriatric homes and diagnostic imaging technology clinic many of which were springing out in the country.'* (KI 6: 29/11/2018)

The Bill therefore sought to fill in the gap created by the Private Hospitals and Maternity Homes Board (1958) and mandate the Health Facilities Regulatory Agency to license the operation of these practices: *'medical and dental services, clinics and hospitals, optometry and optician services, chiropody, convalescent and nursing homes, community health services, geriatric homes, nursing care, nursing agencies, maternity homes, occupational therapy services, physiotherapy services, dental laboratory technology services, clinical and bio-medical laboratory technology services, ophthalmic nursing services and physician assistants clinics'*(14). After first reading of the Health Institutions and Facilities Bill, 2010 in Parliament, the speaker of Parliament in accordance to Article 106 of the Constitution of Ghana referred the Bill to the Parliament select Committee on Health for consideration (13).

## **Parliament Select Committee on Health deliberations**

According to the 22nd March 2011, parliamentary debates report, the Committee on Health requested for written memoranda on the Bill from the general public and stakeholders to engage them in the decision-making process. The Committee met for three days with those who presented memoranda and other stakeholders in the health sector to examine the Bill in detail (15). The Committee reviewed the Bill and considered pharmacies as facilities to be licensed by the Health Facilities Regulatory Agency.

*'During the Committee's consultative meetings there were discussions of adding pharmacies to list of facilities to be regulated by the Health Facilities Regulatory Agency.'* (KI 4: 21/01/2019).

*'The Pharmacy Council had successfully regulated pharmacies over the decades and agenda of the Bill was to replace the Private Hospital and Maternity Board policy and certainly not to take over the regulatory mandate of the Pharmacy Council.'* (KI 2: 14/12/2018)

The stakeholders that met with the Committee to discuss the Health Institution and Facilities Bill are summarised in Table 2 (15). Of these stakeholders, a Pharmacy Interest Group of the PSGH - the Council of Elders, had concerns with the discussion to include pharmacies to the facilities to be licensed by the Health Facilities Regulatory Agency and therefore sent a memorandum dated 1 March 2011 to the Committee.

Table 2

Stakeholders that discussed the Health Institutions and Facilities Bill, 2010 with the Parliament Committee (15)

<b>Minister for Health, Hon Joseph Yieleh Chireh</b>
Deputy Minister for Health, Hon Robert Joseph Mettle-Nunoo
The Acting Chief Director Ministry of Health, Dr. Sylvester Anemana
Chief Executives, Registrars and Directors of Agencies and Departments of the Ministry of Health
Society of Private Medical and Dental Practitioners of Ghana
Ghana National Chemical Sellers Association
The Pharmacy Interest Group of the Pharmaceutical Society of Ghana (Council of Elders)
Officials from the Attorney-General's Department (The Legislative Drafter -principal legal adviser)

In the memorandum, the Council of Elders made the following submissions in relation to the intended addition of pharmacies to the First Schedule of the Health Institutions and Facilities Bill. One, *'it is the practice in most part of the world for a separate and independent Authority to regulate both pharmacy practice including practitioners and licensing of pharmacy premises. This and the fact that under the existing legislation the Pharmacy Council is performing its mandate well and may have informed the decision to exclude pharmacies from the list of premises indicated in the Bill'*. Two, *'the Minister of Health's memorandum to the Health Institution and Facilities Bill as published in the Gazette did not mention pharmacy at all'*. Three, *'currently the Pharmacy Council regulates about 12,000 registered facilities in Ghana made up of Pharmacy Retailers, Wholesalers, Retailers/Wholesalers and manufacturing wholesalers and 10,000 chemical sellers. In addition, Pharmacy Council inspectors pay working visits to public hospitals pharmacies and dispensaries.'* Four, *'for effective and efficient inspection and monitoring of activities in these premises, the Pharmacy Council has set up offices throughout the country. Except for the northern part of Ghana (Northern, Upper East, Upper West) which has a zonal office at Tamale, the rest of the country has regional offices located in the capitals namely Accra, Kumasi, Sekondi, Cape Coast, Koforidua, Ho and Sunyani'*.

## **Framing narratives and decisions relating to pharmacy premises regulation in Parliament**

During the second reading of the Health Institutions and Facilities Bill, the chairman of the Parliament Select Committee on Health in his report to Parliament on the 22nd March 2011 noted that the Bill will expand the scope and mandate of the Private Hospital and Maternity Homes Board to regulate public health facilities as well as pharmacies. On the floor of Parliament, the Committee among other issues recommended adding *'pharmacies and chemical shops'* to the definition of practice under Clause 24 of the Bill (16). But a parliamentarian was against the inclusion and noted that *'the regulation and licensing of pharmacy practice is not bundled up with other healthcare practices in most parts of the world. For*

*instance, the General Pharmaceutical Council in the United Kingdom and State Boards of Pharmacy and the General Pharmacy Council in Nigeria are all responsible for the license of pharmacies and related premises and regulation of pharmacy practitioners'. The parliamentarian further reiterated that the Pharmacy Council should be allowed to continue regulating pharmacies. The Minister for Health who is a parliamentarian supported this call to exclude pharmacies and the need to follow best practices around the world and allow the Pharmacy Council to continue its work. The Minister for Health noted that 'pharmacies were left out by promoter of the Bill for good reasons' and urged members to vote for the motion to exclude pharmacies. The speaker called for a vote on the motion. The question was put, and motion agreed to maintain a list that excludes pharmacies (16).*

On the 23 June 2011, the Bill was discussed in Parliament during the consideration stage. Discussions focused on operationalising the activities of the Health Facilities Regulatory Agency and fine-tuning its functions. A member of the Parliament Select Committee on Health reiterated that 'the Bill gives the Health Facilities Regulatory agency the mandate to determine locations of both public and private health facilities including where district hospitals should be located. In the similar logic, he argued that the agency should determine where pharmacies should be located since they are health facilities. The motion to amend the list of facilities to be regulated by the agency was made and the amendment agreed to (17).

*'Out of Parliament, the pharmacy fraternity were taken by a storm with the deliberations in Parliament to include pharmacies. This dramatic turnaround of events meant the advocacy and lobbying of the PSGH was not taken into account. Pharmacies were added to the list on the floor of Parliament'. (KI 2: 14/12/2019)*

The Health Institutions and Facilities Bill was read the third time and passed on the 20 July 2011(18). The approved Health Institutions and Facilities Bill was gazetted on 31 December 2011 as Act 829 (6). The changes relating to pharmacy premises made to the Health Institutions and Facilities Act 829, 2011 are summarised in Table 3 (6, 14).

Table 3

Summary of provisions (text) modifications relating to pharmacy premises in Act 829 (6, 14)

Health Institutions and Facilities Bill, 2010	Modified in Act 829
<p>Object and functions of the Agency: Clause 3 (1)</p> <p>The object of the Agency is to license facilities for the provision of public and private health care services</p>	<p><b>Object of the Agency: Clause 3.</b></p> <p>The object of the Agency is to license <b>and monitor</b> facilities for the provision of public and private health care services</p>
<p>Facilities to be licensed: Clause <b>10.(1)</b></p> <p>A person shall not operate a private facility unless the facility is licensed under this Act 10.(2) ' <i>A person shall not operate equipment for a service specified in the First Schedule unless the facility in which the person operates is licensed under this Act</i></p>	<p>Facilities to be licensed: Clause 11.(1)</p> <p><i>'A person shall not operate a facility unless the facility is licensed under this Act.</i></p> <p>11.(2) <i>'A person shall not operate equipment in a facility specified in the First Schedule unless the facility in which the person operates is licensed under this Act.</i></p>
<p>Interpretation: Clause: <b>24</b></p> <p><i>Practice includes medical and dental services, clinics and hospitals, optometry and optician services, chiropody, convalescent and nursing homes, community health services, geriatric homes, nursing care, nursing agencies, maternity homes, occupational therapy services, physiotherapy services, dental laboratory technology services, clinical and bio-medical laboratory technology services, ophthalmic nursing services and physician assistants clinics</i></p>	<p>Interpretation: Clause <b>25.</b></p> <p><i>Practice includes medical and dental services, clinics and hospitals, services in pharmacies and chemical shops, optometry and optician services, chiropody, convalescent and nursing homes, community health services, geriatric homes, nursing care, nursing agencies, maternity homes, occupational therapy services, physiotherapy services, dental laboratory technology services, clinical and bio-medical laboratory technology services, ophthalmic nursing services and physician assistants clinics</i></p>

Health Institutions and Facilities Bill, 2010	Modified in Act 829
First Schedule	First Schedule
<i>The following facilities shall be licensed under this Act</i>	<i>The following facilities shall be licensed under this Act</i>
a) <i>Medical and dental (clinics and hospital)</i>	a) <i>Medical and dental (clinics and hospital)</i>
b) <i>Eye care clinics</i>	b) <i>Eye care clinics</i>
c) <i>convalescent and nursing homes</i>	c) <i>convalescent and nursing homes</i>
d) <i>geriatric homes</i>	d) <i>geriatric homes</i>
e) <i>maternity homes</i>	e) <i>maternity homes</i>
f) <i>occupational therapy clinics</i>	f) <i>occupational therapy clinics</i>
g) <i>physiotherapy clinics</i>	g) <i>physiotherapy clinics</i>
h) <i>dental technology laboratory</i>	h) <i>dental technology laboratory</i>
i) <i>clinical and bio-medical laboratory</i>	i) <i>clinical and bio-medical laboratory</i>
j) <i>medical assistant clinics</i>	j) <i>medical assistant clinics</i>
k) <i>diagnostic-imaging technology clinics</i>	k) <i>diagnostic-imaging technology clinics</i>
l) <i>osteopathy clinics</i>	l) <i>pharmacies and chemical shops</i>
m) <i>prosthetics and orthotics clinics</i>	m) <i>osteopathy clinics</i>
n) <i>any other health care clinic or premises that may be determined by the Minister.</i>	n) <i>prosthetics and orthotics clinics</i>
	o) <i>any other health care clinic or premises that may be determined by the Minister.</i>

## 2. Health Professions Regulatory Bodies Act, 2013 (Act 857)

The Ministry of Health drafted the Health Professions Regulatory Bodies Bill, 2010 in consultation with professional regulatory bodies and associations and the Attorney's General office (principal legal advisers) to consolidate existing laws because they are similar in nature.

*'The Ministry of Health in 2010 started a process to consolidate all laws regulating health professions into one Act of Parliament'. (KI 5: 20/02/2019)*

Although the Health Professions Regulatory Bodies Bill was dated 21 July 2010, same as the Health Institutions and Facilities Bill, it was submitted to Parliament on 4th March 2011 for first reading eight months later.

*'The Bills were drafted around the same time but passing the Health Institutions and Facilities Bill into law was a top priority since public health facilities and some private facilities were not regulated and the law regulating private hospitals and maternity homes was outdated.'* (KI 6: 29/11/2018)

The Health Professions Regulatory Bodies Bill, 2010 sought to establish Allied Health Professions Council, Medical and Dental Council, Nursing and Midwifery Council, Pharmacy Council and to provide for related purposes. Part four of the Bill expanded regulations under the existing Pharmacy Act 1994. The Bill establishes the Pharmacy Council and its functions included: *'register practitioners and license premises in the public and private sectors'* (under clause 69c) and *'monitor and inspect pharmacy premises and other premises where pharmaceutical care is provided'* (under clause 69e) (19). After the first reading in Parliament by the Minister for Health in 4th March 2011, the Bill was referred to the Parliament Select Committee on Health for consideration (20).

## Parliament Select Committee on Health deliberations

According to the Committee's report dated October 2012 requests were made for written memoranda on the Bill. The Committee's had several meeting with stakeholders to examine the Bill in detail and these stakeholders are listed in Table 4 (20).

Table 4

Stakeholders that discussed the Health Professions Regulatory Bodies Bill with the Parliament Committee (20)

<b>Deputy Minister for Health, Hon Robert Joseph Mettle-Nunoo</b>
The former Minister for Health, Hon Joseph Yieleh Chireh
The Medical and Dental Council
The Pharmacy Council
The Nurses and Midwives Council
The Allied Health Task Force
The Ghana Health Service
The Psychologists Associations of Ghana
The Law and Development Associates
Officials of the Ministry of Health
Officials from the Attorney-General's Department (The Legislative Drafter -Principal legal adviser)

*'The Committee's meetings with stakeholders were protracted because of the many conflicting issues raised by existing professional regulatory bodies and associations. Among others, were disagreements as*

to which practitioners constitute an allied health professional and the inclusion of a new entity, the Psychology Council. (KI 7: 28/11/2018)

The Committee proposed amendments to the Health Professions Regulatory Bodies Bill, 2010 and the amendments relating to pharmacy premises are listed in Table 5 (20).

Table 5  
Proposed amendments by the Parliament Committee in relation to pharmacy premises (20)

Clause No. (Health Professions Regulatory Bodies Bill)	Proposed Amendment
Clause 69 (Functions of the Council)	<i>Paragraph (e) line 1 delete ' pharmacy premises and other practices' and insert ' pharmacy practices and'</i>
Clause 83 (Licensing of premises)	<p>Delete</p> <p><i>'(1) A person shall not supply restricted medicines from premises unless the premises are licensed in accordance with this Part.</i></p> <p><i>(2) A person who seeks to license premises for pharmacy practices shall apply to the Registrar in a manner determined by the Board</i></p> <p><i>(3) The Board may revoke a licence if satisfied that the physical conditions of the premises have ceased to be suitable for the supply of restricted medicines</i></p> <p><i>(4) A person who supplies restricted medicines from licensed premises shall notify the Board of material alterations in the structure of the premises within six months of the alteration</i></p> <p><i>(5) The licence for premises may be general or limited and is valid for the period determined by the Board</i></p> <p><i>(6) A general licence shall be issued for the supply of all classes of medicines and a limited licence shall be issued for the supply of medicines other than prescription only medicines and pharmacy only medicines.'</i></p>
Clause 97 (Entry of premises)	<i>Paragraph (a) line 2 delete 'the licence of premises' and insert pharmaceutical company</i>
Clause 99 (Power of closure)	<i>Sub-clause(1) line 3 delete ' or where the premises are unlicensed'</i>

## Framing narratives and decisions relating to pharmacy premises and business regulation in Parliament

On the 24 October 2012, the Deputy Minister for Health moved for the Health Professions Regulatory Bodies Bill, 2010 to be read a second time in Parliament (21). The chair of the Committee on Health supported the motion and presented the committee's report to Parliament. Proposed amendment related to licensing of Pharmacy premises presented to Parliament were as follows: One, *'delete pharmacy premises from Sect. 69 and replace with pharmacy practice'*. Two, *'delete the whole Sect. 83 – licensing of premises'*. Three, *'under entry of premise section delete the licence of premises and replace with pharmaceutical company'*. Four, *'under power of closure section delete where the premises are unlicensed'* (21).

*'Clearly the Committee on Health sought to remove any provisions relating to licensing of pharmacy premise from the Health Professions Regulatory Bodies Bill.'* (KI:4 21/01/2019)

The Health Professions Regulatory Bodies Bill, 2011 was put forward for consideration on the 25 October 2012 (22) and 18 December 2012 (23) and on both days no reference was made to pharmacy premises and business regulation as other parts for the Bill were discussed. However, on 20 December 2012, during the consideration stage, the chair of the Committee on Health stated that the Pharmacy Council no longer regulates pharmacy premises because of the Health Institutions and Facilities Act passed in July 2011. Therefore, the Health Professions Regulatory Bodies Bill, 2011 must be amended to avoid a conflict of who is the legitimate regulator. To this a member of Parliament responded and noted that amending the Bill was important for future interpretation of the Act should any issue arise in the courts (24).

The chair of the Committee on Health moved for clause 77 titled 'supervision of pharmacy' be deleted. Clause 77 states that *'A person shall not open or permit any other person to open premises to the public under the description of 'pharmacy', 'dispensary', 'chemist', 'drug store' or any other similar description unless a registered pharmacist is on the premises to supervise the dispensing of the medicines or medication'*. He noted that clause 77 would create confusion and contradiction since the Pharmacy Council will not regulate premises. This motion was contested by a parliamentarian who argued that clause 77 does not entrust the Pharmacy Council with power to license but the clause is a prohibitive provision to make room for creating an offence. In a rebuttal, the immediate past Minister for Health and a parliamentarian, informed the House that the whole clause has been moved to clause 100 (titled offences) where it becomes a subclause. A motion was therefore passed for the amended order to stand as part of the Bill (24).

The following changes were also agreed to by parliamentarians. One, the deletion of clause 83 (licensing of premises); two, amendment to clause 84 (licensing of corporate bodies) and three, amendment to clause 97 (entry of premises). However, a request to delete the text – *'where the premises are unlicensed'* from clause 99 (power of closure) was contested and not agreed by Parliament. Clause 99 (1) states that *'An inspector may close premises that sell or supply restricted medicines where there are grounds to believe that a health hazard may exist on the premises or where the premises are unlicensed'*. The immediate Minister for Health opposed and stated the Pharmacy Council can inspect licence of

pharmacy premises issued by a different authority and that the Council will not demand facilities obtain licence from them (24).

The Health Professions Regulatory Bodies Bill 2011 went through two consideration stages on the 21 December 2012 and pharmacy premises and business were not discussed (25, 26). The Bill was read a third time and passed on 21 December 2012 (26). The Pharmacy Act 1994 (Act 489) (5) was repealed and replaced by part four of the Health Professions regulatory bodies Act, 2013 (Act 857) (1). Table 6 (1, 19) summarizes the main contents modified and maintained in the Health Professions Regulatory Bill, 2010 in relation to pharmacy premises and the business of mixing, compounding, preparing, or supplying restricted medicines by retail. Figure 1 illustrates the decision-making processes and venues for Act 829 and Act 857. Figure 1 titled summary of decision-making processes and venues for Act 829 and Act 857.

Table 6

Summary of provisions (text) relating to pharmacy premises and business of retail in Act 857 (2013) (7, 19)

Health Professions Regulatory Bodies Bill, 2010 provisions modified or deleted in the Act 857	Provisions of the Health Professions Regulatory Bodies Bill, 2010 maintained in the Act 857	Provisions excluded in Bill, 2010 but included in Act 857
<p>Functions of the Council: Clause 69</p> <p>(c) <i>'register practitioners and licence premises in the public and private sectors'</i></p> <p>modified to</p> <p>Functions of the Council: Clause 80</p> <p>(c) <i>'register practitioners'</i></p>	<p>Functions of the Council: Clause 69 (Bill) and Clause 80 (Act 857)</p> <p><i>'(d) ensure the equitable and accessible distribution of pharmaceutical premises'</i></p>	<p><i>License for wholesale supply of restricted medicines: Clause 95</i></p> <p>(1) <i>'A person shall not carry on the business of the wholesale supply of restricted medicines unless that person has a licence for the wholesale supply of restricted medicines.'</i></p>
<p>Functions of the Council: Clause 69</p> <p>(e) <i>'monitor and inspect pharmacy premises and other premises where pharmaceutical care is provided'</i></p> <p>modified to</p> <p>Functions of the Council: Clause 80</p> <p>(e) <i>'monitor and inspect pharmacy practice where pharmaceutical care is provided'</i></p>	<p>Licensing of corporate bodies: Clause 84 (Bill) and Clause 93 (Act 857)</p> <p><i>'(1) The Board may grant a licence to a body corporate or a government institution of satisfied that (a) the applicant is fit to carry on the business of mixing, compounding, preparing or supplying restricted medicines by retail and</i></p>	<p>(2) <i>'The Board may grant a licence for the wholesale supply of restricted medicines subject to conditions which may prohibit or limit the supply of restricted medicines of a particular description.'</i></p> <p>(3) <i>'A promotional or marketing office where a person intends to engage in the wholesale pharmacy business shall be licensed and supervised by a registered pharmacist.'</i></p>
<p>Licensing of corporate bodies: Clause 84</p> <p>(1b) <i>the applicant's business is carried on under the supervision of a superintendent pharmacist</i> modified to</p> <p>Licensing of corporate bodies: Clause 93</p> <p>(1b) the business of the applicant is carried on under the supervision of a superintendent pharmacist</p>	<p>Power of closure: Clause 99 (Bill) and Clause 108 (Act 857)</p> <p>(1) <i>An inspector may close premises that sell or supply restricted medicines where there are grounds to believe that a health hazard may exist on the premises or where there are unlicensed'</i></p>	

Health Professions Regulatory Bodies Bill, 2010 provisions modified or deleted in the Act 857	Provisions of the Health Professions Regulatory Bodies Bill, 2010 maintained in the Act 857	Provisions excluded in Bill, 2010 but included in Act 857
<p>Entry of premises: Clause 97</p> <p><i>(a) to inspect the registration of a pharmacist, pharmaceutical care providers or the licence of premises</i> modified to</p> <p>Entry of premises: Clause 106</p> <p><i>(a) to inspect the registration of a pharmacist, pharmaceutical support staff or pharmaceutical company</i></p>	<p>Regulations: Clause 101 (Bill) and Clause 111 (Act 857)</p> <p><i>(e) prescribe conditions including the type of premises for the issue of general and limited licence of the Council</i></p>	
<p>Supervision of pharmacy: Clause 77</p> <p><i>' A person shall not open or permit any other person to open premises to the public under the description of 'pharmacy', 'dispensary', 'chemist', 'drug store' or any other similar description unless a registered pharmacist is on the premises to supervise the dispensing of medicines or medication</i></p> <p>moved to</p> <p>Offence: Clause 110 (c) and text maintained</p>	<p>Interpretation: Clause 102 (Bill) and Clause 112 (Act 857)</p> <p><i>premises" includes pharmacy premises or other facility authorized for practitioners under this Part and a Pharmacy department of a hospital, clinic, a house, building, structure, tent, caravan, land, ship, boat, an aircraft mechanically propelled device and other place or facility in which pharmaceutical services are offered.</i></p>	
<p><i>Licensing of premises: Clause 83</i> – Deleted</p>		

## Discussion

The study highlights the varied roles policy actors played in shaping the content of Act 829 and Act 857 in different decision-making venues and processes. The Ministry of Health with the assistance of the legislative drafter - Attorney General's department - drafted the Health Institutions and Facilities Bill, 2010 and Health Professions Regulatory Bodies Bill, 2010 within its bureaucratic system with inputs from its agencies such as the Pharmacy Council and the Private and Maternity Homes Board. In the Ministry of Health, the Bills were agreed upon by the formulators and therefore submitted to the Parliament for passage into law. Content contestations started when the Bills were discussed in broader stakeholder engagements and venues.

Decision making venues are important as these can determine who participates or is ignored during a decision making process (27). Legislative powers are vested with parliamentarians and exercised in accordance with the Constitution of Ghana (28). Parliamentarians debated the principals and policies (28) of the Health Institutions and Facilities Bill and the Health Professions Regulatory Bodies Bill through the legislative processes (28). In this decision-making venue, the Committee interrogated the Bills and involved other policy actors in the process. Although, the PSGH through the Council of Elders made their suggestions relating to pharmacy premise regulation, the ultimate decision rested with the parliamentarians. The parliamentarians took the final decisions based on consensus and non-legislative actors such as PSGH could not intervene in the framing narratives and decisions relating to pharmacy premise regulation and business on the floor of Parliament.

The venues of policy choice influence options and actions and are thus important in understanding emergence and unfolding of laws making (27, 28). Though, the Bills formulators agreed on the initial provisions of the Health Institutions and Facilities and Health Professions Regulatory Bodies Bills, the reframing of pharmacy premises as a health care facility occurred in a venue that they had no control over and could not participate to solicit support and influence that decision. Decisions and suggestions made outside of Parliament may be relevant and technically sound, however, the way parliamentarians framed and pushed pharmacy premise regulation issues during proceedings influenced decisions. Parliamentarian as powerful policy actors were able to interpret issues from their understanding and convinced others for consensus (9).

The Committee framed pharmacy premise as a health care facility and promoted this labelling and the need for regulation by the Health Facilities Regulatory Agency. Pharmacy premises are indeed health facilities and there were no contentions with this fact. Since, Health Institutions and Facilities Bill and Health Professions Regulatory Bodies Bill were developed concurrently, the formulators did not foresee the challenge that labelling of pharmacies as health facilities could present. The part four of the Health Professions Regulatory Bodies Bill expanded the existing Pharmacy Act 1994 (Act 489) and these amended expansions did not consider potential conflict with the Health Institutions and Facilities Bill. Conflict in pharmacy regulation may be attributed to a process of repeated amending of existing regulations without due consideration to the impact that such amendments have (29). This, however, was not the case here, the Bills were in tandem and complementary and not a mere repetition of existing laws. In Parliament, the Bills were discussed separately, and this synergy was not realised.

The implementation of these statutory regulatory laws is not evaluated and research is needed to investigate the impact on pharmacy practice in Ghana. Findings from implementation can serve as evidence to support revisions of the Acts or otherwise and present a window of opportunity (30) for reengagement of major policy actors to take a second look at the unfolding development in the greater public interest or maintain the status quo.

## Conclusion

The final content of the Health Institutions and Facilities Act and Health Professions Regulatory Bodies rested with the parliamentarians (with legislative power). Decision making venues and processes limited participations and inputs from other policy actors although these non-legislative actors had some level of influence. While framing and labelling of policy issues are important tools in decision making, the venues of framing and labelling are equally vital. Powerful legislative actors ultimately determined which statutory regulatory body regulates pharmacy premises and the business of mixing, compounding, preparing, or supplying restricted medicines by retail. As legislative processes and health sector bureaucratic system may be similar in other LMICs, we hope this paper contributes to learning and the formulation of Pharmacy premises and business regulation laws.

## **Abbreviations**

HeFRA: Health Facilities Regulatory Agency

PSGH: Pharmaceutical Society of Ghana

LMICs: Low to Middle Income Countries

## **Declarations**

### **Ethics approval and consent to participate**

Ethical approval was sought from the College of Health Science Ethical and Protocol Review Committee at University of Ghana (approval number: CHS-Et/M.10-PI.1/2017-2018) and written and verbal informed consent obtained from all key informants.

### **Consent for publication**

Not applicable

### **Availability of data and materials**

Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

### **Competing interests**

The authors declare that they have no competing interest.

### **Funding**

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### **Authors' contributions**

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by AK, RSB, JKNN and DAD. The first draft of the manuscript was written by AK and all authors commented on previous versions of the manuscripts. All authors read and approved the final manuscript.

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## Figures

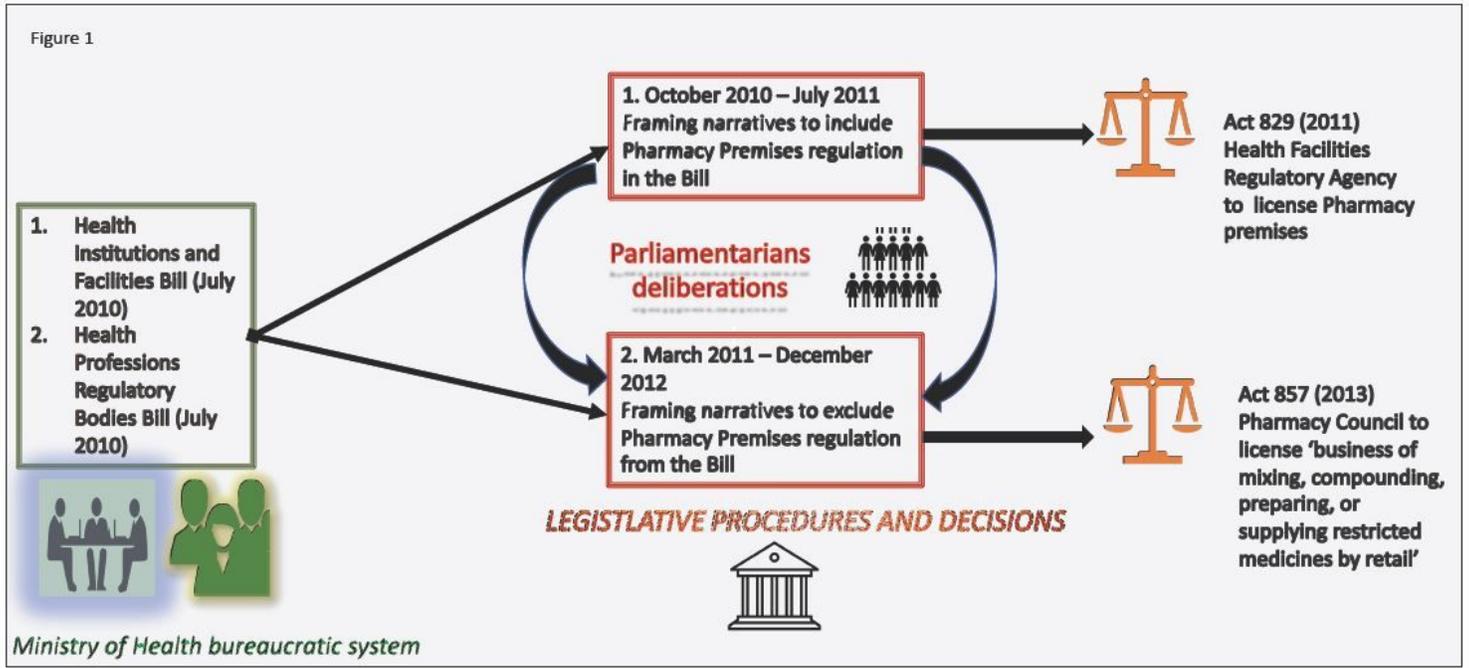


Figure 1

Summary of decision-making processes and venues for Act 829 and Act 857.