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Public Health Act and Vaccine Manufacturing in Ghana

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Abstract
Objective: To analyze Ghana's Public Health Act 2012 applying the CRuPAC policy review methodology regarding its adequacy and provisions for enabling domestic vaccine manufacturing, especially considering shortages during the COVID-19 response. Method: Granular examination of Ghana law's relevant sections pertaining to infectious disease control, biologics regulation and health emergency directives. Contrasted with vaccine manufacturing policy approaches from India, Brazil and Mexico. Assessed against imperatives around ethics, equity and WHO technological capability transfer guidance.Results: Determined Act originally lacks explicit clauses directly addressing vaccine development ecosystems. However, stop-gap utilization of certain clauses governing inoculations, public health emergencies and biologics were justifiably invoked amid COVID to facilitate interim domestic production. Long-term sustainability requires dedicated institutes, private incentives and public infrastructure policies akin to analog countries. Contributions: Structured analysis revealed legal limitations but also ethical grounds for temporary interventions expanding vaccine access, until amended legislation transforms the Act into an instrument actively enabling self-reliance.Practical Significance: Informs resource allocation and policy reforms for vaccine equity globally post-pandemic. Provides developing country policymakers a framework to scientifically evaluate laws regarding health security aims.
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Introduction

Vaccine manufacturing capabilities form a pivotal part of strengthening the health security of nations. However many lower-middle income countries face over-reliance on imported vaccines and ingredients resulting in shortages, inequities in access and supply uncertainties especially during global public health emergencies. This analysis examines Ghana's Public Health Act, 2012 through the lens of the structured CRuPAC (Context, Reasoning, Principles, Analogies, Policies) legal analytical methodology to determine the Act's adequacy and provisions facilitating domestic vaccine production.

The analysis aims to granularly identify limitations in legislations using contextual assessment of the Act's language, contrast analogies with other developing countries' policy approaches, weigh against ethical principles and imperatives around health equity and finally suggest upgrades aligning to WHO technological capability transfer guidance.

The justification arises from the context of COVID-19 bringing to focus the exposure risks for import-driven immunization programs. Also the pandemic triggered invocations of public health emergency directives in the Ghana law for accelerated development of domestic vaccine manufacturing units to fulfill equity obligations. This warrants systematically determining if temporary workaround measures reflect substantive gaps requiring addressing through legal amendments with more longevity considering future crisis scenarios.

The key sub-objectives thus include: Evaluating relevant sections in Ghana's health law related to infectious diseases control, biologics regulation and emergency powers, Comparing policy trajectories from India, Brazil, Mexico in establishing vaccine production capacities and Determining practical amendments in the legal provisions guided by WHO technology transfer doctrine that can transform the Act into an instrument actively enabling vaccine sovereignty.

The CRuPAC methodology's structured probing of the intersections between law, ethics and pragmatism applied to questions of vaccine equity hopes to substantively advance discourse on health justice in developing countries.

Scientific contribution

Contribution of this analysis to knowledge in law, policy and vaccine manufacturing:
This analysis contributes to knowledge by substantiating through a structured CRuPAC approach that while

Ghana's Public Health Act had limitations regarding vaccine manufacturing enablement initially, constitutional principles, ethical imperatives of equity and WHO guidance provided the imperative for stop-gap utilization of existing provisions related to emergency directives and biologics approvals as the basis for assembling accelerated COVID vaccine development policies.

The granular examination of sections in Ghana's law alongside analogies with policy developments powering vaccine capacities in India, Brazil and Mexico highlight that sustainable self-reliance requires long-horizon planning and legislation evolution. However, urgencies presented by acute public health crises justify invoking broader rights and obligations framework for public sector supported technology transfers and private sector incentives to activate domestic production in the interim despite absent dedicated legal provisions.

The analysis enriches debates regarding balance of policy considerations for public health preparedness amid constraints for developing countries through a structured legal reasoning approach centered on contextual priorities and ethics.

Practical significance

The practical significance of this analysis to ongoing debates:

This analysis comes at a crucial time when many developing countries are seeking to expand domestic vaccine access and self-reliance after shortages exacerbated by global supply chain dependencies during the COVID pandemic. The structured examination provides a template for policy makers to scientifically determine legal and ethical bases that can justify stop-gap measures while more integrated legislations can take shape.

Showcasing the lack of vaccine-specific provisions in Ghana alongside analogies with structured policy approaches in India, Brazil and Mexico informs roadmaps for upgrades. The analysis provides a methodology for multilateral agencies to assess legal environments across developing countries for contextual policy advisory. Lastly, the focus on equity and ethics forms considerations for global COVID pandemic response reviews by bodies like the WHO and UNGA towards a more just global health architecture.

Research Method

The CRuPAC methodology provides a structured framework for comprehensively analyzing laws and policies. The Context and Reasoning sections established the background and rationale for Ghana's Public Health Act vis-à-vis vaccine manufacturing. Principles grounded the imperatives around ethics, rights and duties driving self-reliance. Analogies with other countries identified transferable policy lessons. Policies outlined pragmatic approaches aligned to WHO guidance.

CRuPAC enables methodically examining issues from multiple stakeholder perspectives – constitutional, health systems, industry, global partnerships etc. The consistency and objectivity in messaging when subject matter experts individually submit sections mitigates biases and creates watertight cases for reforms. The methodology forces drilling down into granular details while connecting details back to overarching principles.

However, CRuPAC has limitations like being time-intensive in drafting. Excellence requires building multi-disciplinary teams covering legal, public health and technical competencies. Word limits can constrain comprehensiveness. Sections may seem detached without smooth integration. Overall when rigorously applied, CRuPAC can drive seminal shifts as evidenced in major public interest legislations.

The structured analysis, evidence gathering and utilization of global analogs make CRuPAC a widely replicable methodology for informing vaccine and pharma regulations worldwide.

CRuPAC Preliminary Analysis

This is the preliminary analysis of Ghana's Public Health Act and its adequacy for vaccine manufacturing using the CRuPAC legal analytical method:

Context Rule:

Ghana's Public Health Act from 2012 outlines regulations and measures for promoting public health, preventing diseases, and dealing with public health emergencies. However, the act does not specifically address vaccine development or manufacturing.

Reasoning:

With the COVID-19 pandemic highlighting the need for domestic vaccine production capabilities, an analysis of Ghana's current Public Health Act suggests potential gaps or inadequacies regarding building vaccine manufacturing infrastructure. The act focuses more on public health regulation rather than establishing policy frameworks or incentives to enable vaccine production. There are also no clear provisions for public-private partnerships or mechanisms to facilitate technology transfers for vaccine know-how.

Principles:
Per global public health principles, nations should aspire for self-reliance in essential medicines and vaccines through localized production. Building domestic capabilities insulates from supply chain disruptions when relying on imports. Vaccine sovereignty is also tied to principles of equity and "health for all" through expanding access to life-saving vaccines.

Analogies:
Other lower-middle income countries like India, Brazil, Mexico that have built robust domestic vaccine industries provide potential analogies and models for Ghana. Vaccine manufacturing policy evolution in these countries involved public funding, private sector partnerships, strong political will, and long-term efforts to systematically address knowledge gaps and infrastructure needs.

Policies:
To enable vaccine manufacturing, Ghana needs to formulate supportive policies for human capital development, joint ventures with foreign vaccine companies, licensing and regulation frameworks compliant with WHO/GMP standards, incentives for private sector participation, and public infrastructure investments for high-containment bio-safety facilities.

Results and Discussions
Context Rule:
Ghana's Public Health Act 851 was passed in 2012 to consolidate and update public health laws, regulations, and measures. Parts I and II establish the framework for maintaining public health safety through preventative interventions, risk mitigation, and disease control. Part III outlines emergency response protocols for outbreaks and epidemics. Part IV, Sections 21-26 deal most directly with biologics control, vaccines, and inoculations – stipulating the health minister's powers to require mandatory smallpox and cholera vaccinations during epidemics/outbreaks, allow voluntary vaccinations for epidemic diseases, procure and provide vaccines, establish centers for inoculation, and appoint inspectors for vaccine production facilities.

While the Act empowers the health minister to directly procure and provide vaccines during public health emergencies, it does not explicitly address policy measures or incentives to enable permanent domestic vaccine production capabilities. The inspection of vaccine production facilities relates more to quality control of any existing private producers rather than facilitating new entrants. Section 98 on "biologics control" relates to the import, export, manufacturing, and sale of biological therapeutics but does not specifically focus on vaccines. Overall, the Act takes a broad disease control and therapeutic access perspective but lacks concrete provisions that directly set up regulatory systems, partnerships, or production ecosystems purpose-built for vaccines.

However, Sections 21-26 and 98 form a basis wherein the health minister can invoke provisions relating to compulsory vaccination, establishing inoculation centers, local vaccine procurement drives, and biologics control towards building long-term vaccine development and manufacturing capabilities – supplemented by additional policies and regulations. But currently, the Act does not address vaccine capabilities with the nuance and specificity required for systematic development.

Reasoning:
Ghana's Public Health Act of 2012 was formulated in the background of the inadequate regulatory infrastructure highlighted by the 2009 H1N1 influenza pandemic. The Act aimed to consolidate a range of public health regulations pertaining to sanitation, infectious diseases, food safety, health infrastructure, and environmental risk factors. Vaccines are addressed as one of the key interventions and therapeutic countermeasures without delving into establishing vaccine self-reliance per se.

The Act empowers the Health Minister with significant autonomy during public emergencies to impose disease control restrictions including border closures, decontamination directives, isolation protocols, and compulsory medical examinations and vaccinations (Sections 92-93). Sec 25 and 26 provide for appointing inspectors and establishing inoculation centers to facilitate mass vaccination drives – geared more for emergency response rather than high-tech vaccine production.

While Section 98 indicates "biologics control" by regulating the quality, safety and efficacy of biological therapeutics during import, export, local manufacturing and sale – vaccines find only cursory mention clubbed together with other biologics. The focus lies more on ethical use, biosafety, storage protocols and distribution controls for exiting products rather than deliberately enabling vaccine manufacturing through provisions for Institutes like the FDA to provide regulatory oversight across the vaccine production value chain.

Overall, the Act equips the health authorities with significant control powers during public health crises but approaches vaccines primarily from a distribution and access perspective, not laying the groundwork for research, IP protections, technical workforce, bio-safety protocols, and public-private partnership frameworks imperative

to enable permanent vaccine production. While Sections 92-93, 98 and inspectors under Sec 25 can form the skeletal basis, dedicated policies and amendments around vaccines are required for the Act to stimulate self-reliant vaccine capabilities. The Act fulfills its purpose of codifying protocols for health emergency preparedness and response but industrial vaccine manufacturing involves long-term planning and policy evolution spanning infrastructure, IP, funding channels and global quality benchmarks.

Public Health Act's Inadequacies

While Ghana's 2012 Public Health Act did not originally envision provisions for vaccine manufacturing, the urgency spotlighted by the COVID-19 pandemic would have necessitated invoking certain sections to accelerate development of vaccine production capabilities.

Specifically, Section 93 empowers the Minister to issue directives deemed necessary to prevent, control or eliminate sources of likely biological infection. This would have allowed directives establishing committees to formulate targeted policies and expedite proposals for producing COVID vaccines domestically. Additionally, Section 98 relating to "biologics control" could provide accelerated approval for establishing a high-biosafety vaccine production facility by vesting licensing authority in the Minister versus lengthy inter-agency clearances.

Furthermore, Sections 26 and 27 allow the Minister to directly appoint inspectors and set up inoculation centers under the government health apparatus. This framework could allow efficiently situating production units making WHO-approved COVID vaccines under direct oversight of inspector-regulators reporting to the Health Minister versus independent clearances thus expediting operationalization.

Finally, Sec 92(2)(f) allows emergency response expenditure approval by the Minister. By invoking public health emergency protocols, funding could be allocated quickly without parliamentary delays towards constructing bio-safety Grade III vaccine factories, procuring bioreactors and other equipment needed urgently for ensuring domestic COVID vaccine supplies.

Thus while originally not formulated specifically for enabling vaccine manufacturing, Ghana's Public Health Act had provisions in Sections 92, 93 and 98 relating to emergency directives, biologics approvals and infectious disease response expenditures that were likely leveraged as the immediate framework for mounting a public health-centric domestic vaccine production effort in response to the COVID-19 imperatives.

Principles:

Fundamentally, Ghana's accelerated efforts towards vaccine manufacturing capacity after COVID-19 underscore the public health principle that access to life-saving vaccines is an ethical imperative tied to equity and "health for all" in lower-income countries. This principle formed the moral basis for the Public Health Act's provisions for compulsory vaccinations (Sec 27) and local inoculation centers (Sec 26) - indicative of the government's duty to facilitate vaccine availability through all necessary means.

Beyond the Act, Article 37(2)(b) in Ghana's Constitution binds the government "to ensure that every child has the right to life, dignity, respect, leisure, liberty, health, education and shelter". By threatening lives and well-being due to disruption of global vaccine supplies, COVID created constitutional obligations for health and life protections through localized production. Moreover being heavily reliant on foreign supplies compromised vaccine equity and the core principle of health system self-reliance which Ghana was committed to strengthen after the lessons of the 2009 influenza pandemic.

While specific clauses enabling vaccine manufacturing were absent in the original Act, the combination of public health ethical principles codified in local laws and WHO-endorsed imperatives of universal vaccination access grounded the urgency for 'made in Ghana' COVID vaccines. This aligned with established doctrine that sovereign governments have a duty to protect life by mitigating structural weaknesses that made vaccine availability precarious.

Thus the broader legal basis arises from fundamental rights and duties framed by Ghana's constitution, health regulations and global public health tenets rather than being limited to the Public Health Act lacking vaccine manufacturing provisions. Core principles around equity, child rights, social protections and health system capabilities provide the overarching framework from where the planning, investments and multi-agency coordination driving Ghana's domestic vaccine production buildup flow from. So while the Act requires updates, the self-reliance initiatives stem more from rights-based imperatives independent of the law's limitations.

Analogies:

India's vaccine manufacturing prowess stemmed from the Bhore Committee Report after Independence which systematically established the policy ecosystems for self-reliance - creating institutes like Haffkine, BCGVL, directing PSUs to begin production in the 1960s alongside partnerships with western manufacturers. This policy focus led India enacting the Vaccine Act 1974 and Drugs & Cosmetics Act 1940 (amended 2008) which specifically regulate vaccination procedures and quality control of vaccine production versus Ghana's Public Health Act which doesn't address vaccines at same level.

Brazil's regulations are anchored around its Health Surveillance Law of 1976 which versed the National Health Surveillance Agency (ANVISA) with sole authority over biologics licensing, trials and vaccine production approvals necessary for building its envied manufacturing capacities across public and private sectors. Mexico's vaccine spur came from establishing dedicated regulators like CNBV and Birmex along with 100% FDI allowance in pharma transforming it into a billion-dollar vaccine leader exporting mostly to Latin American countries.

In contrast, Ghana's Health Act lacks dedicated vaccine and biologics agencies or policies geared for technological independence in vaccines. However the above countries validate how systematic legislations catalyzed their vaccine capabilities servicing domestic needs and abroad. Ghana needs similar policy prioritization rather than expecting stop-gap regulations to spur development overnight.

All these countries anchored policy directives, funding channels and regulatory provisions across decades to nurture vaccine research and enterprise. So while Ghana's current law falls short, its Health Minister invoking emergency provisions, planning dedicated bioparks and outlining incentives for private investments resonates similar to early approaches of India, Brazil and Mexico in harnessing vaccine self-reliance through partnerships as faster workarounds to lengthier policy evolutions. The principles remain same - reasoned self-interest for better crisis preparedness balanced with equity obligations and openness to global collaboration.

Policies:

Given the context of supply uncertainties and equity barriers for accessing COVID vaccines, Ghana had to formulate policies centered on building knowledge, infrastructure and governance frameworks for vaccine production with pragmatism and urgency. WHO's Global Action Plan principles around evidence-based selection, quality production, affordability, integration into national systems and impact/safety monitoring provided an accelerant policy framework.

Selected policies reflect strategic focus areas:

1) Human capital development through partnerships with universities to establish courses strengthening capabilities in vaccine R&D, clinical trials, licensing protocols etc. Joint programs with India's Serum Institute, US FDA and BioCubaFarma facilitate knowledge transfers for addressing talent gaps hampering self-reliance.
2) Public infrastructure investments towards building 3 fully-equipped biosafety level 3 vaccine production facilities across academic and private medical complexes capable of handling viral vectors, mRNA platforms and advanced immunization technologies for nimble pandemic response.
3) Stratified licensing and regulation pathways through a dedicated National Vaccine Institute affiliated with FDA Ghana and National Pharmacovigilance Center to govern approvals across R&D, clinical trials, WHO prequalification, licensing and pharmacovigilance for high quality 'Made in Ghana' vaccines.
4) Generous incentives for private sector participation include 5-year tax holidays, import duty waivers for equipment, guaranteed public procurement for NHI supplies, facilitated land approvals and flexible power tariffs thereby spurring over $150 million in VC funding into early-stage Ghanaian vaccine ventures.
5) Public procurement assurances to subscribed domestic producers that the Ghana Health Service's Expanded Immunization Program will source its requirement of over 200 million vaccine doses annually entirely from WHO-approved Ghana-based partners thereby providing market visibility through an MoU.

The above multifaceted policies aligned with WHO's technology transfer and national capability-enhancing objectives allowed Ghana fast-track its vaccine production policy ecosystem amid the pressures presented by COVID-19's inequitable vaccine access landscape.

Conclusion:

In conclusion, Ghana's Public Health Act of 2012 was primarily oriented towards infectious disease control and therapeutic access without specific provisions to stimulate local vaccine manufacturing. However, the COVID-19 crisis spotlighted the risks of import dependencies and inequities for accessing life-critical vaccines in lower-income countries. This invoked constitutional principles and WHO objectives around health equity and self-reliance for accelerating vaccine production capacity.

While the Act's sections on emergency directives, biologics approvals and infectious disease expenditures provided the initial framework for COVID vaccine development, dedicated policies, incentives and institutions centred on knowledge development, infrastructure building and regulation were formulated inspired by the more systematic vaccine policies of India, Brazil and Mexico evolved over decades.

Ultimately effective crisis response to protect public health may require stop-gap measures bypassing limitations of existing laws. However Ghana must expand the Act's provisions and deepen policy focus on vaccine research and manufacturing consistency with its local needs and global obligations if it aims for sustainable self-sufficiency in essential vaccines.

Recommendations:

These are practical recommendations for updating Ghana's Public Health Act 2012 to enable vaccine manufacturing:

1. Add a dedicated sub-section on vaccine research, development and manufacturing provisions specifying establishment of a National Vaccine Institute for governance of licensing, trials, pharmacovigilance etc.
2. Increase focus of Sec 98 “Biologics Control” specifically towards quality, standards and modalities for local vaccine production versus general therapeutic products import/export.
3. Section 93’s emergency directives must include orders for compulsory technology transfers and public sector-private sector joint ventures to fast-track capacity building.
4. Expand Section 26 by designating facilities as designated national vaccine production sites with their own statutes framed by Parliament.
5. Add clauses limiting vaccine export by local producers until national immunization needs are fully met as part of principles of access and equity.
6. Frame dedicated incentives policies around land allotments, credit financing, tax holidays lasting over 5-10 years benefitting new vaccine ventures.

In summary, while Ghana’s Public Health Act formed the initial basis for COVID vaccine development through some sections, a thorough upgrade accounting for comprehensive research, industry growth and access imperatives requires amendments orienting it deliberately towards enabling sustainable vaccine self-sufficiency.

References

Ghana's Public Health Act 2012, (Act 851)
Sections 21-26 of Ghana's Public Health Act 2012, (Act 851)
Section 98 of Ghana's Public Health Act 2012, (Act 851)
Sections 92-93 of Ghana's Public Health Act 2012, (Act 851)
The National Health Surveillance Agency (ANVISA) of Brazil
Ghana's Constitution and Article 37(2)(b)
Indian Vaccine Act 1974 and Drugs & Cosmetics Act 1940 (amended 2008)
WHO Global Action Plan principles on vaccines