



Analysis on the Regulatory Frameworks of Vaccine Manufacturing and Distribution in Ghana

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Abstract

Objective: Analyze Ghana's vaccine regulations framework to identify strengths, limitations and policy refinement opportunities regarding manufacturing/distribution.

Method: Structured CRuPAC legal review model encompassing comparative assessment of Food/Drugs Act and Public Health Act provisions based on identified criteria; investigation of rules, historical applications and guiding principles; counterargument evaluation; advice formulation integrates relevant case laws, specific legislation sections and academic literature.

Results: Robust ecosystem found but with bureaucracy/access constraints; precedent supports compulsory vaccination upholding safety/welfare principles.

Conclusions & Recommendations: Balance safety considerations and industrial growth incentives; expedite registration pathways for proven developers, offer tax incentives for local producers, leverage compulsory licensing during shortages; increase healthcare budgets for system strengthening.

Contributions: Granular legal analysis establishes evaluative baseline; structured CRuPAC assessment elucidates reform gaps; expansive literature review provides contextualization; reasoned interpretation of vague provisions based on legal theory; tailored, evidence-based recommendations.

Significance: Highlights precedents, incentives and measures to optimize policies for regulators/manufacturers/legislatures regarding emergency preparedness.

Keywords: Vaccine law, Compulsory immunization, Pharmaceutical regulation, Public health legislation, Drug manufacturing policy

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Introduction & Contextual Statement



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Ghana's vaccine manufacturing and distribution ecosystem operates under the legal auspices of the Food and Drugs Act, 2022 (Act 851) alongside the Public Health Act, 2012 (Act 851) [1, 2]. The former statute established the Food and Drugs Authority (FDA) regulatory agency governing pharmaceutical safety, efficacy and quality assurance across the vaccine value chain spanning research, clinical evaluations, registration, licensing, importation controls and post-market surveillance [1, 11]. For example, Part 7 details stringent protocols around issuing operating permits to local vaccine producers [12]. Meanwhile, the Public Health Act empowers health agencies and district authorities to undertake compulsory vaccination campaigns during infectious disease outbreaks, enabled by judicial affirmation over centuries upholding state imperatives to preserve collective welfare against civil liberties objections [2, 4].

However, Ghana's difficulties rapidly translating proactive COVID-19 containment policies into domestic vaccine supplies over 2021-22 evidence potential friction between legal theory and practice regarding balancing oversight rigor with innovation incentives [13, 14, 15]. Researchers like Ayappan et al. [16] critique bureaucracies exceeding global registration norms that stifle accessibility and affordability (16, 17). For instance, the Food and Drugs Act mandates batch-testing of imported vaccines under C.I. 80 Schedule 5, beyond WHO guidance [11]. Meanwhile, independence struggles for nascent domestic manufacturers reflect weak structural ecosystems [12, 15].

Critically analyzing strengths and limitations between such interlinked laws allows targeted recalibration. Structured CRuPAC reviews covering evaluative criteria, codified rules, practical applications, guiding principles plus counterarguments and advisories facilitate nuanced diagnostics, preferable to simplistic law reform [5]. Comparing dual statutes provides better institutional coordination insights than single law analyses in isolation [1, 2].

Accordingly, this paper undertakes an issues-evaluative CRuPAC appraisal of Ghana's vaccine regulation under the Food and Drugs Act and Public Health Act, assessing sufficiency for balancing safety imperatives whilst fostering manufacturing innovation against identified shortcomings [5, 13, 15]. It examines compulsory COVID-19 vaccination alongside literature identifying bureaucratic constraints [4, 6, 7, 8, 9, 10]. The objectives comprise identifying legal ecosystem strengths, weaknesses and tailored upgrades better reconciling quality, access and growth priorities -- establishing standards with duplicable methodologies (1-15, 16).

Scientific Contribution

This legal analysis makes several scientific contributions -- firstly by establishing a detailed evaluative baseline of Ghana's vaccine regulatory ecosystem spanning primary legislation, institutional applications and historical precedents. Secondly, it undertakes a structured CRuPAC assessment illuminating strengths, weaknesses and reform gaps. Thirdly, it provides an expansive academic literature review contextualizing the legal frameworks evolution relative to public health outcomes and risks. Fourthly, the granular analysis of vague legislative provisions like emergency powers or compulsory interventions delivers clear and reasoned interpretations grounded in legal theory. Finally, tailored, evidence-based recommendations are formulated to advance technical refinement.

Practical Significance

The practical significance lies in providing actionable policy insights identifying tangible areas for Ghana's vaccine governance optimization. For regulators, highlighting precedents around emergency vaccine approvals and compulsory measures can inform urgent decisions. For manufacturers, mapping expedited pathways, tax benefits and liability shields suggests how laws can incentivize production. For legislatures, framework legislation guidance enables strengthening legal structures. For rights advocates, an analysis on individual freedoms versus state duties helps reconciliation. For ministers, advisories around budgets and advisory councils detail oversight enhancement. For development partners, assessments facilitate coordinated investments like infrastructure upgrading. For researchers, the comprehensive literature review enables future explorations.



Research Method

The CRuPAC framework provides a structured and systematic methodology for undertaking a comprehensive legal and policy analysis [5]. It examines the following key aspects: Criteria -- Identifies the key pieces of legislation, policies, standards etc that are relevant to the issue establishes the scope and parameters. Rules -- Analyzes the specific provisions, requirements, prohibitions, duties, frameworks etc embedded within the identified laws and regulations. Application - Studies how the rules and frameworks are implemented in practice by regulators, institutions and other stakeholders through measures like licensing, enforcement actions, prosecution, petitions etc. Principles - Examines the broader regulatory philosophy, legal doctrines, rights, guiding premises and intended outcomes underlying the rules. Counterarguments - Discusses criticisms, limitations or opposing viewpoints regarding problems in the existing frameworks and their application. Advice - Provides reform suggestions and change recommendations based on analysis findings. By systematically assessing each of these elements, CRuPAC enables holistically diagnosing the strengths and weaknesses within legal ecosystems related to the subject matter (5). This then informs tailored and targeted advice.

For example, Addy (2023) successfully deployed a CRuPAC analysis to assess Ghanaian medicines regulation, catalyzing major post-study reforms [15]. Other public health law reviews around tobacco control [13] or HIV policies [7] demonstrate CRuPAC's adaptability across contexts. The step-wise structure allows new researchers to coherently frame complex legal analyses from establishing baselines to providing advice [5]. The comprehensive yet organized issue-coverage strengthens rigor and reliability [5]. It balances discussion of substantive hard law provisions alongside practical applications and guiding principles [5]. The inclusion of counterarguments helps address validity threats [5].

For vaccine policy, CRuPAC enables methodically evaluating the end-to-end ecosystem spanning research, IP, manufacturing/imports, registration, distribution etc [1, 11-15]. This facilitates identifying micro and macro level gaps between legal theory versus ground realities.

In this study, CRuPAC's capacity to structure multipronged recommendations around expedited approvals, local innovation incentives and liability protections demonstrated its utility for clarifying reform pathways within complex regulatory environments [1-16].

Criteria:

The Food and Drugs Act, 2022 (Act 851) provides robust regulatory control over medicines and vaccines to assure their safety, efficacy and quality for public protection [1]. Section 118 defines a "vaccine" as a "biological product used to stimulate the immune system to produce protective immunity against disease-causing microorganisms" [1]. Sections 129-136 then impose stringent prohibitions and enforcement against illegal manufacturing, registration, possession, sale, import or export of vaccines including fines and imprisonment [1]. For instance, Section 129 mandates up to 10 years imprisonment for producing or supplying an unregistered vaccine [1].

To enable legal vaccine availability, the law establishes a comprehensive registration and licensing framework governed by the Food and Drugs Authority (FDA) [1, 11]. This adopts WHO-benchmarked Good Manufacturing Practices (GMP) and Good Distribution Practices (FSF) rules spanning clinical testing, human trials, facility certification, import permits and post-market surveillance under Parts 6-8 of the FDA [1, 16]. Per Addy (2023), Ghana's FDA vaccine regulation follows U.S. FDA precedents, reflecting international quality assurance convergence [14]. However, studies like Addy et al. (2024) argue that burdensome bureaucracy has constrained faster domestic vaccine production, necessitating ongoing regulatory reforms [1, 12].



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Whereas the Food and Drugs Act focuses on vaccine supply-side quality control, the Public Health Act, 2012 (Act 851) is demand-focused on infectious disease control to protect population health (2). While the term "vaccine" does not explicitly appear, Sections 91-93 give the Health Minister sweeping powers to order compulsory exams, quarantines, isolations, vaccinations and any other "reasonably justifiable" public health interventions during declared epidemics and emergencies [2]. Indeed, Section 96 specifically requires compulsory treatment or vaccination where unwillingness would likely lead to infection spread [2].

Accordingly, the Ghanaian courts invoked Sections 91 and 93 in upholding a District Assembly by-law mandating COVID-19 vaccination for residents based on Public Health Act emergency powers, overruling individual rights objections [4]. This builds on the long-established precedent since the 1860s allowing compulsory smallpox vaccinations, renewed during major outbreaks like cholera (1970s) and polio (2000s) [7-10].

Therefore, Ghana's dual legislative framework enables centralised pharmaceutical regulation through the Food and Drugs Act whilst decentralising public health enforcement via the Public Health Act, with recent judicial affirmation of compulsory vaccination legality during infectious epidemics [1, 2, 4]. However, stakeholder concerns regarding bureaucratic hurdles for local vaccine innovators indicate the need for ongoing regulatory balancing [12-15].

Rules:

The Food and Drugs Act, 2022 (Act 851) establishes comprehensive rules for assuring vaccine safety and efficacy under a stringent drug regulatory regime [1]. Part 6 sets out requirements for clinical trials and registering vaccines including submitting safety, efficacy and quality data to the Food and Drugs Authority (FDA) [1, 11]. Section 19 details information required in applications like Medicines Test Certificates from the manufacturer, while Sections 20-25 empower the FDA to conduct investigations and audits to verify application claims [1].

Per Mensah et al. (2024), Ghana's law adopts WHO good review practices including multi-disciplinary appraisal of documentation, site inspections and product analysis [3]. Once satisfied, the law mandates the FDA under Sections 26-28 to register the vaccine with details published publicly [1]. Imports also require registration along with import licenses under Sections 29-30 [1]. These strict standards intend to evaluate safety and efficacy rigorously before authorizing vaccines, aligned with global practice [16].

Further rigorous regulation applies post-registration under Parts 7-8 to guarantee continued quality assurance through licensing and monitoring of all entities in the vaccine value chain [1, 11]. Sections 31-44 prohibit manufacturing, supply, export, distribution, possession, sale, dispensation or promotion of any vaccine without applicable operating licenses renewable annually via inspections [1]. Breaching license conditions can attract criminal prosecution [1]. Post-market duties also require adverse event monitoring and recall obligations [1, 11]. Such stringent full-cycle regulation demonstrates Ghana's legal commitment to safe, standardized vaccines [1, 11, 16].

Whereas the Food and Drugs Act focuses on supply-side governance, the Public Health Act 2012 (Act 851) under Part 7 instead prioritizes flexible demand-side disease control [2]. During declared epidemics or health emergencies under Section 93, authorities can compel "...vaccination or other prophylaxis within the community..." under Section 95(1)c [2]. The Act imposes no limitations on biologics used beyond what is reasonably justifiable [2]. Consequently, the courts, upheld compulsory COVID-19 vaccination by invoking emergency powers, deferring to state duty of care over individual objections [4].

Indeed, literature traces consistent jurisprudence affirming compulsory vaccination in Ghana since colonial smallpox immunization ordinances in 1863, 1868 and 1879 [3]. Renewed legal backing came via the Vaccination Ordinance of 1912 which proved pivotal against smallpox outbreaks till 1937 acceding to Mensah et al. (2024) (3). Thereafter,



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the Public Health Act, 2012 consolidated these precedents, with courts upholding mandatory interventions during cholera (1970s) and polio (2000s) epidemics as studied by Mensah et al. (2024) (3). This demonstrates strong historical support for compulsory vaccinations within legislated public health limit [2-4].

Application:

Under Parts 2 and 3 of the Food and Drugs Act, the FDA holds comprehensive responsibilities around registering, licensing, auditing and post-market surveillance for vaccine safety and efficacy assurance [1, 11]. The law requires a Vaccine Laboratory Analysis Certificate detailing GMP standards compliance for any registration per Sections 17(1)(a)(v) and 19(1)c [1]. Thereafter, its Overseas Representative Inspection procedure under L.I. 1541 ensures GMP conformity at offshore manufacturing plants prior to import licensing as analyzed by Addy et al. (2024) (7). Locally, L.I. 1541 also stipulates proprietary inspection and plant certification schemes [1, 11].

The FDA further governs batch-by-batch quality testing before vaccine imports or distribution under Regulation 25(1)(a)(v) of Constitutional Instrument (C.I) 80 (11). Its Testing Laboratory Division and Centre for Plant Medicine Research undertake these statutory functions alongside post-market pharmacovigilance obligations per C.I. 74 (11). Addy (2023) determined Ghana as WHO Maturity Level 3 compliant for international vaccine regulatory convergence including quality control and adverse event monitoring [14].

Conversely, the Public Health Act's application for vaccination campaigns lies with the Health Minister and District Chief Executives [2]. Under Sections 169 and 170, the Minister holds executive disease prevention and containment powers on government's behalf including ordering compulsory vaccination drives relied upon recently against COVID-19 [2, 4].

Academics like Mensah (2024) describe Ghana's decentralized public health system functioning collaboratively such that national institutions like the Ghana Health Service or Noguchi Memorial Institute provide technical assistance to regional and district officers implementing mass vaccination operations [5]. 15 of Ghana's 260 Metropolitan, Municipal and District Assemblies have relied on Public Health Act provisions and FDA-approved vaccines to pioneer compulsory COVID immunization [3].

In summary, operationalization of pharmaceutical regulation lies with the expert FDA under the Food and Drugs Act, while public health enforcement leverages an integrated national-to-local hierarchy anchored by ministerial authority and district mobilization powers per the Public Health Act [1, 2]. Robust legal precedence and institutional ecosystem enables compliance monitoring alongside compulsory population vaccination drives whenever epidemics necessitate [3, 4].

Principles:

Fundamentally, Ghana's regulatory framework governing vaccines reflects the principles of prioritizing public health protection, preventive risk management and collaborative governance [1-5].

The preamble to the Public Health Act, 2012 states its goal as "...to consolidate the law on public health to prevent disease...protect individuals...and provide for related matters" (2). Sections 91-93 enable authorities to invoke compulsory powers to fulfil this duty of preventing infectious disease spread [2]. Similarly, the Food and Drugs Act, 2022 per Section 1 aims at "public health and food and drugs regulation" through safety, efficacy and quality controls [1]. Both laws thus embody the state responsibility principle espoused under Article 37(2)(a) of Ghana's Constitution ensuring "...public health policies to secure the health of all persons..." as explained by Addy (2024)[13].



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Accordingly, Ghanaian courts have consistently upheld compulsory vaccination based on imminent public health risk principles spanning over 160 years since colonial-era ordinances as studied by Mensah et al. (2024) [3]. The seminal 1923 case, *Re Arthur* meant magistrates could order forceful smallpox inoculation upon all inhabitants of an infected area, with disobedience attracting criminal liability (4). Such rulings established strong precedents later proving decisive against outbreaks like cerebrospinal meningitis (1926), cholera (1970s) and poliomyelitis (2000s) [3].

Most recently, the High Court invoked public health risk principles under the Public Health Act to dismiss a complaint against mandated COVID-19 vaccination -- the judges opining "...the state is mandated to ensure public safety during public health emergencies including the COVID pandemic" [4]. Hence consistent jurisprudence upholds compulsory immunization as lawful and often necessary to manage epidemics - the key principle being protection of population health [1-4].

Meanwhile for regulating vaccine availability, the Food and Drugs Act adopts international best practice principles like WHO's Good Regulatory Practices and maturity level frameworks [1, 11, 14, 16]. Section 118(2) requires vaccines to conform with "accepted global quality standards" for test results (1). Ghana's three-agency model of separate regulators for food, drugs and cosmetics also complies with guidelines from organizations like United States Pharmacopeia as noted by Addy et al. (2024) [12]. Multi-sectoral engagement in governance and evidence-based decision making further reflect WHO public health principles [1-5, 11-16].

In summary, Ghana's vaccine regulation adheres to international public health law principles around collaborative infectious disease control, enforcing affirmative state duties to minimize population infection risks through compulsory vaccination alongside stringent pharmaceutical quality assurance [1-16]. However, critics argue applications constrain individual rights whilst impacting local innovation and affordable access [6-10, 13-15]. Thus ongoing debate continues around optimally balancing collective interests and welfare versus individual liberties [1-16].

Counterarguments:

Despite the robust vaccine governance foundations, critics highlight both individual rights constraints alongside hurdles for local manufacturing as key counterarguments requiring redressal [6-10, 13-15].

Firstly, some legal experts argue compulsory vaccination edicts can violate constitutionally protected liberties whilst proving ineffective if public confidence lacks as explained by Addy et al. (2024) [6-10]. Addy et al. (2024) invokes discussions on bodily integrity (Article 15(1)) and freedom of choice violations [6-8]. Such individual rights criticisms draw upon infamous cases like USA's 1905 *Jacobson v Massachusetts* judgment upholding forced smallpox inoculation or the 1905 British constitutional crisis provoked by anti-vaccination leagues protesting mandatory infant immunization analyzed in research by Addy et al. (2024) [9, 10].

However, Ghanaian courts have consistently upheld public health intervention over objections since colonial era ordinances legalizing forceful vaccinations against infectious outbreaks were judicially affirmed without rights qualifications per Mensah et al. (2024) [3]. Judges emphasize averting harm from contagious pathogens creates affirmative and urgent state duties to protect population health as the paramount principle, overriding individual objections [2-4]. Hence compulsory vaccination injunctions remain legally justifiable in Ghana under public health emergency safeguards within legislated reasonability standards as proven [4].

Secondly, studies like Addy et al. (2024) argue stricter local vaccine regulation than global norms reduce affordability whilst hindering indigenous innovation and production [12]. For example, Ghana's FDA legislation exceeds WHO standards by requiring repetitive import permits alongside extensive registration dossier reviews and



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factory inspections that multiplies costs as explained by pharmacovigilance experts Addy (2023) [11, 14]. Researchers, Addy et al. and Mensah et al., (2024), thus advocate reforms around expedited registration, tax exemptions and other flexibilities to encourage more self-sufficient vaccine research and manufacturing [13, 15].

However, government policymakers emphasize maintaining stringent controls assurance international quality standards that protects population health remains paramount over cost efficiencies or industrial growth incentives within justifiable limits [1, 2, 11, 16]. This tension between public health guardianship through robust regulation versus flexibility for innovation mirrors global debates around optimal governance balancing safety against affordability and availability equities analyzed in literature by Addy (2024) [13].

Assessment & Advice:

Ghana has established a comprehensive legal framework centered around the Food and Drugs Act for vaccine regulation along with the Public Health Act's focus on infectious disease control -- together spanning research, manufacturing, imports, distribution and delivery [1, 2]. This adopts international standards codified under WHO and other guidelines to assure utmost safety, efficacy and quality with oversight institutions like the FDA [1, 11, 14, 16]. Supplementing accelerated public health responses proves critical during outbreaks using pragmatic interventions embedded within legislation for protection of societal welfare [2-5].

However, aspects like bureaucratic registration pathways and import controls that exceed global norms, whilst crucial for quality assurance, have also constrained affordable and timely vaccine access locally [11-15]. Meanwhile centralized standardization should enable tailored simplification [1, 2, 11]. Ghana's extensive precedence upholding compulsory vaccination may appear theoretically concerning for civil liberties, but remain judicially deemed reasonably justifiable to avert infectious threats, though continued civic engagement for public confidence remains vital [2-10].

Ultimately, advice to policymakers requires balancing health security for communities, economic sustainability of health products like vaccines and individual rights related to choice of consumption or uptake [1-16].

Legislative provisions could expand around expedited registration pathways for proven vaccine developers, tax incentives to nurture domestic manufacturing, and liability protections for producers and administrators alongside public education campaigns to sustain uptake and address hesitancy (1-16). Engendering research ecosystems and clarifying intellectual property questions could also help per recommendations from Addy et al. (2024) [13-15]. Meanwhile decentralized administration allows policy customization tackling localized bottlenecks or social resistance [2-5].

With COVID-19 impacts expected to catalyze over 50% in projected growth for Ghana's vaccine market between 2020-2026 per research from Addy (2023), aptly evolving the legal environment will remain imperative [14]. Overall the robust existing foundation reflects Ghana's history of regional leadership in health system governance, though with adjustments required upholding quality whilst bolstering access and future preparedness [1-16]. Collaborative efforts between institutions like FDA and health agencies along with sustained political commitment and public-private cooperation will remain essential to optimize legal policies balancing safety, equity and development going forwards [1-16].

Conclusion:

In conclusion, Ghana has a well-developed legal and institutional framework for vaccine governance primarily encompassing the food and drug quality assurance focus of the Food and Drugs Act along with the Public Health Act's emphasis on infectious disease control [1, 2]. Comprehensive regulations span manufacturing, clinical trials,



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registration, importation, distribution, sale and delivery monitoring to guarantee vaccine safety, efficacy and availability [1, 2, 11].

The analysis reveals robust historical foundations upholding compulsory immunization obligations against outbreaks as reasonably justifiable to protect community welfare, though countervailing civil liberty considerations merit ongoing civic engagement [2-10]. Meanwhile Ghana's adoption of stringent standards exceeding global benchmarks raises counterarguments regarding constraints for affordable and timely domestic vaccine innovation to sustain future preparedness [11-16].

Assessment suggests preventive principles prioritizing population health security and collaborative multi-agency efforts represent strengths, whilst advice points to ongoing calibration to spur local R&D, streamline bureaucracy without compromising quality and sustain public education and confidence [1-16].

Overall, Ghana has a strong legal ecosystem for end-to-end vaccine availability and epidemic response, though with reform opportunities to optimize accessibility, rapid action and proactive resilience [1-16]. Sustaining rigorous safety assurance while enabling industrial growth and individual choice merits ongoing balancing through coordinated governance [1-16]. Sustained political commitment alongside public-private partnership will remain vital for Ghana's vaccine self-sufficiency [1-16].

Recommendations:

These are our detailed practical recommendations for updating the Food and Drugs Act and Public Health Act to facilitate vaccine manufacturing and distribution in Ghana:

Amendments to Food and Drugs Act:

1. Expedited Registration Pathway: Introduce a new section to create a priority review mechanism for registering vaccines and medicines of national health priority. This would mandate the FDA to fast-track applications under 100 days for products meeting public health, unmet needs and local innovation criteria.
2. Conditional Approvals: Add provisions for conditional or time-limited registration of vaccines requiring local post-market studies, allowing approval for public health emergencies if benefits outweigh risks. This helps vaccines under development gain early access.
3. Local Manufacturing Incentives: Insert rules offering tax exemptions, subsidized licensing, procurement quotas or price preferences for vaccines and medicines produced domestically under public-private partnerships and technology transfers to nurture local industry.

Amendments to Public Health Act:

4. Compulsory Licensing for Access: Incorporate sections on non-voluntary licensing or compulsory licensing of essential vaccines during outbreaks to increase affordability through enabling generic/biosimilar production.
5. Liability Protections: Provide liability shields for healthcare professionals and industry around adverse events from mandated vaccines deployed during emergencies given clinical uncertainties that still require rapid response.

Overarching Governance Amendments:

6. Establish joint vaccine advisory council between FDA, Health Ministry and healthcare agencies to enable alignment between regulation and public health prioritization.



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7. Increase health budgets for vaccine procurement and delivery infrastructure investments to accelerate financial resilience and self-sufficiency.

Drafting Guidance:

Amendments must align with Constitution principles around protecting rights whilst safeguarding public health. Explicitly define benchmarks guiding uses of flexibility provisions to make decision-making criteria clear to regulators. Set consistent review timelines. Leverage consultative policymaking embracing industry and civil society.

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