



Centre for MultiLateral Affairs

DECEMBER 9, 2025

**Submission on the National Drug and Health
Products Authority Bill, 2025**
CFMA

Executive summary

CfMA welcomes the Bill's objective to modernise regulation of drugs, medical devices, cosmetics, public-health products and nutritional supplements. The Bill introduces useful institutional capacities (e.g., a national laboratory and structured licensing) but contains provisions that risk (i) insufficient procedural safeguards for regulated persons, (ii) excessive centralisation of powers, (iii) disproportionate criminal sanctions for routine regulatory failures, and (iv) duplication or uncertainty in the relationship with existing regulators. We propose targeted amendments so the Bill complies with constitutional administrative-law safeguards and the principles of **legality, legitimacy, proportionality and necessity**.

1. Key observations (short) — how the Bill measures against the four principles

1. Legality (clear enabling rules & due process)

The Bill establishes a modern regulatory architecture including the Authority, a Secretariat and an Executive Director (see Executive Director, Secretariat and staff provisions, including **section 11** and staff rules). However, the Bill vests extensive enforcement powers in inspectors and the Authority **without specifying robust procedural safeguards** (see inspectors, appointment and powers at **section 100** and enforcement/obstruction penalties). This raises legality and fair-administrative-action concerns.

2. Legitimacy (public-interest purpose and institutional independence)

The Bill's stated functions (Parts II–X) align with legitimate public-health objectives (licensing, surveillance, lot release, clinical trial oversight). But the governance design (board/appointment and ministerial rule-making powers) lacks clearer protections of institutional independence that promote legitimacy in the public eye.

3. Proportionality (balancing regulatory objectives against burdens)

Many offence provisions impose steep fines and jail terms across product classes (medical devices, nutritional supplements, public-health products, cosmetics, etc.). The Bill does not always distinguish between deliberate wrongdoing and administrative or technical non-compliance (see examples across Parts VI–IX). This risks disproportionate impact on small producers, traditional healers, pharmacies and distributors.

4. Necessity (evidence, overlap and coordination)

Modernising the NDA regime and creating a national laboratory (see **section 99**) are clearly necessary responses. But several provisions duplicate functions performed by other agencies (standards, advertising, clinical-trial approvals). The Bill requires explicit coordination clauses and a transition plan to avoid duplication and regulatory uncertainty.

2. Detailed critique and recommended amendments

A. Institutional design, independence and transparency (Legitimacy & Legality)

Problem. The Bill creates the Authority, Secretariat and executive roles (see Executive Director at **section 11**, staff and Board functions) but does not sufficiently protect the Authority's independence from politicised interference in appointments or removals. Board rule-making and ministerial regulation powers are broad.

Why it matters. Independent technical regulation increases public trust and reduces regulatory capture. Excess executive/ministerial control risks politicised decision-making and arbitrary interventions.

Recommendations

1. **Amend the clauses on Board appointments so that:**
 - a. A proportion of board members must be appointed after nomination by professional bodies (pharmacists, clinicians), consumer groups and civil society; and the Chairperson's appointment requires parliamentary approval. (Insert at or immediately after the clause establishing the Board/Executive Director provisions such as those found in Part II).
2. **Specify objective grounds and a process** (notice, reasons, independent inquiry) for removal of Board members or the Executive Director (amend the relevant appointment/removal clause).
3. Require the Board to publish an annual regulatory plan, an enforcement policy and all enforcement decisions (sanctions, license revocations) with redactions only for protected information. (Add to the transparency/accountability provisions around the Board/annual report clauses).

B. Enforcement powers, inspections and due-process (Legality & Proportionality)

Problem. The Bill empowers inspectors (see **section 100: Appointment of inspectors**) and gives the Authority powers to seize, detain or destroy regulated products and to issue compliance orders; criminal sanctions are provided for obstruction and non-compliance. However, the **Bill is not explicit enough about the need for warrants, notice, reasons,**

administrative review, and time-bound judicial recourse in non-emergency situations. (See penalties for obstructing inspectors and related offences).

Why it matters. Administrative enforcement must respect **constitutional rights to property, fair administrative action and judicial review (Article 42 and administrative-law principles)**. Overbroad search/seizure powers without a warrant or clear appeal process may be unconstitutional.

Recommendations

1. Insert a requirement that inspectors may **enter premises without consent only where there is a warrant issued by a magistrate or judge, or where an urgent emergency (as defined in the Bill) exists**. Amend the inspection powers clause (100 and the enforcement clauses) to reflect this.
2. Where the Authority seizes or destroys products, require: (a) **written reasons**, (b) **immediate notice** to the affected person, (c) preservation of samples for independent testing, and (d) ability to apply for immediate review (administrative review within the Authority followed by prompt appeal to the High Court). (Reference appeal to the High Court provision at **section 102** for judicial review).
3. Create a narrow offence for obstruction calibrated to wilful obstruction (not mere procedural delay) and include graduated administrative penalties (warnings, corrective orders, suspension) before criminal sanctions. (Amend the obstruction/penalty subsections found near the enforcement provisions).

C. Criminal sanctions and fines (Proportionality)

Problem. The Bill attaches substantial fines and imprisonment across product classes (examples: importation offences, distribution without licence, and non-conformity with standards carry fines and up to five years' imprisonment in many clauses — see clauses on importation of medical devices (**section 58**), distribution offences (**sections 59, 61**) and offences for non-conforming regulated products). The Bill rarely distinguishes between negligent/administrative non-compliance and deliberate harmful conduct.

Why it matters. Harsh criminal penalties for administrative breaches risk chilling small operators, harming access to medicines, and overburdening criminal justice.

Recommendations:

1. Replace imprisonment for first-time technical or administrative non-compliance with **civil fines, remedial orders, mandatory corrective actions and licence suspensions**. Reserve criminal prosecution for deliberate or reckless conduct that causes or risks serious harm (propose specific wording and thresholds). (Amend the offence/penalty provisions across Parts VI–IX).

2. Introduce **graduated penalties**: warnings → fixed administrative fines → licence suspension → criminal prosecution only for repeated or aggravated wrongdoing. Include a proportionality schedule in the Bill or Regulations.

D. Small producers, traditional/herbal practitioners and market access (Necessity & Proportionality)

Problem. The Bill extends regulation to traditional/herbal and small producers but licensing, testing and registration costs (and criminal sanctions) could be prohibitive without tailored measures. The Bill requires a national laboratory (**section 99**) but does not prescribe subsidised testing or simplified pathways.

Why it matters. Uganda's policy objective should protect public health while not excluding local producers or disrupting supply of traditional remedies relied upon by many communities.

Recommendations:

1. Introduce a **simplified registration and risk-based oversight stream** for small traditional/herbal producers (fast-track, lower fees, technical assistance). Place this within the registration/licensing Part.
2. Direct the Authority to provide **subsidised or tiered laboratory testing** via the national laboratory (section 99) for artisanal producers and for essential — low-margin items.

E. Clinical trials, overlapping mandates, and coordination (Necessity)

Problem. The Bill contains detailed clinical-trial authorisation and oversight (see Part IV; clinical trial authorisation and good clinical practice provisions around **sections 90–91** and related paragraphs). It does not, however, set out clearly how the Authority's approval mandate will interact with other statutory bodies (e.g., UNCST for ethics and research approvals, Ministry of Health guidance, international collaborative review processes).

Why it matters. Duplication creates delays for urgent research and creates legal uncertainty for sponsors and investigators.

Recommendations:

1. Include an explicit **coordination clause** that: (a) defines the Authority's role in clinical trial authorisation vis-à-vis UNCST and ethics committees; (b) allows reliance on UNCST or accredited ethics review; and (c) establishes maximum statutory timelines for the Authority's decisions on clinical trial authorisations (e.g., 60 days for initial review, 30 days for amendments). (Amend the clinical trial authorisation section and add cross-references).

F. Duplication with other regulators (UNBS, UCC, MINISTRY) and regulatory impact (Necessity & Legitimacy)

Problem. The Bill gives the Authority powers over standards, advertising, port controls and market surveillance (see regulatory powers/Regulations **section 118**). Without clear inter-agency protocols the Bill risks overlap with UNBS (standards), UCC (advertising), the Ministry of Health (policy), and customs/ports authorities.

Recommendations:

1. Add a **“coordination and memorandum of understanding (MoU)” clause** obliging the Authority to sign MoUs with UNBS, UCC, Ministry of Health, and the Uganda Revenue Authority for specified functions (standards adoption, advertising control, port inspections). (Insert after the regulations clause).
2. Insert a requirement for a **Regulatory Impact Assessment (RIA)** before commencement of large new compliance obligations and a 6–18 month transitional implementation period (the Bill already includes transitional provisions—see **section 121**—but add explicit timelines and RIA requirement).

3. Draft clause amendments

(1) **Inspection warrants** — insert into inspection/inspectors clause (100): **“An inspector shall not enter premises without the consent of the occupant except where the inspector has obtained a warrant issued by a magistrate or judge, or where there are reasonable grounds to believe an emergency exists posing imminent risk to life or health; in the event of an emergency the inspector must, within 48 hours, apply to a magistrate for a retrospective warrant and provide written reasons to the affected person.”**

(2) **Administrative review and appeals** — add to enforcement part: **“The Authority shall provide for an internal administrative review within 30 days of any adverse enforcement decision; any person aggrieved may thereafter appeal to the High Court. The High Court shall hear such appeals on an expedited basis.”** (Links to **section 102** on appeal).

4. Conclusion and next steps

CfMA supports the Bill's public-health aims and the creation of the national laboratory (section **99**) and inspectorate (section **100**) but asks Parliament to adopt the recommended amendments to ensure the law is **constitutional, proportionate, necessary, and legitimate**. Parliament should require (i) stronger procedural safeguards for inspections and seizures; (ii) board and executive protection from arbitrary removal; (iii) graduated sanctions rather than automatic criminalisation of administrative breaches; (iv) special measures for small and traditional producers; and (v) clear coordination arrangements with other regulators and a transitional implementation timetable (see **section 121** for transitional provisions).