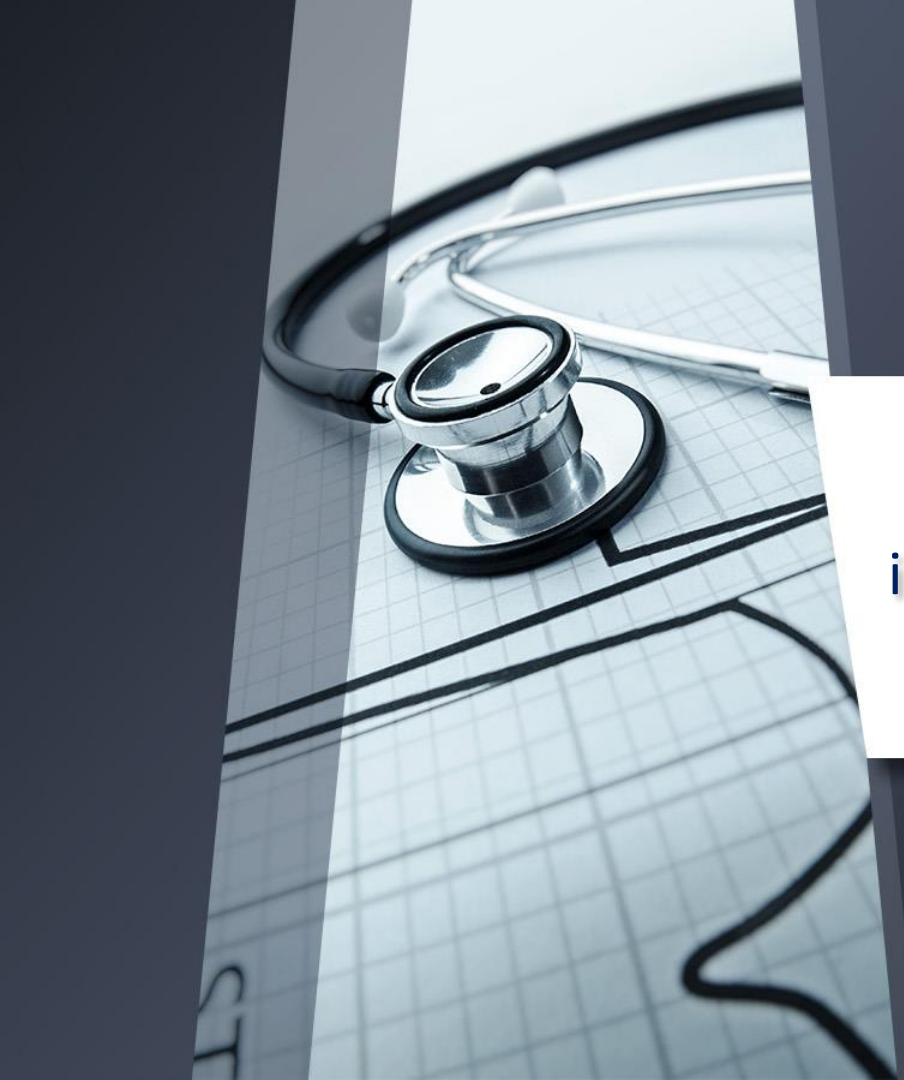

Good Regulatory Practices in the Regulation of Medical Products.

By Maureen Njeri.

Introduction.

- A fundamental role of government is to protect and promote the health and safety of the public, including by delivering health care.
- A well-functioning health care system requires available, affordable medical products that are safe, effective and of assured quality. As medical products are essential in the prevention, diagnosis and treatment of disease, the consequences of substandard and falsified medical products can be life threatening.
- This is a concern, as users of medical products are not usually in a position to judge their quality. The interests and safety of the public must therefore be entrusted to a regulatory body or bodies that ensure that only products in legal trade are available and that marketed products are safe, perform as claimed and are of assured quality.

- The regulation of medical products has become increasingly complex with the globalization of product development, production and supply and the rapid pace of technological and social change in the context of limited financial and human resources.

A sound system of oversight requires that regulatory authorities be supported by an effective framework of laws, regulations and guidelines and that they have the competence, capacity, resources and scientific knowledge to deliver their mandate in an efficient and transparent manner.

STATUTORY INSTRUMENTS ACT, 2013: PUBLIC CONSULTATIONS & REGULATORY IMPACT ASSESSMENT

This Act provides rules for the making and revocation of Statutory Instruments made directly or indirectly under any Act of Parliament or other written legislation.

The object of this Act is to provide a comprehensive regime for the making, scrutiny, publication and operation of statutory instruments by:

- Requiring regulation-making authorities to undertake appropriate consultation before making Statutory Instruments;
- Requiring high standards in the drafting of Statutory Instruments to promote their legal effectiveness, clarity and intelligibility to anticipated users;

- improving public access to Statutory Instruments;
- Establishing improved mechanisms for parliamentary scrutiny of Statutory Instruments; and
- Establishing mechanisms to ensure that Statutory Instruments are periodically reviewed and, if they no longer have a continuing purpose, repealed. The Act also makes provision for the making of regulatory impact statements.

It is worth noting that the exercise of delegated legislative authority by government bodies other than Parliament is usually under strict supervision by Parliament, which donated the power, to ensure that the authority to whom the power is delegated acts within the authority delegated.

The National Assembly scrutinizes all statutory instruments made pursuant to any legislative powers delegated by the Legislature as against the Constitution and the limits of the powers delegated.

Meaning of a statutory instrument.?

- Section 2 of the Statutory Instruments Act, 2013 and the Standing Orders of the respective Houses of Parliament define a statutory instrument as—
  - ***Any rule, order, regulation, direction, form, tariff of costs or fees, letters patent, commission, warrant, proclamation, by-law, resolution, guideline or other statutory instrument issued, made or established in the execution of a power conferred by or under an Act of Parliament under which that statutory instrument or subsidiary legislation is expressly authorized to be issued.***
- The Constitution Article 94 (5) and (6) of the Constitution provide that-
- No person or body, other than Parliament, has the power to make provision having the force of law in Kenya except under authority conferred by this Constitution or by legislation.

Meaning of a statutory instrument.?

- An Act of Parliament, or legislation of a county, that confers on any State organ, State officer or person the authority to make provision having the force of law in Kenya, as contemplated in clause (5), shall expressly specify the purpose and objectives for which that authority is conferred, the limits of the authority, the nature and scope of the law that may be made, and the principles and standards applicable to the law made under the authority.
- Therefore, a Cabinet Secretary or a body or a commission, or an authority or a board with power to make a delegated legislation, must ensure that they act within the power delegated under the Constitution.
- The Interpretation and General Provisions Act (Cap 2) Statutory instruments must conform to the provisions of the Interpretation and General Provisions Act in regard to construction, application and interpretation.

Conformity with the Statutory Instruments Act, 2013

The Statutory Instruments Act outlines the criteria that guide the scrutiny of delegated legislation. The key requirements under the Act are: 4.5.1 Consultations between the regulation-making authority and persons likely to be affected by a proposed instrument (section 5)

These included:

- Definition for public participation;
- Definition of memorandum to include statements on proof of sufficient public consultations;
- The manner in which consultations were carried out;
- The results of public consultations;
- Changes on the legislation after undertaking public consultations, and
- An explanation for lack of public consultations in case there was none. T the principles espoused under Articles 10 and 118 of the Constitution.

Regulatory Impact Statement (sections 6, 7 and 8).

- The Statutory Instrument Act provides for the need for the regulation making authority to provide an impact statement if a proposed statutory instrument is likely to impose significant costs on the community or a part of the community.
- The inclusion of the public throughout the different stages of policy drafting and policy implementation underpins the principle of participation

Public Consultations Generate More Sustainable Solutions.

- Public consultations and engagement with stakeholders pave the way for achieving sustainable regulations and more efficient decisions that take into account the impact of the decisions on the lives of citizens, residents, businesses and the expertise and perspectives of other stakeholders.
- Co-operation with the public in the early phase of drafting regulations can prevent possible conflicts at a later stage.
- Article 25 of the International Covenant on Civil and Political Rights (ICCPR), everyone shall have the right and the opportunity, without unreasonable restrictions, to take part in the conduct of public affairs, directly or through freely chosen representatives.
- For the above reasons, the engagement of the public should not be undertaken as a parallel process independent of other steps that are necessary during the drafting of regulations.

Public Consultations Generate More Sustainable Solutions.

- To summarize what public participation is actually about, we use the core values underpinning participation, as outlined by the International Association for Public Participation:
  - **involving** in the decision-making process those who are affected by or interested in a decision;
  - seeking **input** from participants in designing how they participate;
  - providing participants with the **information** they need to contribute meaningfully;
  - recognizing and communicating the **needs** and interests of all participants, including decision-makers;
  - enabling the public's **contribution** to influence the decision;
  - **communicating** to participants how their input affected the decision.

Public Consultations Generate More Sustainable Solutions.

- Public involvement in policy-making brings several benefits to state administration, which are particularly pertinent when public consultation is combined with RIA:
  - **Smart regulations for growth, investment, innovation, market openness and support to the rule of law:** the involvement of different stakeholders (business associations, trade unions, civil society organizations, academia) significantly contributes to better analysis of the impact of new or amended policies and legislation, and it serves as a very important tool of evidence-based policy making (making possible the projection and simulation of different alternatives and solutions).
  - **Confirmation of the need for a new regulation:** those best placed to help the state administration to identify and define concrete challenges and needs are those that will be affected by the regulation under consideration. Inclusive engagement processes can either confirm the need for the proposed solutions, or provide a basis for re-thinking them or finding better solutions.

Public Consultations Generate More Sustainable Solutions.

- **Early detection of potential obstacles and unintended negative side-effects of proposed regulations:** the public can often better pinpoint the potential obstacles and consequences that have been overlooked, and thus help to prevent potential negative consequences.
- **Quicker and easier implementation:** with well thought-through solutions and wider ownership on the part of the public, the implementation of the regulation becomes much easier.
- **Early conflict resolution:** During participative processes, stakeholders often express different views and opinions. By taking them on board, the chances that stakeholders will oppose the regulation at a later stage are significantly decreased.
- **Greater legitimacy of decisions and higher public trust in public administration:** through participation in policy-making, stakeholders develop ownership and The regulatory making authority must provide a certificate in writing confirming that the guidelines have been complied with and that the statement adequately assesses the likely impact of the proposed instrument.

What are the key elements in a RIA process?

1. **Defining a regulatory problem**

   This phase is the preliminary point of RIAs: identifying the regulatory or policy problem. Problems usually fall within three categories: market failure, regulatory inefficiencies, and new policy targets or objectives.

2. **Identifying different regulatory options**

   During this step, the need for regulatory intervention identified in phase 1 has to be translated into concrete policy options.

3. **Collecting data**

   This phase is crucial and the means to achieve it are diverse and vary greatly among countries. Relevant data for the RIA are collected from public consultations, telephone and face-to-face interviews, paper questionnaires, online surveys, focus groups, etc.

What are the key elements in a RIA process?

4. **Assessing alternative options**

   The central phase of RIAs most of the time results in a cost-benefit analysis, but can also be a costeffectiveness analysis or a risk analysis. Options assessed must include the “no policy change” scenario.

5. **Identifying preferred regulatory option/s**

   Once the different options have been identified and scrutinised (usually by comparing the costs and benefits), the comparison of the different assessment will lead to the identification of the most efficient option.

6. **Communicating results of the conducted RIA**

   Once taken into consideration by the policy makers, best practices suggest publication of the result of the RIA. This allows further exchange with stakeholders and improves the general transparency of the regulatory process.

A Selection of Experiences.

- **UK In** the UK, policymakers have to evaluate existing regulation after five years and determine if it is still relevant. If a measure is shown to be successful and is retained, the review should still consider how the measure could be improved, for example by reducing the costs to business, or improving enforcement.
- **Germany** in Germany the Committee of State Secretaries' 2013 Resolution for the Reduction of Bureaucracy resolved that all laws meeting certain cost thresholds should be subject to systematic ex-post evaluation. Evaluations should take place three to five years after the regulations come into effect.
- **Canada** In Canada, departments and agencies are responsible for ensuring regulation continually meets its initial policy objectives and for reviewing regulatory frameworks on an ongoing basis. Canada also has a "one-for-one" rule, under which departments and agencies are responsible for: controlling the number of regulations by repealing at least one existing regulation every time a new one that imposes an administrative burden and restricting the growth of administrative burden by ensuring that new administrative burden on business caused by a regulatory change ("IN") is offset by an equal decrease in administrative burden on business from the existing stock of regulations ("OUT").

A Selection of Experiences.

- **South Korea**, the Regulatory Reform Committee created a citizens' participation online platform, which enables citizens to submit proposals concerning legislation or amendments to legislation. At the same time, there are still weaknesses in South Korea’s implementation of stakeholder engagement.

Criteria to Evaluate the Effectiveness and Quality of Legislation.

➢ Component[2]	Question(s)	Analytical tasks
1 Problem definition	Q1 (a) What is the problem, the underlying justification for the regulation? (b) Has it changed? This includes new scientific developments, changed social trends, etc.?	A1 (a) Market failure/problem analysis. Is there a market failure/problem and of what form? (b) Analysis of trends in the physical problem and the underlying causal factors.
2 Effectiveness of current regulation	Q2 (a) How effective is the regulation in addressing the problem(s)? (b) Were expected benefits achieved? (c) Have there been unintended consequences?	A2 (a) Analysis of outcomes compared with some counterfactual with no regulation (or some alternative) to isolate the effects of regulation. (b) Comparison of expected and actual outcomes.
3 Regulatory options	Q3 (a) Is regulation still the best way to achieve objectives? (b) Are there regulatory and nonregulatory options?	A3 (a) Analysis of regulatory response suggested by market failure/problem identification. (b) Regulatory review – literature review and international comparative review.

Criteria to Evaluate the Effectiveness and Quality of Legislation.

4 Regulatory analyses	Q4 (a) Do the benefits still exceed the costs? (b) Do alternatives exist with lower costs for the same objective? Can greater cost effectiveness be achieved?	A4 (a) Cost benefit analysis (CBA) (or review of existing CBA) of current regulation and alternatives (initial high-level analysis).
5 Regulatory improvements	Q5 (a) Can the regulation be modified to better partner with other regulatory areas or levels of government? (b) Does it have time-consuming requirements, e.g., paperwork, that can be reduced? (c) Flexibility: is it highly prescriptive?	A5 Transaction cost analysis.

Affordability of the medical devices.

Nearly 70% of Kenya's healthcare services are provided by the public sector, through the Ministry of Health (MOH), and other government-funded bodies.

- ***Lack of raw materials and reliability on imports***

  The medical device sector is heavily reliant on imports with limited domestic production due to limited manufacturing infrastructure and technical capacity as well as lack of access to raw materials. According to the Kenya Medical Research Institute (KEMRI), NCDs such as cancers, diabetes, and others account for 27% of total deaths and over 50% of total hospital admissions.

- ***Accessibility***

  The country's Universal Healthcare Coverage (UHC) program prioritizes broadening access to services, strengthening primary healthcare, increasing medical staff and medical supplies, digitizing health operations, and scaling up the National Health Insurance Fund (NHIF). Most Kenyans cannot be able to access medical covers. This therefore makes most of these medical devices only mostly unfortunately accessed only by the rich.

Affordability of the medical devices.

The government would ease this burden by offering free medical services and to further reduce the cost of devices needed for dragonizing and treatment of diseases.

- **Disaster Preparedness**

  In response to the global economic pressures from the COVID-19 pandemic, the Kenyan government took longer than was necessary to implement and allocate funds additional health, including enhanced surveillance, laboratory services, isolation units, equipment, supplies, and communication.

- **Medical Device Procurement and Bidding Process**

  - Public procurement for both medical equipment and pharmaceuticals is done by the Kenya Medical Supplies Agency (KEMSA), a state corporation and a specialized medical logistics provider for the MOH. Centralized purchasing and procurement are often used in both public and private hospitals to obtain economies of scale.

Affordability of the medical devices.

- ❖ All public tenders are advertised on the KEMSA website and must follow the Public Procurement Act.
- ❖ It is rather unfortunate that important tenders are awarded to people who have deep pockets with the ability to “facilitate” and give ‘Gratuity” for the tenders awarded. The tendering process is controlled by cartels of well-connected “politically correct” individuals within the government. There is need for legislation to guide on the said processes to avoid interference from outside forces.

➢ **Independence of the Pharmaceuticals an Poisons Board.**

- ❖There are constant power fights between the ministry of health and the board of the PPB.
- ❖There is need for formulation of regulations to streamline the powers and duties of all the key players with clear distinction on the power of the minister for medical services as well as that of the board.

Affordability of the medical devices.

- ***Corruption***
  - ❖The agency is still under investigation for concerns regarding fraud, waste, and mismanagement. All corruption cases should be prosecuted and stringent penalties handed to the perpetrators as an act of deterrence.
- **WHO Level 3 Matuarity**

There is necessity for the board to attain 3 matuarity by staying updated and compliant with the WHO guidelines on good regulatory practices, trade and legal references to met the accepted intanational standards.

Affordability of the medical devices.

- **Regulation:**
  - ❖The MOH is the lead healthcare policy setting government institution in Kenya. The Pharmacy and Poisons Board (PPB), an agency under the Department of Medical Services at the MOH, is the regulatory body for registration of medical devices.
  - ❖Kenya should incorporate and adopt all the universal good all medical devices, food supplements, medical cosmetics, herbal products, and other allied borderline healthcare products
- **The Kenya Bureau of Standards (KEBS)**
  - ❖KEBS and PPB announced the import requirements to protect the public against products that do not comply with local quality standards and technical regulations.

Affordability of the medical devices.

- These regulations for imported medical devices increase compliance for importers and improve standards in the Kenyan medical device market.
- A certificate of conformity (CoC) for customs clearance at the border is required by importers of these products before applying for import license permits from the PPB to root out counterfeit medical products

- **VAT Exemptions**
  - The government also announced the exemption of various medical equipment and apparatus from VAT, under the 2022/2023 budget, which continues to drive and encourage investment in the health sector in Kenya.

Affordability of the medical devices.

- This includes exemptions for plant and machinery used in manufacturing of pharmaceutical products. The supply of medical oxygen to registered hospitals, urine bags, adult diapers, artificial breasts, and colostomy or ileostomy bags for medical use are also to be exempt from VAT.
- There is need to formulate regulations to consider the East African Community having a single regulatory body for medical devices across the region under the East African Community (EAC) Medicines Regulatory Harmonization program.

Affordability of the medical devices.

- **Opportunities**
  - **Cancer Care**:

    In July 2020, the government announced the opening of ten county chemotherapy centers as part of deliberate efforts to improve access to cancer services in line with the UHC developmental agenda. In addition to the ten centers, the Ministry has also operationalized the Kenyatta University Teaching Referral and Research Hospital and is in the process of establishing five additional radiotherapy centers at the Moi Teaching and Referral Hospital, Nakuru County Referral Hospital, Mombasa County Referral Hospital, Garissa County, and Kisii County.

Affordability of the medical devices.

- **eHealth and mHealth**:

  Kenya has a well-defined e-Health Policy (2016-2030) outlining key areas of focus aand implementation. It has provided a sound policy foundation to manage the rollout of various health information technologies in the country. Kenya has a high mobile phone penetration, which creates a market for eHealth products such as connected devices and patient tracking. the MOH mHealth standards provide a regulatory framework that enables coordination and implementation of robust mHealth solutions.

Affordability of the medical devices.

- ***Pharmaceuticals:***

  The attractiveness of Kenya's pharmaceutical market to innovative drug makers is however hampered by low-income levels, a poor rural population, and an underdeveloped healthcare sector, characterized by lack of infrastructure and structured sales channels. In 2022, GOK signed an MOU with covid vaccine manufacturer Moderna for the establishment of the first mRNA manufacturing facility in Africa.

CONCLUSIONS AND RECOMMENDATIONS
Regulation of Public Consultations – Dos and Don'ts

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- There needs to be an oversight body that performs the role of a gatekeeper that has the right and responsibility to refuse draft acts where consultations have not been implemented according to the stipulated requirements.
- Successful consultations demand a targeted approach and flexibility, tailored to the context. Regulations should set minimum requirements, but not a fixed and determined procedure that does not allow any adjustments.
- Regulation needs to allow space for a proportional approach – for more complex, comprehensive and politically sensitive decision-making a more complex approach is needed, while less complex issues may require significantly less time, and more straightforward engagement of stakeholders in general.

CONCLUSIONS AND RECOMMENDATIONS

1. Regulation of Public Consultations – Dos and Don'ts.

- Consultations should not be run independently from, or parallel to, other procedures in drafting laws and decisions.
- It is essential to promote early engagement with the public and stakeholders before the first draft of legislation is written and, in line with current worldwide trends, firmly link consultations with RIA.
- Use of e-consultations brings important efficiencies to the consultation process, but must be combined with different methods, including live consultation events, to ensure equal access to all interested citizens.
- The regulation should encourage development of consultation documents that explain in plain language the purpose of the proposed new law or policy.

CONCLUSIONS AND RECOMMENDATIONS

2. RIA Quality Control – Dos and Don'ts

- Establish near the centre of government an overall oversight and quality control body, equipped with expert staff, to co-ordinate and harmonise the RIA processes throughout all public bodies.
- The body should have a high degree of independence – to protect it from political changes and partisan interests.
- Quality control mechanism needs to include mandatory quality check of RIA reports from the side of those ministries that are responsible for areas where the impact needs to be assessed.
- The government needs to provide comprehensive guidelines on RIA that include guidance on problem analysis, identification and comparison of possible solutions, and consultations with stakeholders.

CONCLUSIONS AND RECOMMENDATIONS

2. RIA Quality Control – Dos and Don'ts

- The RIA methodology must take into consideration the national context and the present organisation of work and the existing processes within public administration;.
- it is essential to encourage stakeholder engagement during RIA as well as consultations with other line ministries and agencies responsible for areas where impact needs to be assessed.
- Regular trainings on RIA should be introduced. Within line ministries, a few staff should be given extra training and mentoring, so that they will be able to then support their ministerial colleagues during RIA processes.

RECOMMENDATIONS.

Formulate a gradual, prioritised roadmap for introduction of the proosed legislation

- Give high priority to ensuring skilled human resources and budget allocations are in place, and to provide indepth training to a few public officials in each ministry or government agency.
- Run pilot simulations of public consultations around Regulatory Impact Assessments, e.g. on Environment and/or Urban Planning.
- Training of NGOs in drafting policy recommendations and amendments to laws
- Training of public officials in drafting green papers (ex-ante outlines of the challenges or problems faced, on the basis of which context and stakeholder analyses can be conducted, and a series of scenarios and policy options drafted, further public consultations held, then a draft law or regulation launched)


Thank you