GOOD GOVERNANCE FOR MEDICINES AND RULE OF LAW

INTERCOUNTRY MEETING EMRO
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Our discussion today

- What is rule of law?
- Why is it important?
- How is rule of law expressed or demonstrated in medicines regulation and good governance?
- Examples of elements you may consider in your national frameworks and action plans.
- Exercises – approximately 10 min. each
- Questions and discussion

Good governance definition and framework components refer to rule of law.

- Formulation and implementation of
  - Draft, approve and make operational
- Policies, procedures that
  - Ensure effective, efficient, and ethical management of
  - The medicines regulatory system and the medicines sector
- In a manner that is
  - Transparent
  - Accountable
  - Minimizes corruption
- ***Follows rule of law***
- ***RoL applies to all components of national framework.***

SDG16 refers to rule of law

- 16.3 Promote the rule of law at the national and international levels and ensure equal access to justice for all
- 16.5 Substantially reduce corruption and bribery in all their forms
- 16.6 Develop effective, accountable and transparent institutions at all levels
- 16.7 Ensure responsive, inclusive, participatory and representative decision-making at all levels

Note: SDGs are intended to be connected: consider SDG3

How is rule of law defined?

- A system in which the following four universal principles are upheld:
- The government and its officials and agents as well as individuals and private entities are accountable under the law.
- The laws are clear, publicized, stable, and just; are applied evenly; and protect fundamental rights, including the security of persons and property and certain core human rights.
- The process by which the laws are enacted, administered, and enforced is accessible, fair, and efficient.
- Justice is delivered timely by competent, ethical, and independent representatives and neutrals who are of sufficient number, have adequate resources, and reflect the makeup of the communities they serve.

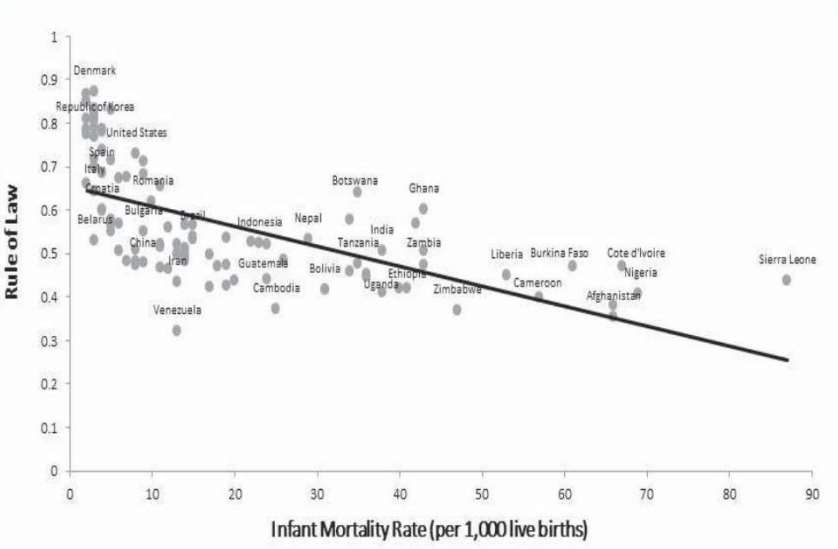
  - *World Justice Project*

Nine factors measure rule of law

- Factor 1 Constraints in government powers
- Factor 2 Absence of corruption
- Factor 3 Open government – now measured by the Open Government Index
- Factor 4 Fundamental rights - human rights
- Factor 5 Order and Security
- Factor 6 Regulatory Enforcement measures the extent to which regulations are fairly and effectively implemented and enforced. *Regulations, both legal and administrative, structure behaviors within and outside of the government.*
- Factor 7 Civil Justice - measures whether ordinary people can resolve their grievances peacefully and effectively through the civil justice system.
- Factor 8 Criminal Justice
- Factor 9 Informal Justice

  – *World Justice Project*

Public Health and the Rule of Law



Exercise 1: Rule of law and public health

- Find your country in the Rule of Law Index
  - *2015* *http://data.worldjusticeproject.org/*
  - *2016 WJP Rule of Law Index® launched October 20th*
  - *For fun estimate the score of your country.*
- Questionnaire
  - *http://worldjusticeproject.org/sites/default/files/media/wjp_rolindex2016_ph_publichealth_english.pdf*
- Record your answers and identify areas of weakness.

Law only act on actors or transactions or products.

- The actors/entities in the system: ***public and private***
  - *The Ministry of Health/ regional health authorities*
    - Minister and secretary, deputies, HQ/RH staff
    - Health professionals and staff in the public hospitals and clinics and pharmacies
    - Non-staff members of committees, commissions, boards
  - *The Medicines Regulatory Authority or office*
    - Staff, senior management
    - Medical stores
  - *Other government offices*
  - *Procurement offices and wining bidders (contract law)*
  - *Wholesalers, retailers, importers, manufacturers, transporters, researchers, prescribers and dispensers*
- Transactions or a procedure/MRA function; import, export, mfg., prescribe, dispenses, test, inspect, procure, license, clinical trials, more.

Is there law? What does it do?

- Law establishes the MRA, defines and limits its functions
  - Vests legal mandates within a scope and manages decentralized systems
  - Coordinates MRA functions and with other government offices and NGO actors/private sector; e.g.. pharmacy council –
- Grants rights or privileges and limits behavior of actors or transactions and the government
- Establishes regulatory (enforcement) system
  - Standard setting (guidelines, instructions, forms)
  - Inspection to determine compliance with standards
  - Licensing, permits and registration
  - Regulatory/administrative enforcement actions
    - Appeal body – administrative tribunal – sanctions
    - Referral for criminal and civil actions

Law is the skeleton and holds up all else.

"Law" continuum across different instruments

Law

- Limits on behavior or grant of privilege
- Authority to impose fees, sanctions, issue regulations, license conditions or standards or guidelines or /schedules/lists, inspection powers and review body powers and some procedures
- Governance bodies, hierarchy of decision making
- Ability to recognize decisions of others, participate in harmonization

Regulations

- The details, specifics, procedures, timelines, steps, required application forms, others as per legal system

Standards, guidelines, list, schedules, conditions

- Scientific and technical requirements e.g. pharmacopeia, international norms; GMP, harmonized systems or fees or lists
- Guidance, codes, guidelines, license conditions

Is the regulatory system effective and efficient?

- Institutional factors – autonomous
  - Is there adequate legislation and regulation?
  - Appropriate organizational structure
- Clearly defined roles and responsibilities to implement these? Limits to the MRA.
  - Relevant guidelines and procedures
  - An effective internal quality control system:
    - QC
    - Supervision, monitoring/evaluation of how the system and staff are working
    - Internal review body/appeal body

- *Regulatory framework for access to safe, effective quality medicines Rago L. 2014*

We know the MRA functions but what about….

- Is it time to add cross cutting functions
  - *Good governance*
    - Would institute transparency
  - *Institutional development –*
  - *Capacity development/socialization*
  - *Management and supervision*
    - Would include accountability - unit TOR
  - *QM*
  - *Coordination with other government offices and donors*
- Are these not functions of a regulator?
- What others would you add to this list?

Exercise 2: Is there adequate legislation?

- Is the MRA clearly defined and authorized to regulate and perform medicines regulation? Is it defined in the law or are you creating an institution?
  - Scope of regulation? What products, actors and transactions?
  - Are all the functions defined? Gaps? New functions?
  - Are the basic limits/permissions on behavior in the law or are they in the regulations?
  - What MRA or MOH or other government office is responsible for what part of each function?
  - What about pathways of authority in decentralized systems?
  - Is it aligned/harmonized?

Rule of Law Index Factor 6 Regulatory Enforcement

Measures the extent to which regulations are fairly and *effectively implemented and enforced*. Regulations, both legal and administrative, structure behaviors within and outside of the government.

- Government regulations are *effectively enforced*
- Government regulations are applied and enforced without improper influence
- *Administrative proceedings* are conducted without unreasonable delay
- *Due process* is respected in administrative proceedings
- The government does not expropriate without *lawful process* and adequate compensation
  - World Justice Project

Implementation and enforcement are different; both are essential to an accountable MRA

- Implementation of the regulatory system
  - Standard setting (guidelines, instructions, forms)
  - Licensing, permits and registration
  - Inspection to determine compliance with standards
    - Are standards and requirements integrated into checklists for inspectors/measurement method?
- Enforcement – when remediation is insufficient
  - Inspection that observes violation or potential one and refers for enforcement action
  - Regulatory/administrative/ enforcement actions
    - Appeal body – administrative tribunal – sanctions
    - Referral for criminal and civil actions

Some references

- Internal Review Boards: An Innovation in Health Sector Governance
- Law as a Guide to Regulatory System Design for the Health Sector: An Essential Tool for Regulating the Private Health Sector in Afghanistan and Other Developing Countries

Financing and Implementing the Post-2015 Development Agenda: The Role of Law and Justice Systems.

The World Bank Legal Review Volume 7

https://openknowledge.worldbank.org/handle/10986/24997

Exercise 3: Enforcement/"Accountable"

- Internal review body - what might should be reviewable?
  - COI breaches
  - Violation of standards determinations
  - Contract performance disputes
  - Insurance reimbursement/claims
  - Other case types
- Rules of procedure, how cases are filed, members of the board, who are they?
  - Look for an appeal body in another ministry in your country and model it.
- It would impose sanctions. Are the sanctions tough enough to deter undesirable behavior? If not what should they be?
  - Body would impose them as per guidelines
- Procurement challenge systems are in procurement laws as are other conflict rules.

Exercise 3: Enforcement/"Accountable"

- Is the MOH or MRA lawyer on your GGM team?
  - Have you educated the lawyer on GGM and medicines regulation?
  - Has the regulator been educated on the content of the law?
  - Do all staff or units have a copy? Have you created a desk book?
  - Do staff understand the content and are they obligated to apply it without adding elements? Or interpreting it without consultation with the legal advisor?
- Map the legal community in your country.
  - AG, prosecutor, MOJ, Parliament, law schools, the office of the legal advisor to MOH/MRA, special offices on corruption, integrity, audit, informal justice systems – tribal or shura councils, others?
  - Socialize them!! Get them involved.

Exercise 4: Transparency

- Collect all the laws relevant to your sector. List them.
  - *MRA, health, public health, vet, AG, councils, poisons, chemicals, radio-nuclear, IP, commerce, customs, food, more.*
  - *Make a desk book, "ahad bab", web site*
- Do you require that meetings and decisions of all public bodies including review bodies and courts are made public?
  - *The Gazette is not enough. SDG 16.10 Ensure public access to information*
- Do you have rule making procedures?
  - *System to share drafts for public comment*
- SDG 16- Ensure responsive, inclusive, participatory and representative decision-making at all levels
  - *Means civil society members on boards, committees*

Exercise 5: Put teeth into your codes of conduct with rule of law mechanics.

- Translate to legal obligations if not already
  - All MRA staff -
  - Conditions for members of committees, boards, commission
  - Procurement bidders and bid review committee members
  - Professionals codes of conduct
- Definition of breach, - define violations
  - For civil servants
  - For members of boards etc.
  - For procurements bidders an review committee
  - For professionals
- Mechanism to determine breach and consequences
  - Sanctions for reprehensible acts – sufficient to deter bad behavior
    - Removal from office, boards or job
    - Financial penalties, reimbursement of benefits if from public funds
    - Public announcement in Gazette

Exercise 6: Minimize corruption

- Define corruption and other wrong behaviors
- Other wrong behaviors: Some administrative violations are also crimes. Which ones are?
- Enforce existing anti-corruption legislation
  - Is your country a member of CAC? Or some other version?
  - What is the body that implements this law?
  - How can MRA coordinate with it. Add it to your stakeholder list – educate them on health and your selves on the legal aspects of corruption.
  - What about decentralized systems?

Shukran qool ahad!
Merci!
Tashakar!

- Law is the critical enabler of health systems.
- Thank you for participating today and to WHO for inviting me.

- If you have any questions please feel free to contact me at:

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24