IVD REGULATORY AND LICENSING ISSUES

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OUTLINE

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- The Players
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- The not so effective strategies
- The challenges
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THE PROCESS

- An analysis of the regulatory framework for IVDs in relation to the registration and licensing of mRDTs and to the sales and/or performance of mRDTs in the 5 UNITAID private sector project countries – desk review
- Obtaining description of the processes (pre-market and post market) and requirements for updating/revising regulation for invitro diagnostics
- Mapping out the different key stakeholders internationally and in each country
- Formation of TWGs or taskforce to push the agenda
- Engaging stakeholders through the TWGs and as well as project partners organising different meetings with the different stakeholders
- Providing technical assistance to regulators through Consultancies when necessary

THE PLAYERS

PLAYERS	INTERESTS
National Malaria Programs	Prompt parasitological confirmation of all fever cases before treatment at all levels
Laboratory professionals	Testing should be done by the appropriate personnel
Regulators	Testing should be done by trained people to ensure patient safety
Manufacturers (Importers and distributors included)	Speedy and cheaper registration process ; balanced supply and demand
Funders	Quality assured RDTs being used by target cadres with regulatory oversight eg. on QA/QC
Patients	Testing should be affordable, accessible and rapid

THE WINNING FORMULA

- National Malaria Programs pushing the agenda for regulatory changes (pre market and post market)
- Engaging the different stakeholders in all project activities – initial assessments of sites, supervisory visits , trainings and meetings
- Capacity building of regulators – supporting positions/focal points, trainings, paying for consultants etc.
- Information sharing among stakeholders of the different countries
- Plugging into international initiatives – PAHWP

NOT SO EFFECTIVE

- Engaging stakeholders individually
  - not as productive as joint discussion where competing interests can be addressed

CHALLENGES

- Regulatory bodies lack the capacity to fully regulate the IVD industry in addition to weak regulatory frameworks
- There are regulatory and physical barriers to performing RDTs and non-malaria fever case management at pharmacies and drug vendor shops such as premarket controls that only allow lab personnel to test or vendors to sell ACTs and restricted time/client and space (to ensure safety and confidentiality).
- The process of changes to regulations is a long and sometimes unclear, one
- Each country is focussed on its own regulations and processes with little harmonization
- Misconceptions about RDTs vs microscopy affecting the acceptability of RDTs by both providers and patients.

CHALLENGES

- Local politics – regulator vs regulator, regulator vs NMP, Regulator vs Lab professional body etc.
- Professional boundaries – Lab vs non lab, clinicians vs drug shops
- High number of unregistered/ unregulated informal private sector
- Public sector is treated differently from private sector presenting challenges in building a case for regulatory changes

WAY FORWARD

- NMPs should continue to advocate for regulatory changes that support their diagnostic and treatment policies
- Countries should have a clear policy on Task Shifting authorizing other cadres to carry out POC testing
- Roles and responsibilities of the different stakeholders should be clearly defined in relationship to licensing and Registration of IVDs and for regulating the sale and performance of POC tests like mRDTs

WAY FORWARD

- There is need to advocate for governments to increase resources to strengthen capacity of regulatory bodies in addition to strengthening regulations – WHO resolution: WHA67.20
- Quality assurance of malaria diagnosis using mRDT cannot be ignored, given that the advocacy is on non-laboratory personnel performing mRDTs
- mRDTs are closely linked with the anti-malarial treatment and malaria case management/ fever case management is linked to antibiotic use hence there is need to address these issues as well

WAY FORWARD

- It is important for countries to take advantage of the efforts currently under way to harmonize the regulation of in vitro diagnostics(IVDs) in Africa as they review their regulations
- Regulators should take note of the uniqueness of malaria, in developing in-country product screening and evaluations protocols.
  - Reference materials for evaluating mRDTs are not easily available in most countries. WHO-FIND offers a comprehensive Product Testing and Lot testing Program that countries can take advantage of and more malaria RDTs are now WHO prequalified (which requires 'passing' grade on dossier review, lab evaluation(WHO product testing) and manufacturer site inspection)
  - WHO prequalification promoting 'joint assessment' options for IVDs

WHO information note on procurement: http://www.who.int/malaria/publications/atoz/rdt_selection_criteria/en/
WHO prequalification IVD list: http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/

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