Maximising Regulatory Effectiveness and Efficiency Through the AMA
Learning from the experience of others

Lawrence Liberti, PhD, RPh, RAC
Head, Regulatory Collaborations
CIRS- Centre for Innovation in Regulatory Science
LLiberti@cirsci.org
Goals of the AMA

• **Coordinating and facilitating initiatives to harmonise** and strengthen African medicines regulation by providing regulatory oversight and guidance

• **Documenting and promoting best practices**

• **Work across national regulatory authorities (NRAs) and regional regulatory initiatives (RRIs)** through the strategic theme of **regional integration, cooperation and harmonisation**

• The AMA will develop systems to **monitor, evaluate and assess the comprehensiveness of systems used by NRAs and RRIs** (to recommend ways to improve their efficiency and effectiveness)
Effectiveness: “DOING THE RIGHT THING”

REGULATORY PERFORMANCE

- **Regulators do not unnecessarily impede the efficient operation of regulated entities.**
- **Communication with regulated entities is clear, targeted and effective.**
- **Actions undertaken by regulators are proportionate to the regulatory risk being managed.**
- **Compliance and monitoring approaches are streamlined and coordinated.**
- **Regulators are open and transparent in their dealings with regulated entities.**
- **Regulators actively contribute to the continuous improvement of regulatory frameworks.**


Efficiency: “DOING THE THING RIGHT”

A Decade of regulatory harmonization in Africa: Where are we? Where do we go from here?
The Pan American Network for Drug Regulatory Harmonization (PANDRH) Objectives

- Encourage the NRAs to develop and maintain well-structured organizations to achieve effective [fit-for-purpose] regulatory functions
- Strengthen the regulatory functions and systems of the countries of the region, promoting cooperation and sharing among countries, with PAHO and with other regional and international organizations
- Develop and implement proposals for the regulation of health technologies, taking into account international guidelines and standards for regulatory convergence.
- Develop core competencies aimed at supporting and strengthening good regulatory practices and regulatory science with the goal of achieving regulatory convergence in the region.
OpERA: *Optimizing Efficiencies in Regulatory Agencies*

The 2 components of OpERA - Process and Metrics

Centre for Innovation in Regulatory Science (CIRS)

Profiles in international regulatory review

State the milestones, target times, and quality of decision making in the assessment and registration process.

*<Date>*

Country Report

*<Country>*

Key Milestones data collected & Summary of review process timelines

The above analysis shows the summation of the main components of the review process and their associated timelines. These are indicated using box-and-whisker analysis, showing the median time and the variability of each component.

The text is extracted from a slide showing the process and metrics involved in regulatory agencies, focusing on key milestones and the summary of the review process timelines. The data collected helps in optimizing efficiencies in regulatory agencies.
Good Regulatory Practices

Process Information Collected by OpERA in Country Reports

<table>
<thead>
<tr>
<th>Region</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Africa</td>
<td>Zimbabwe</td>
</tr>
<tr>
<td>Africa</td>
<td>South Africa</td>
</tr>
<tr>
<td>LatAm</td>
<td>CRS</td>
</tr>
<tr>
<td>LatAm</td>
<td>Brazil</td>
</tr>
<tr>
<td>LatAm</td>
<td>Peru</td>
</tr>
<tr>
<td>LatAm</td>
<td>Mexico</td>
</tr>
<tr>
<td>LatAm</td>
<td>Argentina</td>
</tr>
<tr>
<td>LatAm</td>
<td>Colombia</td>
</tr>
<tr>
<td>LatAm</td>
<td>Cuba</td>
</tr>
<tr>
<td>Australasia</td>
<td>Australia</td>
</tr>
<tr>
<td>Asia</td>
<td>India</td>
</tr>
<tr>
<td>Asia</td>
<td>Malaysia</td>
</tr>
<tr>
<td>Asia</td>
<td>Singapore</td>
</tr>
<tr>
<td>Asia</td>
<td>Taiwan</td>
</tr>
<tr>
<td>UAE</td>
<td>Saudi Arabia</td>
</tr>
<tr>
<td>UAE</td>
<td>GHC</td>
</tr>
<tr>
<td>Europe</td>
<td>Turkey</td>
</tr>
<tr>
<td>Middle East</td>
<td>Jordan</td>
</tr>
<tr>
<td>Ntrh America</td>
<td>Canada</td>
</tr>
</tbody>
</table>

PART 4

GOOD REVIEW PRACTICES (GRevP)
- General measures used to achieve quality
- Quality Management
- Quality in the Review and Assessment Process
- Training and continuing education as an element of quality
- Transparency in the review process

PART 5

QUALITY DECISION-MAKING PROCESSES
- Frameworks
- Challenges
Good Review Practices

How does the agency define GRevP: Is it different from the
If different, country definition

Outline the key elements that make up GRevP in the agency
Has the agency formally or informally implemented GRevP?
If YES, title of formal implementation
If YES, date of formal implementation
How has this been implemented?
Are these documents open and available to the public?
Which factors influenced the establishment of the GRevP based on?
If YES, state the name of agency(ies) or international
Are you satisfied with your existing GRevP framework?
If could be improved or unsatisfied, indicate reason(s) that
If you do not have a formal GRevP system in place are there

Internal Quality Policy

Does the agency have an Internal Quality Policy?
If NO, does the agency plans to establish this within the next two

SOPs

Are there SOPs for the guidance of scientific assessors?
If NO, are there plans to establish SOPs within the next two
Are there SOPs for the advisory committee consulted during
If NO, are there plans to establish SOPs within the next two
Are SOPs used for any other procedures in the regulatory
If YES, specify:

Assessment Templates

Are there Assessment Templates for reports on the scientific
If NO, are there plans to establish this within the next two
If YES, are these based on another agency’s assessment
If YES, specify on which agency was the assessment template
Is there an SOP for completing an assessment template?
Which elements from the list are included in the agency
Would the agency be open to sharing their assessment
Do you produce an assessment report (AR) following the
If YES, is there an SOP for completing the AR?
What language is the AR prepared in?
Do you share your AR with other regulatory authorities?
Do you put your full AR on the website?
Do you put your abridged AR on the website?
Do sponsors get a copy of the full assessment report?
Do sponsors have any involvement in the preparation of assessment reports?
Do sponsors have any involvement in the comments on the
Do sponsors have any involvement in the translation of
Do sponsors have any involvement in the distribution of

Peer Review

Are external peer reviews carried out when a NAS is
If NO, are there plans to introduce these within the next two
Are internal peer reviews carried out when a NAS is
If NO, are there plans to introduce these within the next two

Others

What are other general procedures in place to monitor the
What other tools does your agency use to build quality into

Reasons for introducing

The three most important reasons for the introduction of

Monitoring to improve quality

Reviewing assessors’ feedback and taking necessary action
Reviewing stakeholders’ feedback (e.g. through complaints,
Using an internal tracking system to monitor (e.g.
Carrying out internal quality audits (e.g. self-assessments)
Having external quality audits by an accredited certification
Having a ‘post approval’ discussion with the sponsor to

Management responsibility for quality

Does the agency have a dedicated department for assessing
and/or ensuring quality in the assessment and registration
If YES, how many staff are involved?
How often do you assess and/or ensure quality in the
To whom does this section report
If NO, is the agency thinking of setting up such a

Improving the quality of applications

Does the agency have official guidelines to assist industry in
If YES, how are these guidelines revised?
If YES, what is the quality of that advice?
What language/s are the guidelines available in

Improving quality through interactions with applicants

Does the agency provide pre-submission scientific advice to
If YES, how is the quality of that advice?
If YES, what is the quality of that advice?
Is the applicant given details of technical staff that can be
Extensive formal contact (including scheduled meetings)
Extensive informal contact (frequent telephone or email
Some formal contact (possibility of meetings)
Some informal contact (possibility of telephone or email
None, or minimal formal contact (rare occurrences of

Scientific Committee Procedures

Name of the Committee
Number of Committee members
How frequently does the Committee meet?
For NAS applications and major line extensions does the

Collaboration with other agencies

Do you have a formal training programme for assessors?
Which methods are used for training assessors
Do your agency mainly develop SOP, Guidelines etc., based
Does your agency conduct shared or joint reviews with other
If YES, specify on which agency was the assessment template
Does your agency seek direct assistance of more

Training

Does the Committee review

Shared and Joint reviews with other Regulatory Agencies outside of your country

Is the agency part of any regional alignment initiatives?
YES, specify
Are bilateral/multilateral information sharing agreements in
If YES, what is the general nature of those agreements?
Does your agency conduct shared or joint reviews with other
If YES, do you have formal measures in place to ensure
If NO, do you anticipate undertaking such reviews within the
Have these joint reviews influenced the way in which your

Transparency

Does your agency have an Internal Quality Policy?
For NAS applications and major line extensions does the
Is the applicant given details of technical staff that can be
Outline the key elements that make up GRevP in the agency
Has the agency formally or informally implemented GRevP?
If YES, title of formal implementation
If YES, date of formal implementation
How has this been implemented?
Are these documents open and available to the public?
Which factors influenced the establishment of the GRevP based on?
If YES, state the name of agency(ies) or international
Are you satisfied with your existing GRevP framework?
If could be improved or unsatisfied, indicate reason(s) that
If you do not have a formal GRevP system in place are there

Transparency to the public

What priority does your agency assign to being open and
Does the Committee review

Transparency to companies on the application progress

Are companies able to follow the progress of their own
Are companies given detailed reasons for rejection of an

Facilities for providing information

Are companies given detailed reasons for rejection of an
Are companies able to follow the progress of their own
Are you satisfied with your existing GRevP framework?
If could be improved or unsatisfied, indicate reason(s) that
If you do not have a formal GRevP system in place are there

Peering Review

Are external peer reviews carried out when a NAS is
If NO, are there plans to introduce these within the next two
Are internal peer reviews carried out when a NAS is
If NO, are there plans to introduce these within the next two

Others

What are other general procedures in place to monitor the
What other tools does your agency use to build quality into

GRevP Concepts in OpERA (n=101)
<table>
<thead>
<tr>
<th>Commonly Implemented GRevP Concepts</th>
<th>no</th>
<th>yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are there SOPs for the guidance of scientific assessors?</td>
<td>2</td>
<td>15</td>
</tr>
<tr>
<td>Are there Assessment Templates to document the scientific review of an NAS?</td>
<td>4</td>
<td>13</td>
</tr>
<tr>
<td>Carrying out internal quality audits (e.g. self-assessments) and using findings to improve the system</td>
<td>4</td>
<td>12</td>
</tr>
<tr>
<td>Using an internal tracking system to monitor the review process (e.g. consistency, timeliness, efficiency and accuracy)</td>
<td>6</td>
<td>11</td>
</tr>
<tr>
<td>Are internal peer reviews carried out when a NAS is assessed?</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>Are there SOPs for the advisory committee consulted during the review process?</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>Does the agency have a dedicated department for assessing and/or ensuring quality in the assessment and registration process?</td>
<td>8</td>
<td>7</td>
</tr>
<tr>
<td>Is there an SOP for completing an assessment template?</td>
<td>9</td>
<td>4</td>
</tr>
<tr>
<td>Are external peer reviews carried out when a NAS is assessed?</td>
<td>13</td>
<td>4</td>
</tr>
<tr>
<td>Decision-Making Concepts</td>
<td>no</td>
<td>yes</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------------------</td>
<td>----</td>
<td>-----</td>
</tr>
<tr>
<td>Does your agency have a framework in place that forms the basis of the decision to approve or reject a New Drug Application (NDA)?</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Are there formal assessments in place to periodically measure the quality of decision-making within your agency for the process to approve/reject an NDA?</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Do you think that your agency’s decision-making process for approving/rejecting an NDA could be improved?</td>
<td></td>
<td>4</td>
</tr>
</tbody>
</table>
Summary: How Can AMA Support NRAs and RRIs in Maximising Regulatory Effectiveness and Efficiency?

- Implementing standard operating procedures for the guidance of assessors in concert with international standards (RevP)
- Using assessment templates to document the review and decision making processes
- Promoting the use of internal quality audits
- Establishing tracking systems for agency and industry activities
- Supporting industry interactions
- Encouraging participation in training workshops

A Decade of regulatory harmonization in Africa: Where are we? Where do we go from here?
Conclusion

These common practices:
support the AMA’s goals to recommend interventions to NRAs and RRIs that will

• help to monitor, evaluate and assess the comprehensiveness of regulatory systems
• continue to build quality into the procedures
• and maximise effectiveness and efficiency
Maximising Regulatory Effectiveness and Efficiency
Through the AMA
Learning from the experience of others

Lawrence Liberti, PhD, RPh, RAC
Head, Regulatory Collaborations
CIRS- Centre for Innovation in Regulatory Science
LLiberti@cirsci.org

A Decade of regulatory harmonization in Africa: Where are we? Where do we go from here?