This publication was prepared by the staff of the African Union Development Agency (AUDA-NEPAD) and PATH with technical support from the Medicines Policy and Regulatory Reforms Technical committee and other external contributions. This document is meant to be used as a training guide on regulatory systems strengthening in Africa for National Medicines Regulatory Authorities (NMRAs, Regional Economic Communities (RECs) and all other stakeholders directly or indirectly working in or able to influence and support regulatory systems at country, regional or continental level.

The designations employed and the presentation of material in this information product do not imply the expression of any opinion whatsoever on the part of AUDA-NEPAD and PATH concerning the legal or development status of any country, territory, city, or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

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<table>
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<tr>
<th>Abbreviation</th>
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<tr>
<td>AMA</td>
<td>African Medicines Agency</td>
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<td>AMRH</td>
<td>African Medicines Regulatory Harmonisation</td>
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<td>API</td>
<td>Active Pharmaceutical Ingredient</td>
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<td>AU</td>
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<td>AU Model Law</td>
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<td>EAC</td>
<td>East Africa Community</td>
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<tr>
<td>GMP</td>
<td>Good Manufacturing Practice</td>
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<td>NMRA Authority</td>
<td>National Medicines Regulatory Authority</td>
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<tr>
<td>PE</td>
<td>Pharmaceutical Excipient</td>
</tr>
<tr>
<td>PMPA</td>
<td>Pharmaceutical Manufacturing Plan for Africa</td>
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<tr>
<td>SADC</td>
<td>Southern African Development Community</td>
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This curriculum is for use in regulatory harmonisation capacity-building workshops in Africa. It is meant to be used with Key Documents that can be found on the AUDA-NEPAD website. In addition, you will find annexes at the back of the curriculum that are needed for the various activities throughout the training. These documents should be printed in advance, or soft copies made available to participants where that is possible.

It is important to emphasise that the training is designed to use all these materials, so potential users should make reference to and apply the full range of materials provided in order to effectively deliver the training.

These materials are designed to increase the capacity of key actors at the country level including members of civil-society organisations, policymakers (including parliamentarians), and journalists – to help advance regulatory harmonisation in Africa. The materials have been used with these groups since June 2019 and have evolved and improved based on feedback and training experiences of past participants. In addition, the regulatory authorities and industry players have been used as resource persons. The materials have been modified and expanded over time to improve the quality of delivery of the workshops. To this end, the curriculum includes more detailed facilitator notes, outline of learning objectives for the various sessions and tasks, and case studies and advocacy points to elicit discussions among participants.

With proper acknowledgement, these materials are for free use by anyone who is committed to improving the capacity of African citizens and oversight bodies to advance regulatory harmonisation across the continent.
Definition of concepts

**HARMONISATION**
Means alignment or adjustment of differences and inconsistencies among different laws, regulations, methods, procedures, schedules, specifications, or systems of National Medical Products Regulatory Agencies/Authorities.

**INSTITUTIONAL REVIEW BOARD**
An independent body comprising medical, scientific, and nonscientific members whose responsibility is to ensure the protection of the rights, safety, and well-being of human subjects involved in a clinical trial. Duties include reviewing and approving trial protocols and amendments as well as methods and materials for obtaining and documenting informed consent of trial subjects.

**MARKET**
Includes a variety of systems, institutions, procedures, social relations and infrastructures for medical products sale, and barter or exchange or supply or dispose of to a person.

**MEDICAL PRODUCTS**
Include medicines, vaccines, diagnostics and medical devices.

**MEDICINE**
Means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in: – a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in humans; or b) restoring, correcting or modifying any somatic or psychic or organic function in humans, and includes any veterinary medicine.

**NATIONAL REGULATORY AUTHORITY**
The national agency responsible for authorising and monitoring a clinical trial taking place in its country. Some of these agencies, National Medicines Regulatory Authorities (NMRA), are also responsible for the regulation and control of medical products such as medicines, vaccines, blood products, and medical devices. NMRA also combat substandard and falsified medicines, as called for by the World Health Assembly.

**REGIONAL ECONOMIC COMMUNITIES (RECS)**
Regional groupings of African states that facilitate economic integration between members of the individual regions and through the wider African Economic Community.

**REGULATORY AUTHORITIES**
Bodies having the power to regulate. In the International Conference on Harmonisation Good Clinical Practice guideline, regulatory authorities include authorities that review submitted clinical data and those that conduct inspections. These bodies are sometimes referred to as competent authorities.

**REGULATORY CONVERGENCE**
A process whereby regulatory requirements across countries or regions become more similar or “aligned” over time as a result of the gradual adoption of internationally recognised technical guidance documents, standards, and scientific principles; common or similar practices and procedures; or adoption of regulatory mechanisms that might be specific to a local legal context but that align with shared principles to achieve a common public health goal.

**REGULATORY HARMONISATION**
The processes by which technical guidelines are developed to be uniform across participating authorities.

Aims and objectives of the training

This curriculum aims to enhance the capacity and skills of a range of key stakeholders in medical products regulatory harmonisation to advocate for the safety and quality of medicines and medical products in Africa. The objectives include:

2. Build the capacity of stakeholders to understand key regulatory harmonisation frameworks.
3. Develop advocacy strategies to accelerate regulatory strengthening and support harmonisation.
4. Equip participants to play a greater role in advocacy and accountability for medical products regulatory harmonisation.
5. Advocate for ratification of the AMA Treaty.

(See also the “Facilitator’s guide” section, STEP 3.)

Training duration and methods

This curriculum is designed to be used in a three-day workshop that applies integrated and interactive teaching and learning approaches. The methodology includes presentations on topical issues, open question-and-answer sessions, brainstorming and small group exercises, case presentations, and interactive discussions on each topic. In some instances, and depending on the training location, a field visit to a relevant agency such as a National Medicines Regulatory Authority (NMRA) or a research and product development institution may be integrated into the training program.

At the end of each training, participants will be required to develop action plans that will guide their activities and engagements in regulatory harmonisation promotion as well as policy advocacy in their respective countries and areas of work.

Training participants

This curriculum is designed for stakeholders whose roles could contribute greatly to promoting and strengthening regulatory harmonisation for medical products, yet under normal circumstances they would not speak about the safety and quality of medicines and medical products for realisation of quality and equity to health care. It will be of specific interest to civil-society advocates, the media, and policymakers, including parliamentarians. National Medicines Regulatory Authorities (NMRAs) and industry associations will be part of these trainings as technical resource persons.

Participants may be drawn from any or a mix of the target groups listed above. Participants will usually bring useful knowledge and experiences of their own that will enrich the training. It is expected that upon completing the training, participants will use the knowledge acquired to champion the need for stronger regulatory harmonisation and how this affects every citizen’s life.
Overview of curriculum modules and course content

The curriculum is organised into five modules, including a session on action planning. For each module, a summary is provided, as well as learning outcomes and topic content drawn from resource materials such as literature reviews, policy documents, and case studies. In addition, key policy gaps and potential advocacy issues will be drawn under each module, providing a basis for participants to develop their advocacy priorities and broader action plans. The five modules include:

**Module 1: Understanding regulation of medical products**

Introduces the concept of medical products regulation, rationale for regulation, falsified and substandard medicines and associated risks, and existing legislative and regulatory frameworks and systems, including their set up and application at country level.

**Module 2: Pre- and post-market levels of medical products regulation**

Introduces participants to the concept of pre- and post-market levels of medical products regulation and the impact on health systems.

**Module 3: Regulatory harmonisation**

Provides an understanding of key regulatory harmonisation frameworks, including the AU Model Law and the AMA Treaty, and the importance of regulatory harmonisation in improving health and socioeconomic outcomes. The module also examines the various initiatives that have been established to improve regulatory harmonisation in the region, including their performance and challenges.

**Module 4: Assessing progress and implementation of regulatory harmonisation**

Equips participants with knowledge and skills to effectively assess progress in regulatory harmonisation and prepares participants to maximise their influencing opportunities and expertise to engage in advocacy and accountability for accelerating regulatory harmonisation. The session includes a discussion of developments in health technologies and the need for regulatory systems to adapt in order to test the efficacy and safety of new medical products.

**Module 5: Advocacy**

Enables participants to understand their role as advocates and builds their skills for effective advocacy to accelerate regulatory harmonisation. Participants will develop action plans for taking forward learnings from the workshop, particularly with regard to identified actions and advocacy priorities they will pursue in their respective contexts.
Structure of the training curriculum

The training curriculum has five modules, each with one to three sessions, as listed below:

<table>
<thead>
<tr>
<th>MODULE AND SESSION</th>
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<td>Session 2</td>
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<td>Session 1</td>
<td>Introduction to regulatory harmonisation</td>
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<tr>
<td>Session 2</td>
<td>Continental frameworks and systems for regulatory harmonisation</td>
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<td></td>
<td>- Africa Union (AU) Model Law</td>
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<td>- Case study</td>
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<td>- African Medicines Agency (AMA)</td>
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<td>- Pharmaceutical Manufacturing Plan for Africa (PMPA)</td>
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<td>- Case study</td>
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<td>- African Medicines Regulatory Harmonisation (AMRH)</td>
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<td>- National Medicines Regulatory Authorities (NMRAs)</td>
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<td>- Case study</td>
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<tr>
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Training resources

The training will use a variety of resources, including PowerPoint slide sets, policy documents such as the AU Model Law and the African Medicines Agency Legal Framework, handouts, and links to other reference materials. However, the training duration, methods, activities, and tools presented are only a guide and should be adapted to each setting to ensure effective delivery of the training.

Training evaluation

A pretest will be administered to all participants prior to the training to assess their levels of knowledge on key concepts and topics, as well as experience in the area of medical products regulation. This will guide the facilitators in focusing and tailoring the standard training content to suit the needs of participants.

To gauge the effectiveness of the training in imparting knowledge, a post-test will be administered at the end of the training, and the outcome will be compared with the pretest. In addition, participants will provide feedback via a questionnaire to evaluate the training in terms of their satisfaction with the mode of delivery, relevance and adequacy of content, and ease of achieving learning outcomes.

EACH MODULE OUTLINES THE FOLLOWING ELEMENTS:

1. Purpose
2. Learning outcomes
3. Training tools and teaching aids
4. Facilitators instructions
5. Outline of the content
6. Case studies (on specific sessions)
This guide is designed to assist facilitators in leading the workshop. Facilitators should familiarise themselves with the structure of the sessions in advance and either encourage participants to come with laptops or organise for computers to minimise the need for printed materials.

### Necessary materials

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<th>Item</th>
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<td>Laptop</td>
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<td>LCD projector</td>
<td>✔</td>
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<tr>
<td>Screen</td>
<td>✔</td>
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<tr>
<td>PowerPoint slide set</td>
<td>✔</td>
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<tr>
<td>Flip charts, easels, tape</td>
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<tr>
<td>Colored markers</td>
<td>✔</td>
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<tr>
<td>Index cards</td>
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<tr>
<td>Name tags/name placards</td>
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<tr>
<td>Participants packets</td>
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<tr>
<td>Attendance log</td>
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<tr>
<td>Agenda</td>
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### Venue set-up

Set out an attendance log for participants to sign when they arrive.

Arrange tables and place participant packets at seats.

Load the slides.

Label one flip chart with the heading “Ground Rules” and another flip chart with the heading “Parking Lot.”

Post both flip charts in a visible location.
## Tips to an effective workshop

1. Ensure you have all the resources needed (handouts, flipchart paper, etc.) before undertaking any module, task, or session.

2. In undertaking tasks that require formation of small groups, five to seven people per group is recommended depending on the number of participants and the space being utilised.

3. Ensure that where there are group tasks, each group appoints someone to present the group’s findings.

4. Familiarise yourself in advance with the training resources and methodology.

5. Ensure the participants are aware of the learning outcomes for each module, the objectives for each session, and the tasks before beginning any activity.

6. Always ensure you understand the key takeaways from a session before undertaking it.

7. Where a discussion naturally leads into the next task or question, it is best to allow this to flow and not force the next task or question simply to follow the structure. Encourage discussion if it is focused on the matters at hand.
How to start a workshop

**STEP 1**

Welcome participants to the workshop

- Welcome participants.
- Briefly describe the background and purpose of the workshop.
- Introduce the facilitators and other staff.

**STEP 2**

Participant introductions

- Ask participants to partner with the person next to them or, if they know that person, with someone they don’t already know or don’t usually work with, and briefly share:
  - Their name.
  - The work they do in their organisation.
  - (Optional: Their favorite interest, activity, or hobby outside of work.)
  - Why they are attending this workshop and what they hope to learn.
- After a few minutes, draw participants’ attention back to the larger plenary gathering. Invite each participant to introduce his or her partner and state their partner’s expectation for the workshop.
- Write up each participant’s learning expectation for the workshop on a piece of flipchart paper, so that there is a full list of expectations. Hang this on the wall in the workshop venue.

**STEP 3**

Give an overview of the workshop

Review the workshop objectives and why they are important. To manage expectations, discuss how their learning expectations may or may not overlap with the objectives.

Assure participants that this will be an active workshop! Each session will include discussion, demonstrations, exercises, and small group work. Explain that the workshop is intended to be participatory, with open discussion and debate.

Distribute copies of the training materials, as necessary, to everyone in the group. Explain that it contains the information they will need during the training.

Briefly highlight the structure of the workshop, which appears on pages 5 to 6 of this curriculum as well as Annex 7.
This three-day workshop aims to enhance the capacity and skills of a range of key stakeholders in medicines and medical products harmonisation to:

- Support the acceleration, adoption, and convergence of the AU Model Law with the aim of strengthening regulatory harmonisation in the Africa Region.
- Build the capacity of countries and their key stakeholders to understand key regulatory harmonisation frameworks, including the AU Model Law, AMA, and the importance of regulatory harmonisation in improving health and socioeconomic outcomes.
- Develop advocacy strategies to accelerate regional regulatory strengthening and support harmonisation initiatives.
- Play a greater role in advocacy and accountability for medicines and medical products regulation and regulatory harmonisation at country and regional level.

**Review the agenda.** Emphasise that facilitators will be both mindful and flexible regarding the schedule. Highlight start and end times and breaks. Explain that participants are expected to attend the entire workshop.

**Review content of the participant packets.** Remind participants to bring their materials with them each day.

**Set the ground rules.** Invite participants to suggest a list of ground rules (norms) for working together. Record responses on the “Ground Rules” flip chart. Ideas could include:

- Start on time.
- No phones or laptops during discussions.
- Have fun!

**Respect all viewpoints.**

**Ask questions when confused.**

**Everyone participates.**

This list of ground rules should be posted on a wall in the workshop venue. A polite reminder may be made at the beginning of any session or module as necessary.

**Explain the role of the “Parking Lot” flip chart.** A Parking Lot is a tool to capture ideas or issues that arise but can’t be addressed at the moment. Encourage participants to write questions or topics there during breaks.

**Review workshop logistics** (e.g., restrooms, emergency exits, meals, etc.).

**Definitions**

Explain that we will start with some key definitions (page 2) and by exploring the concept of “regulation of medical products.”
1 Understanding regulation of medical products

PURPOSE
To introduce the concept of medical products regulation; rationale for regulation; falsified and substandard medicines and associated risks.

LEARNING OUTCOMES
At the end of the module, the participants should be able to:
» Explain regulation of medical products and related key concepts.
» Explain the context and rationale for regulation of medical products.
» Understand and differentiate falsified and substandard medicines and their associated risks.

TRAINING TOOLS AND TEACHING AIDS
» PowerPoint slides.
» Questions and answers.
» Interactive discussions.

FACILITATORS INSTRUCTIONS
1 The module content is in Annex 2.
2 Start by asking an open-ended question to participants on their understanding of medical products regulations.
3 After participants have provided their feedback, take them through the presentation on “Understanding regulation of medical products.”
4 Make the sessions as interactive as possible and ensure that participants provide their own country experiences to enhance group learning.
5 Provide specific examples while making the presentations.
MODULE 1 – SESSION 1
Introduction to regulation of medical products

The facilitator may start by asking an open-ended question to participants on their understanding of regulations, why it is important, and the associated risks of lack of or poor regulation of medical products. This will then be followed by a presentation and participatory discussions.

OUTLINE OF MODULE 1 – SESSION 1 CONTENT

Introduction to regulation of medical products
- Overview of key concepts and terminologies.
- What is medical products regulation?
- How are medical products regulated?
- Who regulates medical products?
- Why is regulation of medical products important?

MODULE 1 – SESSION 2
Falsified and substandard medicines

The facilitator may start by establishing participants understanding of the difference between falsified and substandard medicines and the associated risks. This will then be followed by a presentation and participatory discussions.

OUTLINE OF MODULE 1 – SESSION 2 CONTENT

Understanding falsified and substandard medicines
- To comprehend the difference between substandard and falsified medicines.
- To be cognisant of the various entry paths of these products into the public domain.
- To comprehend and evaluate the health implications.
- To comprehend and evaluate economic implications.
Pre- and post-market levels of medical products regulation

PURPOSE
To increase participants’ understanding of pre- and post-market levels of medical products regulation and its impact on health systems.

LEARNING OUTCOMES
At the end of the module, the participants should be able to:
» Outline the levels of medical products regulation.
» Describe the impact of pre- and post-market levels of medical products regulation on the health system.

TRAINING TOOLS AND TEACHING AIDS
» PowerPoint slides.
» Questions and answers.
» Interactive discussions.

FACILITATORS INSTRUCTIONS
1. The module content is in Annex 2.
2. Start by asking an open-ended question to participants on their understanding of medical products regulations.
3. After participants have provided their feedback, take them through the presentation on the two levels of medical products regulation.
4. Make the sessions as interactive as possible and ensure that participants provide their own country experiences to enhance group learning.
5. Provide specific examples while making the presentations.
MODULE 2 – SESSION 1
Understanding pre- and post-market levels of medical products regulation

The facilitator may start by asking what participants understand by pre- and post-market regulations. This will then be followed by a presentation and participatory discussions:

OUTLINE OF MODULE 2 – SESSION 1 CONTENT

Understanding pre- and post-market levels of medical products regulation
- Pre-market regulation.
- Post-market regulation.
- Impact of pre- and post-market levels of medical products regulation on health system.
3 Regulatory harmonisation

PURPOSE
To increase participants’ understanding of key regulatory harmonisation frameworks, including the AU Model Law, and the importance of regulatory harmonisation in improving health and socioeconomic outcomes. The module will also examine the various initiatives that have been established to improve regulatory harmonisation in the region, including their performance and challenges.

LEARNING OUTCOMES
At the end of the module, the participants should be able to:
» Explain regulatory harmonisation and its aims.
» Describe the benefits of regulatory harmonisation.
» Describe the continental frameworks and systems for regulatory harmonisation and their achievements.
» Understand current regulatory harmonisation challenges as well as corresponding actions and advocacy priorities.

TRAINING TOOLS AND TEACHING AIDS
» PowerPoint slides.
» Questions and answers.
» Interactive discussions.
» Case studies.
» Group exercise.
» Reading resources.

FACILITATORS INSTRUCTIONS
1. The module content is in Annex 3.
2. Start the facilitation by explaining what regulatory harmonisation is, its aims, and why harmonisation is important.
3. Make the sessions as interactive as possible and ensure that participants provide their own country experiences to enhance group learning.
4. Provide specific examples while making the presentations.
MODULE 3 – SESSION 1
Introduction to regulatory harmonisation

The facilitator starts by introducing the concept of regulatory harmonisation, providing a background on the importance of regulatory harmonisation. The facilitator needs to emphasise the linkage between strong regulatory systems and improved health and socioeconomic outcomes. This will then be followed by a presentation and participatory discussions:

OUTLINE OF MODULE 3 – SESSION 1 CONTENT

- Explain regulatory harmonisation and its aims.
- Describe the benefits of regulatory harmonisation.
- Describe the frameworks and systems for regulatory harmonisation and their achievements.
- Understand current regulatory harmonisation challenges as well as corresponding actions and advocacy priorities.

MODULE 3 – SESSION 2
Continental frameworks and systems for regulatory harmonisation

The facilitator will present the continental frameworks, their importance, how they are interlinked, and their implications at continental, regional, and national levels.

OUTLINE OF MODULE 3 – SESSION 2 CONTENT

Understanding continental frameworks and systems for regulatory harmonisation

- Africa Union (AU) Model Law
- African Medicines Agency (AMA)
- Pharmaceutical Manufacturing Plan for Africa (PMPA)
- African Medicines Regulatory Harmonisation (AMRH)
- National Medicines Regulatory Authorities (NMRAs)
- Regional Economic Communities
- Case study(ies)
  Case study to be given by representatives of NMRAs or industry: Key topical areas include marketing authorisation, licensing of manufacturing establishments, import and export control, inspection of manufacturing premises and distribution channels, and market surveillance (product quality monitoring, pharmacovigilance, and post-market surveillance. The case study should highlight best practices and lessons learnt.
MODULE 3 – SESSION 3

Regulatory harmonisation challenges and advocacy priorities

The facilitator will present the challenges in regulatory capacity and harmonisation in Africa. The facilitator should then open a discussion for members to bring out the advocacy opportunities from the challenges discussed. Participants go into country groups and document on flip charts the emerging advocacy issues and opportunities.

OUTLINE OF MODULE 3 – SESSION 3 CONTENT

Understanding continental frameworks and systems for regulatory harmonisation

- Challenges in regulatory capacity and harmonisation in Africa.
- Advocacy opportunities.
- Group exercise: After completing presentations for module 1 to 3, the facilitator will ask participants to be in groups of between 8 to 10 depending on the number of participants. They will be asked to come up with a 5-minute video inform of a kit that elaborates the impact of falsified and substandard medicines. In the video they should be able to highlight, gaps that exist at community level in understanding impact of SF medical products, regulatory harmonisation systems at country level, mitigation measures available. Encourage participant to be creative in coming up with the video skit. They may use their phones to capture the video. Participants have 30 – 45 minutes to develop the video skit and another 15-30minutes to present the video and get feedback.
Assessing progress and implementation of regulatory harmonisation

PURPOSE
To equip participants with the skills to effectively assess progress in regulatory harmonisation, engage in advocacy and accountability for accelerating regulatory harmonisation, and maximise their influencing opportunities and expertise. The session will also discuss developments in medicines and technologies and the need for regulatory systems to adapt in order to be able to test the efficacy and safety of new therapies, medicines, and diagnostics.

LEARNING OUTCOMES
At the end of the module, the participants will:
» Outline indicators for assessing progress.
» Understand implementation for regulatory harmonisation.
» Discuss new developments in global health technologies, and their implications for the regulation of medical products.
» Discuss capacities of regulatory systems to respond to emerging issues and identify advocacy priorities.

TRAINING TOOLS AND TEACHING AIDS
» PowerPoint slides.
» Questions and answers.
» Interactive discussions.
» Reading resources.

FACILITATORS INSTRUCTIONS
1. The module content is in Annex 4.
2. Open up a discussion on emerging issues and new developments in global health technologies and their implications on regulation.
MODULE 4 – SESSION 1
Assessing progress and implementation

The facilitator will present the existing indicators and mechanisms for implementation and will open up a discussion to identify gaps and opportunities.

OUTLINE OF MODULE 4 – SESSION 1 CONTENT

Understanding continental frameworks and systems for regulatory harmonisation
- Indicators for assessing progress.

MODULE 4 – SESSION 2
New developments in global health technologies

The facilitator will open up a discussion on emerging issues and new developments in global health technologies and their implications on regulation and advocacy priorities.

OUTLINE OF MODULE 4 – SESSION 2 CONTENT

- Discuss new developments in global health technologies and their implications on regulation of medical products.
- Discuss capacities of regulatory systems to respond to emerging issues and identify advocacy priorities.

Conclude by emphasising that:
- Regulation of medical products will never remain static, given the advances in medicines and health technologies globally.
- NMRAs need to keep up with developments in the medical field in order to be able to test the efficacy and safety of new therapies, medicines, and diagnostics.
- New developments in medicines include therapies such as biologics, stem cell therapy (regenerative medicine), chimeric antigen receptor T-cell therapy, and monoclonal antibodies.
- New diagnostics are being developed for tuberculosis, HIV, hepatitis, cancer, and other diseases.
- This session creates opportunities for the training to keep up with emerging issues in regulation and regulatory harmonisation.
5 Advocacy

**PURPOSE**

To enable participants to understand their role as advocates and equip them with skills for effective advocacy in accelerating regulatory harmonisation, using a 10-part advocacy framework. Participants will identify advocacy priorities in their countries and start to think of advocacy activities they can share with their stakeholders and implement after the workshop. The session will also be used to discuss and identify advocacy capacity needs among participants and the required actions to address them.

**LEARNING OUTCOMES**

At the end of the module, the participants will:

» Understand advocacy and why it is important.
» Understand their roles as advocates.
» Improve their skills as an advocate.
» Understand the 10 steps of advocacy and how to apply them.
» Identify advocacy priorities in their contexts and map out strategies and tactics to effectively drive their advocacy agenda.
» Identify advocacy capacity-building needs/gaps and draw necessary actions to address them.
» Develop action plans for taking forward learning from the workshop.

**SESSION 1: TRAINING TOOLS AND TEACHING AIDS**

» PowerPoint slides.
» Questions and answers.
» Interactive discussions.
» Reading resources.

**SESSION 2: TRAINING TOOLS AND TEACHING AIDS**

» Flip charts.
» Markers.
» Participant laptops.
Advocacy continued

The module content is in Annex 5.

Use the prepared slides to relay the primary content. Facilitators can also use flip charts frequently to record brainstormed ideas, demonstrate examples, or work through group activities.

Facilitators are welcome to add, delete, or update slides as needed to make the slides more appropriate for the participants’ interests.

Setting the scene

While this session will discuss a menu of advocacy steps, strategies, tactics, and tools, it does not and cannot capture all the potential ways to advocate for regulatory harmonisation.

It is important to keep in mind that the most successful advocacy strategies are heavily tailored to reach a specific audience.

As such, participants are encouraged to use the learning from the workshop as a springboard to develop content and tactics that will resonate within their own contexts.
MODULE 5 – SESSION 1
Integrating advocacy into regulatory harmonisation

The facilitator may start by asking, “Which words come to mind when you hear ‘advocacy’?” They may take a few examples of participants’ experiences in medical products regulation advocacy. The facilitator will then present the 10 steps of advocacy, explain the role of the participants in advocacy, and engage participants in mapping out strategies and tactics to effectively drive their advocacy agenda.

MODULE 5 – SESSION 1: IN-DEPTH UNDERSTANDING OF ADVOCACY

- What is policy advocacy?
- The 10 steps of advocacy.
- Roles of advocates.
- Regulatory harmonisation advocacy priorities per country.
- Identify advocacy capacity-building needs/gaps and draw necessary actions to address them.

MODULE 5 – SESSION 2
Action planning

Under the guidance of the facilitator, participants work in small groups to draw their action plans, followed by a plenary presentation and discussion.

OUTLINE OF MODULE 5 – SESSION 2: CONTENT

At the end of the session, participants will:
- Have draft action plans for taking forward the learning and advocacy actions.
- Have clarity on the next steps they will take to implement their action plans.

ACTIVITIES

Facilitators are encouraged to guide this session as needed based on the composition of the participants. Facilitators will share a template that participants can use to record their action plans either on flipcharts or on their laptops depending on their preferences.
PURPOSE

To assess the effectiveness of the workshop through a post-training questionnaire and provide participants with an opportunity to share feedback on all aspects of the training, to inform any future improvements. Participants will be awarded certificates of completion by the organising agency.

» Training tools and teaching aids Post-training evaluation forms (consider using digital survey technology such as Mentimeter).

» Signed certificates of participation.

ACTIVITIES

» Distribute copies of the final evaluation. Allow time for participants to complete it. (This can be done electronically through Mentimeter).

» Present certificates of completion to each workshop participant.

» Invite closing remarks from participants, facilitators, or others and conclude the workshop.

» Thank the participants for their attendance and active participation and wish them well in their advocacy efforts.
Understanding regulation of medical products

Introduction to regulation of medical products

**WHAT IS MEDICAL PRODUCTS REGULATION?**

- Effective medical products regulation promotes and protects public health by ensuring that:
  - Medical products are of the required quality, safety, and efficacy.
  - Medical products are appropriately manufactured, stored, distributed, and dispensed.
  - Illegal manufacturing and trade are detected and adequately sanctioned.
  - Health professionals and patients have the necessary information to enable them to use medicines rationally.
  - Promotion and advertising are fair, balanced, and aimed at rational drug use.
  - Access to medical products is not hindered by unjustified regulatory work.

**HOW ARE MEDICAL PRODUCTS REGULATED?**

- Medical products regulations are a mandate of the National Medicines Regulatory Authority (NMRA) of each country, often under the Ministry of Health.
- NMRA regulate the safety and effectiveness of drugs sold in the country. Medicine and medical products regulation is divided into two phases.
- The preapproval (pre-market) phase. This is when the NMRA reviews manufacturer applications to market drugs in the country. A drug may not be sold unless it has NMRA approval.
- The post-approval (post-market) phase. Once a drug is on the market, the NMRA continues its oversight of drug safety and effectiveness. This phase lasts for as long as the drug is sold.
<table>
<thead>
<tr>
<th><strong>WHO</strong></th>
<th><strong>WHY</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WHO REGULATES MEDICAL PRODUCTS?</strong></td>
<td><strong>WHY IS REGULATION OF MEDICAL PRODUCTS IMPORTANT?</strong></td>
</tr>
<tr>
<td>- National governments are responsible for establishing strong NMRAs with a clear mission; solid legal basis; realistic objectives; appropriate organisational structure; adequate number of qualified staff; sustainable financing; access to up-to-date, evidence-based technical literature, equipment, and information; and the capacity to exert effective market control.</td>
<td>- To ensure the safety, efficacy, and quality of medical products.</td>
</tr>
<tr>
<td>- The role of the World Health Organisation in medical products regulatory support is two-fold. One aspect relates to the development of internationally recognised norms, standards, and guidelines. The other aspect relates to providing guidance, technical assistance, and training to enable countries to implement global guidelines to meet their specific needs.</td>
<td>- or quality assurance along the manufacturing, storage, distribution, and dispensing chain.</td>
</tr>
<tr>
<td>- The successful regulation of medical products is based on fruitful collaboration with the World Health Organisation, other UN agencies, NMRAs, international development agencies and institutions, nongovernmental organisations, national and international pharmaceutical manufacturers associations, health professionals, consumers, and experts.</td>
<td>- For regulation of manufacture, distribution, and dispensing of generic medicines being manufactured locally.</td>
</tr>
<tr>
<td>- To ensure safe conduct of clinical trials that involve human subjects.</td>
<td>- To ensure safe conduct of clinical trials that involve human subjects.</td>
</tr>
<tr>
<td>- To detect fake, substandard, and counterfeit medicines and prevent them from being sold, distributed, or dispensed.</td>
<td>- To detect fake, substandard, and counterfeit medicines and prevent them from being sold, distributed, or dispensed.</td>
</tr>
<tr>
<td>- To track and respond to cases of adverse reactions to medical products.</td>
<td>- To track and respond to cases of adverse reactions to medical products.</td>
</tr>
<tr>
<td>- The reduce the impact of falsified, substandard, and unregistered medical products.</td>
<td>- The reduce the impact of falsified, substandard, and unregistered medical products.</td>
</tr>
</tbody>
</table>
Falsified and substandard medicines

Substandard and falsified medicines are a grave issue and challenge for the pharmaceutical and health care industries (see Figure 1 for a graphical overview). When substandard and falsified pharmaceutical products are discovered on the market, a rapid response is required to ensure patient safety and product reputation.

DEFINITIONS

Substandard medicines

Also termed “out of specification”, these are authorised medical products that fail to comply with their own quality standards, their specifications, or both. Additionally, unregistered and unlicensed medical products that have not undergone evaluation and/or approval by the national or regional regulatory authorities for the market in which they are marketed, distributed, or used, subject to permitted conditions under national or regional regulation and legislation.

Falsified medicines

Medical products that deliberately or fraudulently misrepresent their identity, composition, or source.

Example: A pack states that each capsule contains 500 mg of paracetamol; however, on testing, the capsules can be found to contain only 50 mg of paracetamol.

This image is just an example. At no point was this medicine tested by the author of this curriculum. Source: https://www.indiamart.com/proddetail/paracetamol-tablets.
Entry pathway of substandard and falsified medicines

Due to porous borders, including untrained border staff, and the complexity of medical supply chains, it is relatively easy for medical products to enter into the public domain. This is a global issue and does not only affect the African continent.

This complex system, as illustrated in Figure 2, consists of a high turnover of pharmaceutical products crossing various interfaces, thereby creating a vast opportunity for errors, corrupt distribution practices, and unethical activities.

**Example:** The medicines trade is on a global scale, such that an active pharmaceutical ingredient (API) and pharmaceutical excipient (PE) for a medicine can be produced in countries A and B, respectively. A manufacturer in country C imports the API and PE from these sources and uses the ingredients to manufactures tablets. The tablets are then packaged in foil imported from country W and a carton that was designed in country Z. The final product is then sold and distributed in countries W and Y.

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**Figure 2:** Entry pathway of substandard and falsified medicines.

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Substandard and falsified medicines are difficult to identify in the supply chain, as identification would require sensitive scientific equipment and relevant proficiency. An unscrupulous person can take advantage of various points in the supply chain by:

- Manufacturing or distributing medicines that contain substandard amounts of the active ingredient.
- Manufacturing or distributing fake products that bear detailed visual similarities to the real product in terms of dimensions and color.
- Mislabeling the brand name of a medicine.
- Mislabeling the expiration date or selling expired medicines.
- Removing medicines from their original packaging and replacing them with substandard or falsified substitutes.
- Recirculating batches of medicines that failed one or more tests and should have been destroyed or otherwise properly disposed of.
- Improperly storing the medicines, usually at elevated temperature and humidity, which may accelerate the decay of the active ingredient.

Falsified medical products are manufactured around the world. Successful operations have been undertaken against manufacturers of substandard and falsified medical products, either large-scale manufacturing or small, back-street operations. With the availability of tableting machines, ovens, and specialised equipment, ingredients, and packaging materials, clandestine manufacturing facilities are quick and easy to assemble.

<table>
<thead>
<tr>
<th>TYPE OF PRODUCT</th>
<th>NUMBER OF MEMBER STATES REPORTING</th>
<th>TOTAL NO. OF PRODUCT REPORTS</th>
<th>PERCENTAGE OF ALL PRODUCTS REPORTED TO DATABASE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaesthetics and painkillers</td>
<td>29</td>
<td>126</td>
<td>8.5</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>46</td>
<td>244</td>
<td>16.9</td>
</tr>
<tr>
<td>Contraception and fertility treatments</td>
<td>19</td>
<td>100</td>
<td>6.8</td>
</tr>
<tr>
<td>Diabetes medicines</td>
<td>19</td>
<td>29</td>
<td>2.0</td>
</tr>
<tr>
<td>Heart medicines</td>
<td>7</td>
<td>11</td>
<td>0.8</td>
</tr>
<tr>
<td>HIV/hepatitis medicines</td>
<td>22</td>
<td>75</td>
<td>5.1</td>
</tr>
<tr>
<td>Lifestyle products b</td>
<td>9</td>
<td>43</td>
<td>2.9</td>
</tr>
<tr>
<td>Malaria medicines</td>
<td>37</td>
<td>124</td>
<td>8.5</td>
</tr>
<tr>
<td>Mental health medicines</td>
<td>26</td>
<td>286</td>
<td>19.6</td>
</tr>
<tr>
<td>Vaccines</td>
<td>19</td>
<td>45</td>
<td>3.1</td>
</tr>
</tbody>
</table>

The highest amount of substandard and falsified medicines is noted for antimalarial medicines followed by antibiotics, and analgesics/anesthetics.

Figure 3: Substandard and falsified medicines reported to World Health Organisation Global Management System.
Other causative factors contributing to substandard and falsified medicines

- **Limited access** to affordable, quality medicines due to severe shortages and increased demand. Some products are very expensive and hence prone to being falsified.

- **Ineffective technical capacity**, inadequate repertoire of tools and technological capacity to ensure Good Manufacturing Practice (GMP) and Good Distribution Practice.

- **Inadequate governance**, poor standardisation, and absence of a supporting regulatory framework along with severe corruption permeating both the private and public health sector.

The penetration of substandard and falsified medicines into a supply chain can lead to disastrous health and economic outcomes.

### Health implications

Circulation of substandard and falsified medical products affects patients and health institutions directly, but also poses a global threat.

**Patients and individuals**

- Medicine does not cure but rather extends illness, affecting the patient emotionally and physically.

- Medicine may have unknown and unpresented adverse effects.

- Medicine may cause additional damage to patient.

- Medicine may strengthen the disease when it develops a tolerance against the active ingredient.

- Medicine may lead to death of the patient.

**Health institutions**

- Medical staff spend a great deal of time treating a disease using various alternatives, while being unaware that the products are not of the right composition, quality, efficacy, and safety.

- Prolonged exposure leads to loss of confidence in medicines, health care providers, and health systems.

**Global health**

- Falsified antibiotics and vaccines may lead to a higher tolerance of a virus or bacteria towards a certain treatment or even the mutation of the virus or bacteria. The mutation can be then spread globally with its unaware travelling host.
Economic implications

Burden on the health system
One of the burdens of substandard pharmaceuticals is the impact on public health. Of the 1 million malaria deaths that occur globally each year, 200,000 are reportedly a consequence of substandard or falsified antimalarial drugs.

Burden on economy
Malaria is estimated to cost African nations at least $12 billion annually in lost economic output.

Negative impact on sales revenue
The procurement of counterfeit drugs takes away from the purchase of legitimate drugs.

A 2009 United Nations report on substandard and falsified medicines found sales of 45 million counterfeit antimalarial medicines resulted in revenues for their providers of $438 million, more than the GDP of a Guinea Bissau.⁵ Another report stated that substandard or falsified drugs represented up to 40 percent of drugs sold; approximately $130 million annually.⁶

Loss of tax revenues
Counterfeit goods, including pharmaceuticals, have resulted in hundreds of millions of dollars in lost tax revenue throughout the African continent.

Reports indicate losses amounting to millions in unpaid taxes as a result of substandard pharmaceutical products.⁷

This lost revenue could be ploughed back into the national economy to build required infrastructures, improve public services, etc.

Determent of foreign investments
Economic analyses by the Organisation for Economic Co-operation and Development indicate that direct investment from developed countries such as Germany, Japan, and the United States is relatively higher in economies with lower rates of counterfeiting and that pharmaceutical multinationals are less likely to invest in countries where they are more likely to have their products copied. This is an issue that results in economic and job losses, causing increased demand for cheaper but less effective or ineffective substandard products and exacerbating public health problems.

Contending with substandard / falsified medicines incurs large costs
Replacing substandard medical equipment and drugs, resupplying government stores and institutions, and fixing the damage caused by counterfeit goods also incurs costs.

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TEST YOUR KNOWLEDGE

1. What is the definition of falsified medicine?
2. What is the definition of substandard medicine?
3. How easy is it to differentiate substandard/falsified pharmaceuticals/products from the original products?
4. What are some ways that substandard and falsified medicines infiltrate the supply chain?
5. Which medicine category accumulated the highest amount of substandard medicines as reported to World Health Organisation Global Management System?
6. What are the health implications of substandard and falsified medicines?
7. What are the economic implications of substandard and falsified medicines?
8. What are the causative factors contributing to substandard and falsified medicines?

REFLECTIVE LEARNING

- What is your view on the health and economic implication of these products? Prior to this workshop, were you aware of these implications?
- Do you think there are implications other than those mentioned or highlighted? If yes, state them.
- What can you do to create the awareness of these products when you need to purchase them for yourself, family, and friends?
Understanding pre- and post-market levels of medical products regulation

Registration of medicines is at the center of the medical products regulatory function. It involves the pre-market assessment of data submitted by applicants to establish the compliance of products with standards of quality, safety, and efficacy. The clear presentation of technical requirements for registration is important for effective enforcement, as it gives NMRAs the power to refuse registration or to remove products from registers. Regulatory systems for medical devices have an important role in supporting market access to technological innovations while duly protecting public health. In order to meet this aim, robust pre-market assessment and post-market vigilance are required.
Pre-market regulation

Pre-market approval is the NMRA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. A pre-market approval application is the most stringent type of device marketing application required by NMRA. Only by obtaining NMRA approval can the applicant market its device. Pre-market approval is based on a determination by the NMRA that the application contains sufficient valid scientific evidence to ensure that the device is safe and effective for its intended use(s).

- **Control of clinical trials:** Effective regulatory control of clinical trials is another important aspect of medical products regulation. For this purpose, laws must contain detailed provisions on how pharmaceutical companies should apply for permission to carry out clinical trials, and how NMRA should perform ethical and regulatory review, approve clinical trials, inspect clinical trial sites, and follow-up periodically on the conduct of trials according to the approved protocols.

- **Good Manufacturing Practice (GMP):** is that part of quality assurance which ensures that pharmaceutical products are consistently produced and controlled at quality standards appropriate for their intended use and as required by their marketing authorisations. GMP ensures that pharmaceutical products do not place the populace at risk. GMPs are more commonly known as Current GMPs (CGMPs), which have been established flexibly to permit every manufacturer to use their discretion in implementing the best controls for their own organisation. This flexibility also allows manufacturers to make use of the latest and most innovative technologies to result in products of better/higher quality. The “current” addition also implies that the NMRA expects companies to continuously stay up to date with regulations as they are altered to suit changing market and consumer needs. This is because the systems, machines, and equipment that were in use a few years ago may not be as efficient or effective today, and hence are inadequate in ensuring maximum consumer protection.

The following is the full list of CGMP regulations, detailing coverage of each part.

- **Part 1** Improving Documentation of GMP Procedures
- **Part 2** Better Compliance through Master Manufacturing Records
- **Part 3** Improving Batch Production Records
- **Part 4** Specifications That Improve Compliance
- **Part 5** Improving Quality through In-Process Control
- **Part 6** Documenting Deviations for Improved Compliance
- **Part 7** Supplier and Vendor Qualification
- **Part 8** Complaints and Recalls
- **Part 9** Packaging and Labelling
- **Part 10** Equipment for Dietary Supplement Manufacturing
- **Part 11** Facility Design for Dietary Supplement Manufacturing
- **Part 12** Facility Areas for Dietary Supplement Manufacturing
- **Part 13** Testing in Dietary Supplement Manufacturing
- **Part 14** Training Documentation
Quality control

Quality control is that part of GMP which is concerned with sampling, specifications, and testing, and with the organisation, documentation, and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use, nor products released for sale or supply, until their quality has been adjudged to be satisfactory. The basic requirements of quality control are that:

a. Adequate facilities, trained personnel, and approved procedures are available for sampling, inspecting, and testing starting materials and packaging materials as well as intermediate, bulk, and finished products, and where appropriate for monitoring environmental conditions for GMP purposes.

b. Samples of starting materials, packaging materials, and intermediate, bulk, and finished products are taken by personnel and by methods approved by quality control.

c. Test methods are validated.

d. Records are made manually and/or by recording instruments, which demonstrate that all the required sampling, inspecting, and testing procedures were actually carried out. Any deviations are fully recorded and investigated.

e. The finished products contain active ingredients complying with the qualitative and quantitative composition of the marketing authorisation, are of the purity required, and are enclosed within their proper containers and correctly labelled.

f. Records are made of the results of inspection and that testing of materials and intermediate, bulk, and finished products is formally assessed against specifications. Product assessment includes a review and evaluation of relevant production documentation and an assessment of deviations from specified procedures.

g. No batch of product is released for sale or supply prior to certification by an authorised person that it is in accordance with the requirements of the relevant authorisations.

h. Sufficient retention samples of starting materials and products are retained to permit future examination of the product if necessary and that the product is retained in its final pack unless exceptionally large packs are produced.

Post-market regulation

Quality control laboratories are an important component in effective regulation of medical products. Their role is in pre- and post-registration testing of product samples to confirm that a product conforms with its specifications at all times. Post-market surveillance comprises an elaborate framework within each country; it includes review of authorised products, random audits of notified variations, GMP inspections of local manufacturers, laboratory testing of samples either selected randomly or suspected of being substandard, monitoring of adverse drug reactions, monitoring of advertising and other promotional activities, drug utilisation studies, and more.
To ensure that drugs reaching consumers are effective, safe, of good quality, and affordable, governments may exert control in several areas through various means. However, the areas controlled and the agencies responsible for controlling them may differ from country to country. Medical products regulations are often done at four levels:

- Product registration.
- Licensing of manufacturing, importation, and distribution.
- Control of drug promotion and information.
- Pricing.

Legislation should specify the requisite qualifications of personnel handling specific tasks; the procedures used to produce, import, and distribute pharmaceutical products; and the health and safety conditions of the premises in which any of these processes takes place.

- International frameworks and systems for medical products regulation:
  - World Health Organisation.
  - European Medicines Agency.
  - US Food and Drug Administration.

- Legislation should specify the requisite qualifications of personnel handling specific tasks; the procedures used to produce, import, and distribute pharmaceutical products; and the health and safety conditions of the premises in which any of these processes takes place.

- International frameworks and systems for medical products regulation:
  - World Health Organisation.
  - European Medicines Agency.
  - US Food and Drug Administration.
**Benefits of regulatory harmonisation**

- Improved operational efficiencies.
- Potentially faster and more consistent review and approval processes. A modelling study by PATH showed that without regulatory harmonisation, the average registration time for medicines in the East African Community is two years. Regional regulatory harmonisation could accelerate this review timeline by 40% to 60%.\(^8\)
- Greater availability of generics that may otherwise not be registered in certain markets.
- More affordable generic medicines.
- Regulatory convergence, promotion of regulatory science, and the strengthening of regulatory authorities.
- Greater regulatory oversight and peer review.
- Reduction in overall regulatory burden and less duplication of effort.
- Lower regulatory and product development costs/times.
- Greater alignment of industry submission practices.
- Fewer parallel registrations.
- Mutual learning and consistency in applying international guidelines such as Good Clinical Practice, International Conference on Harmonisation ICH Q8 (R2).

**Challenges of regulatory harmonisation**

- Unfamiliarity with regulatory systems of other regulatory authorities.
- Differences in:
  - Legal frameworks: definitions of terms (“generic”, “reference product”, “data exclusivity”, “pharmacopoeia”, “variations”, etc.)
  - Culture.
  - Treatment guidelines/therapeutic traditions between countries, both in terms of the medicines acceptable for market authorisations by regulatory authorities and acceptable indications.
  - Technical requirements (e.g., bioequivalence requirements for complex products).
  - Product and API differences: source, method of manufacture, packaging, etc.
  - Assessment timelines, which may be anchored in regulations.
  - Timing of applications due to differences in data exclusivity/patent rules.
  - Divergence following joint approval due to separate handling of post-approval changes.
  - Potential reduction in number of manufacturing sites, impacting supply.
  - Complexity of setting up and maintaining a collaborative review system.

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\(^8\) [https://www.path.org/resources/making-case-how-regulatory-harmonisation-can-save-lives-africa/](https://www.path.org/resources/making-case-how-regulatory-harmonisation-can-save-lives-africa/)

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In many African countries, a lack of harmonised technical requirements and capacity for medical products registration jeopardises timely access to essential medical products. Harmonisation improves public health by increasing timely access to safe and effective medical products of good quality for the treatment of priority diseases. This session explores the frameworks and systems that have been formed across the continent to address these challenges.

Continental frameworks and systems for regulatory harmonisation

The AU Model Law:

- Is a legislative governance document that supports, facilitates, and improves the capacity of AU Member States and RECs in strengthening and harmonising the regulatory environment for the delivery of quality, safe, and efficacious health technologies; it provides a generic framework for medical products regulation across the African continent.
- Creates collaboration among various stakeholders and is a road map for shared responsibility and solidarity.
- Has been translated into four languages: Arabic, French, Portuguese, and English.
- Strengthens national laws on medical product regulation and promotes autonomous NMRAs; AU Member States are at liberty to domesticate and adapt the AU Model Law to ensure alignment with their constitutional principles and legal systems.
- Contributes to the Pharmaceutical Plan for Africa (PMPA).
- Complies with World Health Organisation regulations and pharmaceutical product quality standards.
- Assists in the mitigation of substandard and counterfeit drugs.
- Will improve the predictability and efficiency of marketing approvals, so that innovative new health technologies can be delivered and used sooner—ultimately improving health outcomes of patients in need.
- Avoids duplication of regulatory reviews, accelerates scientific risk-benefit-adjusted reviews, facilitates mutual recognition, and accelerates access.
- Will be an important tool in promoting an integrated and coordinated approach for medical products regulation and facilitating the efficient and speedy introduction of new health technologies.

African Union Model Law on Medical Products Regulation (AU Model Law)

The AU Model Law came into effect in January 2016. It is expected that a minimum of 25 AU Member States will have adapted the AU Model Law into their national laws by 2020.

The AU Model Law:

- Is a legislative governance document that supports, facilitates, and improves the capacity of AU Member States and RECs in strengthening and harmonising the regulatory environment for the delivery of quality, safe, and efficacious health technologies; it provides a generic framework for medical products regulation across the African continent.
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- Contributes to the Pharmaceutical Plan for Africa (PMPA).
The African Medicines Regulatory Harmonisation (AMRH) Initiative

The AMRH supports African countries to build effective medicines registration through regional harmonisation and capacity-building. The focus of AMRH is predominantly on harmonised technical and procedural guidelines for registration of medicines, diagnostics, devices, vaccines, blood, and blood products; GMP; inspection guidelines; quality management systems; and information management systems.


Aim of the AMRH
- Increase collaboration among stakeholders supporting regulatory systems development and implementation in Africa.
- Foster mutual responsibility, accountability, and shared impact.
- Minimise duplication and coordinate efforts at all levels of implementation.
- Improve the fragmented regulatory system for medical product registration in Africa by changing from a country-focused approach to a collaborative regional and more aligned one.

What are the essential provisions of the Model Law?
- Some authority responsible for regulating medical products.
- The products to include medicines, vaccines, diagnostics and medical devices.
- Approval of medical products must be based on safety, efficacy and quality.
- Assessments must be conducted by appropriately qualified technical experts (or the country may rely on the expertise of another regulator).
- In addition to registration of medical products, the authority must also undertake the licensing of manufacturers, importers, exporters, wholesalers and distributors.
- The authority must also be responsible for the approval of clinical trials, and quality and safety surveillance of products circulating in the market.
- There must be in place procedures for regulatory inspection and enforcement, with appropriate powers; fairness and due process; and appeal procedures.
- There must be in place procedures for regulatory reliance on decisions made by other agencies.

// Advocacy notes
- Advocates play a critical role in ensuring that their country begins the process of domestication of the AU Model Law, ultimately enacting a version that fits their country’s context and strengthens national regulatory capacity.
- The next phase entails ongoing work on domestication of the AU Model Law across Africa and supporting the African Medicines Agency.
Timeline and key facts

February 2009
NEPAD in collaboration with a consortium of partners convened the AMRH consensus meeting with NMRAs and Regional Economic Communities (RECs).

EAC-MRH
The East African Community Medicines Regulatory Harmonisation Project was launched in 2012 involving five countries: Tanzania, Uganda, Kenya, Burundi, Rwanda.

Vision
Move from 55 countries acting independently to six RECs that converge medical products registration assessments and other regulatory functions in support of one African Medicines Agency (AMA). (Figure 4).

Stepwise approach
Start by harmonising and streamlining technical requirements for product registration, leading to increased and timely product access.

Platform
Build African regulatory capacity by region 9.

Figure 4: Vision of the African Medicines Regulatory Harmonisation.

9 EAC – East Africa Community; COMESA – Common Market for Eastern and Southern Africa; CEN-SAD – The Community of Sahel-Saharan States; Southern Africa Development Community (SADC); Common Market for Eastern and Southern Africa (COMESA); Economic Community of West African States (ECOWAS); Economic Community of Central African States (ECCAS); Arab Mahgreb Union (AMU); Intergovernmental Authority for Development (IGAD)
Issues addressed

- Marked differences in capacity among the NMRAs and lack of a mutually recognised legal framework.
- Discrepancy between regulatory frameworks and procedures within RECs and within the African region.
- Considerable and inefficient efforts duplication by over-burdened NMRAs, resulting in delays that ultimately impact negatively on patient health.

Thematic areas of focus and technical working groups

- Clinical Trials and Oversight – AVAREF
- Laboratory Access and Testing – AMQF
- Regulatory Systems – Policy, Legal, and Regulatory Reforms
- Medical Devices & Diagnostics – PAHWP
- Blood and Blood Products – ABRF
- Regulatory Inspections – GMP
- Market Surveillance and Control – AMQF
- Registration and Marketing Authorisation

Key Accomplishments

**Milestone 1**
Established governance framework (systems and structures) for harmonisation of regulatory standards at regional and continental levels such as Technical Working Groups and Steering Committees and regional continental levels

**Milestone 2**
Regulatory capacity for marketing authorisation, GMP inspections and clinical trials oversight strengthened

**Milestone 3**
Improved legal frameworks for regulation of medical products using the AU Model Law as a reference guide.

**Milestone 4**
Improved reliance amongst countries e.g., in the EAC region, a lead country for registration products, GMP inspections, pharmacovigilance etc; provides technical leadership in the coordination of joint regulatory activities

**Milestone 5**
Shorter approval timelines for products assessed through the RECs e.g., ZAZIBONA (median 9 – 10 months) compared to the time to market authorisation for products assessed in the individual countries and subsequent improved market access by manufacturers.
**AMRH as a foundation for the African Medicines Agency**

- The AU Executive Council Decision (EX.CL/Dec.857 (XXVI)) in January 2015 which endorsed the milestones for the setting up of a single medicines’ regulatory agency in Africa within the context of the AMRH Initiative, and as part of the PMPA Framework.
- Advocacy for ratification by at least 15 Member States.

**Five key AMRH challenges**

- **Regulatory capacity**: Varying levels of medical products regulatory capacity among countries participating in a regional platform with subsequently delayed national decision-making by some countries following approval of jointly assessed products.
- **Frameworks**: Inadequate legal framework for regulation of medical products.
- **Guidelines**: Varying guidelines and standards for registration of medicines, quality management systems, and information management systems across RECs.
- **Technical capacity**: Limited technical capacity to manage and coordinate medicines regulatory harmonisation programs at national, regional, and continental levels.
- **Resources**: Low availability of resources to undertake a fully-fledged regional medicine regulatory harmonisation project and ensure its sustainability.
African Medicines Agency (AMA)

The AMA will be established by a Treaty which defines the AMA’s purpose, objectives, functions, guiding principles, and more. The AMA Treaty was adopted by African Heads of State on 11 January 2019.

Purpose of the AMA

The AMA ensures the coordination and strengthening of continental initiatives to harmonise medical products regulation, provides guidance, complements and enhances the efforts of AU-recognised RECs and Member States, and contributes to improving access to medical products on the continent.

Functions of the AMA

1. The AMA shall undertake such functions as may be necessary to achieve its objectives.
2. Without departing from the generality of the foregoing, the AMA shall undertake the following functions:

   a. Promote the adoption and harmonisation of medical products regulatory policies and standards and scientific guidelines and coordinate existing regulatory harmonisation efforts in the RECs.

   b. Provide regulatory guidance, scientific opinions, and common framework for regulatory actions on medical products, as well as priority and emerging issues and pandemics.

   c. Examine, discuss, and/or express regulatory guidance on any regulatory matter within its mandate, either on its own initiative or at the request of the AU, RECs, or Member States.

   d. Provide guidance on regulation of traditional medicines.

   e. Provide guidance on regulation of clinical trials on medical products and health technologies.

   f. Designate, promote, strengthen, coordinate, and monitor Regional Centers of Regulatory Excellence with a view to developing the capacity of medical products regulatory professionals.

   g. Promote international cooperation and seek partnerships that will lead to effective mobilisation of financial and technical resources to ensure sustainability of the AMA.

   h. Promote and advocate for use of the AU Model Law on medical products regulation in Member States and RECs to facilitate regulatory and legal reforms at continental, regional, and national levels.

   i. In collaboration with the World Health Organisation, convene the African Medicines Regulators Conference and other meetings related to medical products regulation in Africa.

   j. Collect, manage, and disseminate relevant information and knowledge.

   k. Develop systems to monitor, evaluate, and assess the comprehensiveness of national medical products regulation with the view to recommending interventions that will improve efficiency and effectiveness.

   l. In the event of a public health emergency with cross-border or regional implications for the continent, the AMA will mobilise expertise across the continent and beyond to provide scientific opinion in consultation with affected Member State NMRAs.
Structures of the AMA

- **The Conference of the States Parties**
  - The highest policymaking organ of the AMA

- **The 9-member Governing Board**
  - Appointed by and answerable to the Conference of the State Parties

- **Technical Committees of the AMA**
  - Established by the Board on a permanent or ad hoc basis

- **The Secretariat of the AMA**
  - Responsible for coordinating the implementation of the decisions of the Conference of the States Parties, policy organs of the AU, and Board of the AMA
  - Headed by the Director-General

Urgency of the AMA

- The AMA will help unlock the following challenges experienced in Africa:
  - The increasing complexity of medical products, which requires higher skills and resources to be controlled.
  - The increased economic integration of the continent, which will be dramatically reinforced by the African Continental Free Trade Agreement, leading to easier circulation and harder control of medical products.
  - The limited attractiveness of country-level markets for pharmaceutical industry due to lengthy, complex, and non-standardised processes.

Value addition of the AMA

**African patients**
- Faster release of innovations to the market.
- Enhanced safety of medical products.
- Accelerated access to medical products in emergencies.

**NMRA**s
- Increased capacity to assess complex dossiers.
- Higher visibility on product safety.
- Reduced duplication across NMRA and REC.
- Support where expertise gaps exist.
- Global representation of pan-African interest and expertise.

**REC**s
- Enhanced capacity to work with the NMRA.
- Support on regional harmonisation process.
- Reduced duplication across NMRA and REC.
- Support where expertise gaps exist.
- Global representation of pan-African interest and expertise.

**Industries**
- Simplified, less fragmented processes.
- Shorter timelines for product registration processes.

**AMRH stakeholders**
- Renewed momentum to build on successful AMRH activities.
- An established legacy for the most important results achieved.
What the AMA will and will not do

The AMA will...

- Be a platform of NMRAs and RECs steered by States Parties
- Be complementary to NMRAs and RECs
- Be an advisory institution
- Rely on other regulatory authorities

The AMA will not...

- Be a standalone institution, functioning independently
- Replace NMRAs or RECs
- Be a binding institution with power to enforce decisions on States Parties
- Duplicate already performed work

Financial support to the AMA

The AMA budget can come from the following main sources:

- States Parties’ contributions.
- International donors’ funding.
- Fees from industry for conduct of assessments, inspections, and provision of scientific advice.

The first five years of the AMA

1. Coordinate joint assessments and inspections on a select group of products, along the whole product life cycle, including variations assessment, and provision of regulatory and scientific advice to industry.

2. Coordinate guideline development and capacity-building to foster reliance and regulatory and legal harmonisation.

3. Create and manage an API database and increase the knowledge on and reliability of APIs in the continent by capitalising on existing API data and inspections.

Ratification of the AMA

- The AMA will be established once the Treaty is ratified by 15 AU Member States.
- The Treaty shall enter into force 30 days after the deposit of the 15th instrument of ratification and accession.
- The Chairperson of the Commission shall inform all Member States of the AU of the entry into force of the present Treaty.
AMA five-year road map: 3 phases

<table>
<thead>
<tr>
<th>YEAR 0</th>
<th>YEARS 1 AND 2</th>
<th>YEAR 3</th>
<th>YEAR 4</th>
<th>YEAR 5</th>
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<tr>
<td>Prepare</td>
<td>Initiate</td>
<td>Review and extend</td>
<td></td>
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<td>Objective</td>
<td>Prepare as much as possible before the AMA comes into existence</td>
<td>Set up the AMA secretariat</td>
<td>Review and refine execution of core activities to enhance impact</td>
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<tr>
<td></td>
<td>■ Set up the core activities of the AMA together with RECs/NMRAs</td>
<td>■ Set up the core activities of the AMA together with RECs/NMRAs</td>
<td>■ Assess the possibilities to extend the scope of AMA activities</td>
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<tr>
<td></td>
<td>■ Ramp up core activities</td>
<td>■ Ramp up core activities</td>
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<td>Primary responsibility</td>
<td>AU Commission and AUDA-NEPAD</td>
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<td>One-time setup costs</td>
<td>$0.8M</td>
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Pharmaceutical Manufacturing Plan for Africa (PMPA)

Introduction to PMPA
- A toolkit developed by the AU during the Summit in Abuja, Nigeria, in January 2005.
- The PMPA was developed with the framework of NEPAD and forms a platform that encourages local production of generic medicines within the African continent.
- The AU Commission accelerated the development and facilitation of the implementation of the PMPA.
- The AU Commission, in collaboration with the World Health Organisation, conducted a drug production capacity-mapping exercise in a unified decision on local drug production.

Objectives of PMPA
- Support local pharmaceutical manufacturing in Africa to increase access to affordable, quality medicines.
- Ensure sustainable supply of essential and affordable quality medicines.
- Improve public health outcomes.
- Promote industrial and economic development.

PMPA initiatives
- Regulatory.
- Access to capital.
- Business linkages.
- Market and management information system.
- Advocacy and communication.
- Legislation, policy, and incentives.
Benefits of a viable pharmaceutical sector

- Jobs creation, thus reduction in poverty and promotion of social development.
- Facilitation of technology transfer.
- Savings on foreign exchange.
- Export stimulation.
- Local production of raw materials is readily available and cheaper than importing.
- Improvement of self-sufficiency in drug supply.

Challenges

- Pharmaceutical production is capital, technology, and knowledge intensive.
- Technical expertise in terms of appropriate and relevant skill sets.
- Capability of the education system to produce sufficient number of skilled personnel in a sustainable manner to enhance local production of affordable, quality medicines.
- The continent is not homogenous; therefore, legislative frameworks and capacity for enforcement varies.
- Countries are at different levels of development; therefore, labor costs will vary, which will inevitably impact the final price of commodities.
- Limited acceptability of locally produced generics by both providers and consumers unless an effective marketing strategy is performed.

National Medicine Regulatory Authorities (NMRA)

Regulatory oversight is the cornerstone of a well-functioning medical products supply chain and key to attaining universal health coverage. Without regulated medical products, a country cannot offer equitable access to quality health care. Thus, NMRA are responsible for:

- Regulation of health products intended for human and animal use.
- Licensing of manufacturers, wholesalers, and distributors of medicines, medical devices, radiation-emitting devices, and radioactive nucleoids.
- Import and export control.
- Inspection of manufacturing premises and distribution channels.
- Market surveillance (product quality monitoring, pharmacovigilance, and post-market surveillance).
- Conduct of clinical trials.

NMRA may be structured to include divisions within the agency such as Medicines Regulatory, Medical Devices Regulatory, Borderline Products Regulatory, Clinical Trials Regulatory, and a national advisory body.
Mandate of NMRAs – Overview

NMRAs must ensure:

■ The efficient, effective, and ethical evaluation and registration of medicines, medical devices and in vitro diagnostics that meet defined standards of quality, safety and efficacy.

■ The periodic reassessment and monitoring of medicines, medical devices, and in vitro diagnostics.

■ That the process of evaluating and registering medicines, medical devices, and in vitro diagnostics is transparent, fair, objective, and concluded timeously.

■ That evidence of existing and new adverse events, interactions, and information about pharmacovigilance is being monitored, analysed, and acted upon.

■ That compliance with existing legislation is being promoted and controlled through a process of active inspection and investigation.

■ That clinical trial protocols are being assessed according to prescribed ethical and professional criteria and defined standards.

// Advocacy notes

Ensure that NMRAs:

■ Are part of the regional regulatory harmonisation initiative.

■ Share information on medicines under review with other NMRAs.

■ Utilise the common technical document adopted by the research ethics committee.

■ Conduct joint factory inspections and/or recognise factory inspections conducted by fellow NMRAs.

Regional Economic Communities (REC)

Why use a REC-based approach?

■ To keep up with the AU’s strategy for development collaboration across countries in the form of RECs.

■ Several RECs have already supported harmonisation of medicines registration. For instance, in East Africa under the provisions of Chapter 21 (Article 118) of the East Africa Community (EAC) treaty, medicines registration harmonisation is an explicit policy priority. Likewise, in Southern Africa, ministers of health approved the Southern African Development Community (SADC) Pharmaceuticals Business Plan, with explicit goals to harmonise medicines registration.

The work of the RECs

■ Harmonised standards (technical and procedural requirements / guidelines).

■ Joint and regional dossier assessments/GMP inspections.

■ Work sharing / pooling of resources.

■ Streamlined decision-making processes.

Challenges experienced by RECs

■ Lack of financial and technical resources inhibits implementation of policies.

■ RECs continue to work largely in isolation.

■ Coordination is needed to avoid duplication of efforts and ensure consistent approaches, especially given that more than three-quarters of African countries belong to two or more RECs. This is where the AMRH Initiative can add value.
Case studies from NMRA or RECs

Key topical areas include marketing authorisation, licensing of manufacturing establishments, import and export control, inspection of manufacturing premises and distribution channels, and market surveillance (product quality monitoring, pharmacovigilance, and post-market surveillance).

Challenges in regulatory capacity and harmonisation in Africa:

- **Weak or nonexistent medicines regulatory systems** impacting access to quality, safe, and effective health technologies.

- **The comprehensiveness of regulatory legislation**—and therefore the strength of NMRAss—varies from country to country; however, many countries have not developed plans to fully implement their regulatory legislation.

- **Weak implementation of national regulatory legislation** and gaps in resource allocation; many NMRAss are inadequately funded, understaffed, and overburdened.

- NMRAss often **lack the expertise and experience to provide guidance** to product developers who are seeking clinical trial or product registration, nor do they have proper control over numerous products that are studied, introduced, and used in their countries.

- **Insufficient capacity of NMRAss** can lead to costly delays in product development and introduction, ultimately impacting patients in need of treatment.

- Researchers and manufacturers must **file duplicative evidence dossiers with multiple NMRAss** in order to register a health technology in all countries where it could have public health impact.

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**TEST YOUR KNOWLEDGE**

What is the definition of falsified medicine?

1. What regulatory mechanisms exist at national level?
2. How are they set up?
3. What are their core functions?
This session will be delivered as an open discussion to allow participants to explore different ways to assess progress and implementation of regulatory harmonisation initiatives and efforts as well as understand how new developments and emerging issues in global health impact on regulatory systems and what that means for regulatory harmonisation.

African Medicines Agency (AMA) Treaty

Four categories can be used to determine a country’s progress towards the ratification of the AMA Treaty. A country would be considered to have:

1. Neither signed nor ratified the AMA Treaty.
2. Signed the AMA Treaty but has yet to ratify.
3. Ratified the AMA Treaty in-country but the ratification instrument has not yet been deposited.
4. Ratified and deposited the instrument of ratification to the AUC.

There are several considerations that differentiate signing versus ratifying the AMA Treaty. Although these are determined by the statutes of each member state, the scenarios below provide a general guide of the differentiators.

Signing the AMA Treaty

Once the President of the country, the Minister of Foreign Affairs, or the country’s Permanent Representative at AU headquarters in Addis Ababa have signed the treaty, countries are considered to have completed the signing process. Signing of the AMA Treaty shows the intent by a country to fully walk through the journey of ratification and is an assurance that the country agrees to the instruments under the AMA. However, the country must still go through their AMA’s legal processes to ratify the treaty. Countries that have signed the AMA Treaty are not considered parties to the treaty establishing the AMA, but it is a good demonstration and a step towards ratification.
Ratifying the AMA Treaty

There are at least two pathways in which the ratification process can be performed. Both legal processes can be performed either at presidential or parliamentary level. It is important to note that signing and ratification are multistakeholder processes. The following steps outline the journey most countries follow:

- Ministries of Health: Initiate and follow up on the process until instruments of ratification are deposited.
- Ministries of Justice: Provide a legal opinion that ensures consistency of the treaty with national law.
- Cabinet: Approve the treaty.
- Parliament: Ratify the treaty.
- Office of the President: Finalise approval for signing the treaty.
- Ministry of Foreign Affairs: Facilitate the signing process in Addis Ababa (AU Head Quarters) and deposit the instrument of ratification.

Upon adoption/signing of the ratification instruments at country level, countries must deposit the ratification instrument with the AUC, in the office of the chairperson (through the AU Office of the Legal Counsel).

To assess member state progress towards the ratification of the treaty, stakeholders may track the status of the country ratification process. However, advocacy approaches differ depending on the status of ratification. Countries that have neither signed nor ratified the treaty may require more effort and strategies to move them towards ratification than those that have signed or ratified the treaty but have yet to deposit instruments to the AUC.

Stakeholders can play advocacy roles at different levels, depending on the member state’s ratification status. Below are some suggested moments for intervention:

- Target advocacy efforts in countries that have signed to ratify and deposit.
- Target countries that have ratified to deposit.
- Target countries that have indicated signed the treaty but are aligned to the principles of regulatory harmonisation.
- Support NRAs to engage Ministries of Health to initiate the process with relevant stakeholders.
- Ministries of Health: Initiate and follow up on the process until instruments of ratification are deposited.
- Ministry of Justice’s legal opinion: Ensure consistency of the treaty with national law.
- Cabinet: Approve treaty.
- Parliament: Ratify treaty.
- Office of the President: Give final approval for signing the treaty.
- Ministry of Foreign Affairs: Facilitate the signing process in Addis Ababa (AU headquarters) and deposit the instrument of ratification.

Differences between a treaty and a model law

<table>
<thead>
<tr>
<th>TREATY</th>
<th>MODEL LAW</th>
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<tbody>
<tr>
<td>Creates legally binding obligations</td>
<td>Recommended text for enactment as part of national law</td>
</tr>
<tr>
<td>Disadvantage: More difficult to negotiate</td>
<td>Advantage: Easier to negotiate</td>
</tr>
<tr>
<td>Disadvantage: May take years to ratify</td>
<td>Disadvantage: Perception of the adoption of a foreign law</td>
</tr>
<tr>
<td>Requires ratification and deposit of instrument</td>
<td>Requires domestication (adoption) into national law</td>
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<td>following a normal legislation process</td>
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</table>
The products must include medicines, vaccines, diagnostics, and medical devices.

Approval of medical products must be based on quality, safety, and efficacy.

Assessments must be conducted by appropriately qualified technical experts (or the country may rely on the expertise of another regulator).

In addition to registration of medical products, the authority must also undertake the licensing of manufacturers, importers, exporters, wholesalers, and distributors.

The authority must also be responsible for the approval of clinical trials and quality and safety surveillance of products circulating in the market.

There must be procedures in place for regulatory inspection and enforcement, with appropriate powers, as well as fairness, due process, and appeal procedures.

There must be mechanisms in place for regional collaboration, harmonisation of guidelines and standards, information sharing, and regulatory reliance on decisions made by other agencies.

As part of adopting the AU Model Law, member states need to ensure that their medicines’ regulatory legal laws are in alignment with the eight essentials. It is only upon this alignment that countries are considered to have fully adopted the AU Model Law.

Civil society and all key stakeholders should work with the Ministry of Health and other agencies responsible to make sure the eight essentials provisions are fully integrated into the national medicines law.

There are various degrees of domestication that are considered for the AU Model Law. These are summarised below:

If AU Model Law is regarded as having been domesticated in a country:

- A country’s regulatory law is already in alignment with the AU Model Law.
- A country adopts the AU Model Law verbatim as its regulatory law.
- A country adopts all the essential provisions of the AU Model Law.

If AU Model Law is regarded as having not been domesticated in a country:

- A country adopts some but not all the essential provisions.
- A country does not make any changes to align with the AU Model Law.

The AU Model Law stipulates essential provisions that should be met in order to achieve full domestication. These provisions include the following:

1. There must be an NRA that has responsibility for regulating medical products, which:
   a. Proposes establishment of a [National] Medical Products Regulatory Agency/Authority, which is a juristic person (with legal capacity) which is autonomous (independent of), but functionally and financially accountable to, the line ministry (usually the ministry responsible for health).
   b. Proposes that the Authority will be composed of the Board, the Head of the Authority, and the Technical Committees.

New developments in global health technologies and their implications on regulation of medical products are as follows:

- Advancement in the practice of medicine and the need to keep populations healthy and productive by ensuring early detection and prevention and safer, more efficient, and more effective treatment and management of disease has warranted the need for the introduction of new technologies and innovations.

- The need to introduce new technologies may demand that regulatory authorities and their regulators acquire new skills, capacities and capabilities, and legislation for regulating these technologies.

- Of importance to note is that NRAs and regional RECS must remain agile and prepare for the future by always remaining abreast of new technologies that are under clinical trials and those that show promising results for eventual use as well as those ready for market introduction.

- Due to the complexities that some of the products pose in their regulation, NRAs and RECs would need to apply reliance principles to enable them to evaluate such products with speed while considering safety and efficacy.

- To fully guarantee safety and efficacy of new medical products, NRAs must continuously strengthen their legal and regulatory frameworks and aim towards achieving higher maturity levels. This would include ensuring regulators are continuously building capacity and are trained on new technologies.

- To do this, member states and NRAs need to allocate resources that would be used to improve the capacities and capabilities of the regulatory authorities.

- NRAs also need to utilise the resources and opportunities provided through the Regional Centres of Regulatory Excellence (RCOREs) in strengthening their regulatory capacities.

Finally, it is important to emphasise the following points:

- Regulation of medical products will never remain static, given the advances in medicines and health technologies globally.

- NMRAs need to keep up with developments in the medical field in order to be able to test the efficacy and safety of new therapies, medicines, and diagnostics. By the years 2021/2022, some of the new developments in medicines include therapies such as biologics, stem cell therapy (regenerative medicine), chimeric antigen receptor T-cell therapy, and monoclonal antibodies. These new developments change over time and the regulatory systems must remain ahead of the game in regard to preparing the skill set, capacities, and capabilities of regulating new technologies.
This session will be delivered as an open discussion to allow participants to explore new developments and emerging issues in global health and what that means for advocacy.

What is advocacy? (definition)
- “Advocacy” can have many meanings across countries and contexts.
- Advocacy encompasses any activity that a person or organisation undertakes to influence policies, such as any action that speaks in favor of, recommends, argues for a cause, supports, defends, or pleads on behalf of others.
- It also means engaging with partners and stakeholders, including related initiatives and networks to create awareness on a particular issue, advocating for policy changes, and promoting new ways of thinking and acting at community, national, and international levels.

What is policy advocacy?
- Policy advocacy is the deliberate process of informing and influencing decision-makers in support of evidence-based policy change and policy implementation, including resource mobilisation.
- It is a deliberate process that requires planning and strategy. It is not effective if done haphazardly.
- It tries to influence those who have the formal power to make the change.
- Policy advocacy seeks changes that are evidence-based. It is important to have program experience or data that prove the issue is important and the suggested solution will work.
- The goal of policy advocacy is to achieve a desired policy change or ensure an existing policy is implemented. It is not enough to educate policymakers: we want to convince them to take action.
- Policy change and implementation can happen at a global, national, or subnational level. It can even happen at an organisation or facility level if they are the target of your advocacy efforts.
Key points

- Many of the terms for policies are used interchangeably within common themes (e.g., “plans, strategies, agendas, frameworks” and “protocols, guidelines, regulations”).
- Generally speaking, health policies are those documents or statements issued by governments or institutions that guide, inform, influence, fund, or govern matters of health concern.
- Policy advocacy emphasises changing written documents. Even if a declarative statement is made, it should ultimately be captured in writing, in the form of policy. This helps ensure a more lasting or permanent change.

Types of policy change and policy implementation

Policy change can include:

- Eliminating a harmful policy.
- Updating or amending an existing policy.
- Developing a new policy.
- Allocating or committing resources within a budget to support implementation of a policy.

Policy implementation can include:

- Disseminating a policy.
- Enforcing a policy.
- Disbursing allocated funds appropriately.
- Demonstrating accountability for policy commitments and carrying out the provisions called for within policies.

Why advocate? The importance of advocacy

Advocacy is an important function of a modern society. It facilitates the drive for justified alteration of the status quo. It is a peaceful, civilised, and systematic action that can either reverse wrongdoings or apply new developments to fine-tune existing social affairs. Policy advocacy is one of the most effective ways to achieve public health goals. It ensures that necessary resources, policies, and political will are available to support, scale up, and sustain global health programs.

In some cases, a public health policy may exist, but it is not being implemented. At times, additional policies may be needed to ignite implementation; for example, a high-level policy framework may require accompanying guidelines. In such cases, what is needed is advocacy to hold decision-makers accountable for implementing policies already in place.

SKILLS OF A GOOD ADVOCATE

- Able to research, collect, and analyse data to provide strong arguments and insights to support a case.
- Determined, methodical, and persistent.
- Patient and understanding.
- Persuasive and resourceful.
- Collaborative.
Introduction to the 10-part Policy Advocacy Strategy – Participant’s guide

### PART 1  Advocacy issue

Before you can really begin your advocacy strategy, you must decide the issue you want to address with policy advocacy. Your issue should be specific and clear, align with your organisation’s mission, and be able to be realistically addressed through advocacy within five years.

- Identify the qualities of a good issue for advocacy.
- Evaluate potential issues for advocacy.

### PART 2  Advocacy goal

You will develop your policy advocacy goal to help focus your strategy. This is your policy solution to the issue—what you’d like a policymaker to do to address it.

- Identify the essential components of an advocacy goal.
- Develop a policy advocacy goal for your strategy.

### PART 3  Decision-makers and influencers

Identify decision-making institutions as part of your advocacy goal and identify specific decision-makers within these institutions. These are the individuals who can say yes or no to your goal.

- Identify key decision-makers and influencers.
- Target your advocacy goal to the appropriate decision-makers.

### PART 4  Decision-makers’ key interests

You will need to understand what the identified decision-makers know about your issue and advocacy goal (their level of awareness) and how they feel about your issue and goal (their position) to determine how best to persuade them.

- Evaluate the awareness and position of key decision-makers on your issue and advocacy goal.
- Identify decision-makers’ key interests as a means to persuade them on your issue and advocacy goal.

### PART 5  Advocacy opposition and obstacles

It is just as important to understand the actors or organisations that may resist or oppose your desired policy action as it is to understand your decision-makers.

- Identify obstacles—like competing priorities, political controversy, or insufficient resources—that might hinder progress.
- Identify mechanisms for addressing resistance, opposition, and obstacles to your policy advocacy goal.
## PART 6  Advocacy assets and gaps

Policy advocacy can involve a range of approaches and tactics that requires different skills, expertise, or resources to implement. These are your advocacy assets.

- List the types of skills, expertise, and resources needed for your advocacy efforts.

## PART 7  Advocacy partners

Advocacy through partnership is almost always more successful than solo efforts. Be strategic about the partners you choose and how you partner with them.

- Assess the qualities of a strategic partnership.
- Identify different types of collaboration.

## PART 8  Advocacy tactics

You will take all of the information from Parts 1 through 7 to develop a concrete work plan to achieve your advocacy goal.

- Design objectives to reach your advocacy goal.
- Determine your advocacy activities and tactics.
- Develop an advocacy work plan.

## PART 9  Advocacy messages

Develop a concise and compelling message about your advocacy goal and identify people who can deliver that message effectively to your target decision-makers or key influencers.

- Craft targeted and effective advocacy messages to influence decision-makers.
- Evaluate potential messengers for advocacy communications.

## PART 10  Plans to measure success

Advocates often focus on just one main success of their efforts: achieving their desired policy solution (their advocacy goal).

- Distinguish between output and outcome indicators.
- Develop indicators to help measure progress toward achieving your advocacy goal.
Integrating advocacy into regulatory harmonisation

Group work

Participants are given different scenarios where they need to identify barriers like competing priorities, political controversy, or insufficient resources in regulatory harmonisation. The groups will then develop an advocacy plan to address these barriers and indicate the role that they will play as advocates:

- Supporting advocacy and accountability efforts for governments to accelerate advocacy harmonisation, including ratifying and operationalising legal instruments such as the AU Model Law or strengthening the capacity of NMRAs.
- Policy analysis to identify gaps and priorities for policy change.
- Working within coalitions/networks/partnerships at the local, national, or regional level to push for effective regulatory systems. This involves holding governments accountable to the commitments and resolutions taken at key forums.
- Empowering relevant stakeholders to understand the importance of regulations and regulatory harmonisation and be champions in their own spaces.
- Using different opportunities and platforms (including conferences, high-level political events such as the UN General Assembly, AU summits, etc.) to promote visibility and debates on regulation. Using these spaces as opportunities to engage, influence, and ensure that regulatory harmonisation and related issues are prioritised in policy commitment and accountability documents.
- Representing and amplifying the voices of population groups particularly impacted by the challenges and gaps in medical products regulation and regulatory harmonisation – including sharing evidence and experiences.

Platforms for advocacy

- National-level forums.
- Regional and global policymaker platforms.
- Media.
- Social media channels such as agency Twitter handles, agency Facebook pages.

Advocating on behalf of government agencies (how to advocate)

- Decision-makers often need to be advocates too; they must advocate for policy change or implementation within their institution, across institutions, and throughout different levels of the governance system.
- Governments are often subject to social and bureaucratic barriers. Advocates can help move new policies forward.
- Governments agencies also need advocates to forward and support their goals through the vast and complicated network of other governmental agencies or departments, as well as various related private entities.
Ways to advocate

- **Representative**
  - Speaking for people

- **Accompanying**
  - Speaking with people

- **Empowering**
  - Enabling people to speak

- **Negotiating**
  - Bargaining with officials

- **Networking**
  - Building coalitions

- **Modelling**
  - Demonstrating practice

- **Mediating**
  - Facilitating communication

### MODULE 5 – SESSION 2

### Action planning

#### Group work

Participants will go into small groups that are country based and spend 30 to 45 minutes to start drafting their action plans from the workshop. Based on the composition of the group, participants may prefer to develop their own individual plans or work in country teams to develop shared country action plans.

#### Presentation of action plans and plenary discussion

After the group discussion, each of the countries represented will have five minutes to present their action plan. This will be followed by a five-minute plenary discussion.

### TEST YOUR KNOWLEDGE

1. How would you define the term “advocacy”?
2. What is the importance of advocacy for government agencies?

### REFLECTIVE LEARNING

1. How do you intend to advocate to the various entities discussed in this model?
2. What platform do you intend to use?
3. Formulate an action plan.
1. What do you hope to take away from the workshop?


2. How would you rate your level of knowledge on regulatory harmonisation? (tick one)
   - Low
   - Medium
   - High

3. Health regulation is important because


4. When I think about regulatory harmonisation, I think of


5. My experience with advocacy is? (tick one)
   - Low
   - Medium
   - High

6. Advocacy is important because


## Workshop agenda

### Structure of the training workshop

<table>
<thead>
<tr>
<th>MODULE AND SESSION</th>
<th>SUBJECT</th>
<th>TIME</th>
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<tbody>
<tr>
<td><strong>D A Y 1</strong></td>
<td><strong>M O D U L E 1</strong> UNDERSTANDING REGULATION OF MEDICAL PRODUCTS</td>
<td>2 HOURS</td>
</tr>
<tr>
<td><strong>INTRODUCTIONS</strong></td>
<td>INTRODUCTIONS AND WELCOME</td>
<td>1 HOUR</td>
</tr>
<tr>
<td><strong>ARRIVAL AND REGISTRATION</strong></td>
<td>8:30 – 9:00</td>
<td>30 MINUTES</td>
</tr>
<tr>
<td>Introduction Session</td>
<td>9:00 – 10:00</td>
<td>1 hour</td>
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<tr>
<td>■ Welcome and opening remarks</td>
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<tr>
<td>■ Participants introduction</td>
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<td>■ Overview of the workshop</td>
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<tr>
<td>■ Brief introduction of AUDA-NEPAD and Agenda 2063</td>
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<tr>
<td><strong>SESSIONS</strong></td>
<td><strong>SESSIONS</strong></td>
<td><strong>TIME</strong></td>
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<tr>
<td>Session 1</td>
<td>Introduction to regulation of medical products</td>
<td>10.00 – 10.30</td>
</tr>
<tr>
<td>Session 2</td>
<td>Falsified and substandard medicines</td>
<td>10:30 – 11.00</td>
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<tr>
<td><strong>BREAK</strong></td>
<td>TEA BREAK</td>
<td>11.00 – 11.30</td>
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<tr>
<td><strong>MODULE 2</strong></td>
<td>PRE- AND POST-MARKET LEVELS OF MEDICAL PRODUCTS REGULATION</td>
<td>1 HOUR</td>
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<tr>
<td>Session 1</td>
<td>Understanding pre- and post-market levels of medical products regulation</td>
<td>11.30 – 12.00</td>
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<tr>
<td>Regulatory harmonisation</td>
<td></td>
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<tr>
<td><strong>MODULE 3</strong></td>
<td>REGULATORY HARMONIZATION</td>
<td>6 HOURS 45 MINUTES</td>
</tr>
<tr>
<td>Session 1</td>
<td>Introduction to regulatory harmonisation</td>
<td>12.00 – 12.30</td>
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<tr>
<td><strong>BREAK</strong></td>
<td>LUNCH BREAK</td>
<td>12.30 – 1.30</td>
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<tr>
<td>Session 2</td>
<td>Continental frameworks and systems for regulatory harmonisation</td>
<td>1.30 – 4.45</td>
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<tr>
<td>■ Africa Union (AU) Model Law</td>
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<td>■ African Medicines Agency (AMA)</td>
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<td>■ Pharmaceutical Manufacturing Plan for Africa (PMPA)</td>
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<tr>
<td>■ African Medicines Regulatory Harmonisation (AMRH)</td>
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<td>■ National Medicines Regulatory Authorities (NMRAs)</td>
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<td>■ Regional Economic Communities</td>
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<tr>
<td><strong>CONCLUSION – SUMMARY OF DAY’S ACTIVITIES</strong></td>
<td>4:45 – 5:00</td>
<td>15 MINUTES</td>
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<tr>
<td>MODULE AND SESSION</td>
<td>SUBJECT</td>
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<tr>
<td><strong>Day 2</strong></td>
<td><strong>Recap from Day 1</strong></td>
<td>8.30 – 9.00</td>
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<td><strong>Session 3</strong></td>
<td>Regulatory harmonisation challenges and advocacy priorities</td>
<td>9:00 – 9:30</td>
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<td>Case studies from NMRAs</td>
<td>9:30 – 10:15</td>
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<tr>
<td><strong>Break</strong></td>
<td><strong>Tea Break</strong></td>
<td>10.15 – 10.45</td>
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<tr>
<td><strong>Task 1.1</strong></td>
<td>Video the impact of falsified and substandard medicines</td>
<td>10:45 – 11:30</td>
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<td>Group presentation (10 minutes per group i.e. 5 minutes video watching and 5 minutes reactions)</td>
<td>11:30 – 12:00</td>
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<tr>
<td><strong>Module 4</strong></td>
<td><strong>Assessing Progress and Implementation of Regulatory Harmonisation</strong></td>
<td>1 HOUR 30 MINUTES</td>
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<tr>
<td><strong>Session 1</strong></td>
<td>Assessing progress and implementation</td>
<td>12:00 – 12:30</td>
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<tr>
<td><strong>Session 2</strong></td>
<td>New developments in global health technologies</td>
<td>12:30 – 1:00</td>
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<td><strong>Break</strong></td>
<td><strong>Photo Session and Lunch Break</strong></td>
<td>1.00 – 2.00</td>
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<td><strong>Module 5</strong></td>
<td><strong>Advocacy</strong></td>
<td>2 HOURS</td>
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<tr>
<td><strong>Session 1</strong></td>
<td>Integrating advocacy into regulatory harmonisation</td>
<td>2:00 – 3:00</td>
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<tr>
<td><strong>Session 2</strong></td>
<td>Action planning</td>
<td>3:00 – 4:00</td>
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<td>Key advocacy messages for participants</td>
<td>4:00 – 4:15</td>
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<tr>
<td><strong>Conclusion – Summary of Day’s Activities</strong></td>
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<td>4:15 – 4:30</td>
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</table>

| **Day 3** | **Recap from Day 1** | 8.30 – 9.00 | 30 MINUTES |
| | Groups presentation on action plan | 9:00 – 10:00 | 1 hour |
| **Break** | **Tea Break** | 10.15 – 10.45 | 30 MINUTES |
| | Certification of participants | 10:30 – 11:00 | 30 minutes |
| | Workshop evaluation and feedback session | 11:30 – 12:00 | 30 minutes |
| **Conclusion – Close of Workshop’s Activities** | | 12:00 – 12:30 | 30 MINUTES |
| **Lunch and Departure** | | 12:30 – 1:30 | 1 HOUR |
References

References to documents used in the preparation of this manual
