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**AMA Patient Champion Network Guide**



Contents

[I. Introduction 3](#_Toc494362389)

[II. Why AMA? 3](#_Toc494362390)

[III. The Entebbe Statement 4](#_Toc494362391)

[IV. The Campaign 5](#_Toc494362392)

[Phase 1 – Network Building 6](#_Toc494362393)

[Phase 2 – Creating an Action Plan 7](#_Toc494362394)

[Phase 3 - Putting the action plan into practice 8](#_Toc494362395)

[Phase 4 – Next steps 9](#_Toc494362396)

[4. Milestones 9](#_Toc494362397)

[5. Key resources 9](#_Toc494362398)

# I. Introduction

On 4th – 5th July 2017, the International Alliance of Patient Organisations (IAPO) and the Uganda Alliance of Patients’ Organizations (UAPO) held the African Regional Meeting in Entebbe, Uganda, under the theme ‘Harmonisation for Patient-Centred Universal Health Coverage’. This was an opportunity for the community of IAPO’s African members to come together and discuss how patients can engage with the African Medicines Agency (AMA) due to be launched by the end of 2018.

A key outcome of the meeting was the elaboration of a draft joint statement – the Entebbe Statement – calling for a patient-centric African Medicines Agency. The statement highlights the importance of ensuring that patients are placed at the centre of medicines regulatory harmonisation processes undergone in Africa.

Following the regional meeting, IAPO’s African members - provided comments on the draft of the Entebbe Statement, which has been finalised (see page 4). Now is the time to turn this statement into action.

IAPO created this document with the aim of guiding you to use the statement as a campaigning tool, to ensure that patients are recognised as key partners in AMA. It provides a set of tips to help you adapt the campaign to your own national and regional contexts, to ensure that we are maintaining pressure at all levels of decision-making.

At the core of this guide is the use of networks as a foundational starting point. We believe that working together in sub-networks will ensure that policy-makers in each sub-region are aware of our calls for meaningful patient engagement in AMA.

Throughout the campaign, IAPO will be available to support you in developing the networks. As we plan the 2018-2020 IAPO strategy and the 2018 work plan we will be seeking opportunities for building the network through resources and capacity building.

# II. Why AMA?

The African Medicines Agency (AMA) is intended to be an organ of the African Union (AU) with the goal of creating and enabling regulatory environment for medical products in Africa. The Agency is a response to the enormous health challenges on the continent, including lack of access to affordable, quality essential medicines.

The Agency will serve as a catalyst for coordinating national and sub-regional regulatory systems for medical products, providing regulatory oversight of selected medical products, as well as promoting cooperation, harmonisation and mutual recognition of regulatory decisions.

There are four main reasons why a strong regulatory system is needed in Africa:

* **Better access for countries with limited resources.** The establishment of a well-functioning and successful AMA can provide countries with limited resources to have better access to safe and quality assured medicines. According to AMRH, 90 per cent of African NMRAs are incapable of guaranteeing quality, safety, and efficacy due to resource constraints. Because inefficient regulation can results in higher costs for medicines, low and middle income countries are likely to particularly suffer from the lack of a harmonised strategy in medicines regulation.
* **Reducing regulatory fragmentation.** According to the WHO and NEPAD, as of today there are more than 50 different NMRAs in Africa working independently to assess and authorise medicines. These authorities rely on different procedures and have different standards in place, determining a situation of structural fragmentation. One of the primary objectives that the AMA will pursue is stronger consistency across quality standards and regulatory frameworks in the continent.
* **Transparency and certainty.** As highlighted by the WHO, at the moment what is also lacking is a sufficient amount of clarity of the time needed to process an application and arrive at a decision. This lack of clarity places itself within a more general context in which little transparency is in place both “before” and “during the registration process”. The WHO maintains that a more “harmonised” environment would create the conditions for a better understanding of “registration processes” by all stakeholders.
* **A cross-stakeholder process.** It is important that a clear strategy is in place as to the role patients and patient representative could play in a more harmonised regulatory environment. The ongoing conversation on how to set up a more standardised, harmonic, and efficient regulatory process in Africa provides an unprecedented opportunity for healthcare stakeholders to work together and shape rules, policies and procedures in such a way as to render the harmonization process better reflective of the stakeholders’ needs and values in the Region.

Against this background, IAPO and UAPO held the African Regional Meeting to raise awareness about the initiative to harmonise regulatory systems in Africa and discuss how African patients can play an active role on the development of the African Medicines Agency.

# III. The Entebbe Statement

**The Entebbe Statement**

**Call for patients to be recognised as key partners in the African Medicines Agency (AMA)**

* Welcoming the commitment made at the meeting of the African Ministers of Health in Luanda, Angola, in April 2014 to launch AMA by the end of 2018, as a vehicle to harmonise the regulatory activities of all African Union Member States;
* Recognising the need for all patients in Africa to have access to safe, effective, quality, affordable and timely medicines that meet internationally-recognised standards, in line with the Sustainable Development Goal 3.8’s commitment to “leave no-one behind”;
* Recognising the current structural fragmentation of standards and procedures for assessing and authorising medicines in Africa, and the limited resources and capacities of national medicines regulatory authorities, resulting in inefficient regulation, higher medicine costs and therefore unequal, slow and unsafe access for patients;
* Recognising the gap thus far in patient awareness and knowledge of harmonisation in Africa and AMA;
* Recognising some progress but also remaining gaps in AMA’s Institutional Framework (of 26 January 2017) and draft Treaty (of 14 May 2017), regarding the long-term vision of how to involve patients in all of AMA’s governance structures.

We, IAPO’s patient organization members, collaborators and participants of the IAPO African Regional Meeting held in Entebbe, Uganda, 4th - 5th July 2017, call upon the:

1. **AMA Taskforce and Governing Board to recognise patients as key partners in the management structures and development of AMA, making a stronger commitment than that currently present in the** [**AMA Treaty**](https://au.int/sites/default/files/newsevents/workingdocuments/32672-wd-ama_legal_framework_post_addis_-_rev_14_may_clean_copy.pdf)**[[1]](#footnote-1)**
2. **African Union Member States to endorse and ratify the AMA Treaty, recognising patients as key AMA partners;**
3. **The AMA Governing Board to adopt a legally binding patient engagement framework to ensure patients are meaningfully engaged in its core activities to ensure that AMA is patient-centred.**

# IV.The Campaign

This guide is not a rigid prescriptive plan of how you should campaign for patient engagement in AMA. Instead it should be adapted according to each specific network’s priorities and needs.

We have divided the campaign in four phases. These are organised in a chronological order although some can be undertaken simultaneously:

|  |  |  |
| --- | --- | --- |
| Phase 1 | Network Building | September 2017 – December 2017 |
| Phase 2 | Creating an Action Plan | October 2017 – January 2018 |
| Phase 3 | Putting the Action Plan into Practice | November 2017 – November 2018 |
| Phases 4 | Next steps | 2018 (end of campaign TBC) |

As you progress at each phase of the campaign, please don’t hesitate to discuss with us and queries you may have and support that we can offer.

## Phase 1 – Network Building

Only by coming together and pooling our resources, expertise and experiences can we achieve the change we are seeking. Therefore it is crucial that we build robust networks that will allow patient advocates across Africa to maintain the pressure on decision-makers.

One idea to emerge from the African Regional Meeting in Entebbe, Uganda was that delegates wanted to work more closely with sub-regional groups. IAPO members therefore are invited to establish **AMA Patient Champion Networks**. In the spirit of patient empowerment, these will be your networks and therefore you have the freedom to decide what form of network would work best for your local and sub-regional needs and priorities. The networks could be divided along recognised economic area lines, such as East and Central Africa (EAC) , Southern Africa (SADC) , West Africa (ECOWAS) and North Africa, or they could be based on other groupings, such as individual countries.

The goals of the AMA Patient Champion Networks are to:

* Maintain momentum to ensure patients in your sub-region advocate with one strong voice in the call for AMA to recognise patients as partners;
* Develop a pool of skilled and influential patient advocates who AMA and other stakeholders can call on;
* Monitor progress made by patient advocates in your sub-region;
* Update other AMA Patient Champion Networks on progress;
* Coordinate efforts and resources among members and between sub-regions.

Some of the tasks to be undertaken by the AMA Patient Champion Networks could include:

* Develop a stronger understanding of the goals, objectives and desired outcomes of AMA for patients;
* Understand and represent the interests of patients as stakeholders in AMA;
* Monitor and update others on AMA’s developments;
* Respond to and proactively seek opportunities to communicate positively about the Entebbe Statement;
* Undertake stakeholder mapping to seek the key decision-makers and policy-makers from whom the network should be seeking endorsement;
* Support other members of the network in campaigning for change through encouragement, sharing of resources and skills, advice etc.

Below are a few key questions to help guide you when establishing the network and deciding how it will operate in practice:

*Deciding the scope of the network*

* What are the benefits and challenges of building a network composed of organizations from one country, various countries or a sub-region?
* What is feasible to be accomplished?
* Is similarity or diversity of members experience important, or both?

*Engaging with other IAPO members in the network*

* What is the most effective channel for engaging with other members? E.g. email group, telephone, social media?
* If language is a barrier, what can be done for overcoming this / Are there bilingual members who can assist?

*Skills mix of the network*

* What skills and expertise can members bring to the network? E.g. media engagement, social media skills, administration skills, project management, advocacy, links to policy-makers, fundraising experience?
* How can the network benefit from these skills?
* Do you want to allocate specific roles and responsibilities to ensure an efficient network?

*Mastering key topics*

* What knowledge does the network need to have in order to be better prepared for advocating for the statement? E.g. African Medicines Regulatory Harmonisation Initiative, African Medicines Agency, medicines regulation, national regulatory frameworks (what’s essential and what’s in place in the countries).
* How can the network acquire this knowledge?
* Will certain members focus on this?
* Do all members within the network have the same level of knowledge?
* Where to search for information and how to assess its reliability?

*Tip: Refer to* [*IAPO Webinar ‘Making sense of evidence’ Handout - Fiona Morgan*](../../../../../../Capacity%20Building/Webinar%20programme/2017%20webinars/Webinar%201%20-%20Patient%20Info/Fiona's%20docs/IAPO%20-%20Making%20sense%20of%20evidence_Fiona%20Morgan_Handout.pdf)

* What are the best ways to systematise the acquired knowledge in a useful way for the network?

## Phase 2 – Creating an Action Plan

*Planning the activities*

* How does the AMA Patient Champion Network aim to achieve the statement endorsement and ensure that key stakeholders are aware of our calls? E.g. online campaign, event, march, formal submission of the statement to MoH/WHO/NEPAD, proclamation.
* What activities need to be put in place for achieving this?
* How and when does each activity need to be undertaken?
* Which members within the network are responsible for each activity?

*Mapping key stakeholders*

* Which stakeholders are key for the successful implementation of the action plan? E.g. NEPAD, WHO country representative, Ministry of Health, National Medicines Regulatory Authorities, other patient organizations, NGOs working with health (local, regional and international), health reporters, key decision makers, opinion leaders/influencers and potential sponsors.
* What is the role of each stakeholder as well as their level of power and interest in the plan?
* When and how to engage each stakeholder in the plan?
* Are there any stakeholders able to support the network with funding?

*Engaging with other coalitions*

* What are other coalitions doing?
* Is there room for collaboration with other coalitions?
* Can you plan joint events, or even seek to host a side meeting at another organization’s event?

*Getting ready to monitor the action plan*

* What tool will the network use to monitor the plan?
* Who in the network will be responsible for updating the monitoring tool and the other AMA Patient Champion Networks (i.e. in the IAPO African Facebook group)?

## Phase 3 - Putting the action plan into practice

*Reaching out to key stakeholders and establishing meaningful collaborations*

* What activities can be put in place to help create bonds with stakeholders? E.g. Holding regular meetings or phone calls, sharing key information, engaging on social media, planning an activity together.

*Tip: Refer to* [*IAPO’s toolkit ‘Working with partners and stakeholders’*](https://www.iapo.org.uk/sites/default/files/current/iapo_toolkit.html)

*Increasing visibility*

* What are the messages that the network wants to share?
* Are these messages target at the same stakeholder or is it necessary to adapt them to different audiences?
* What are the potential avenues for sharing the messages? E.g. social media, press or broadcast platforms.

*Tips on social media:*

* [PSD2016 Handbook](https://www.iapo.org.uk/sites/default/files/files/PSD2016_handbook_ENG(2).pdf) (p.13)
* [Ten tactics for mastering social media success](https://powerfulpatients.org/2017/07/19/patient-advocacy-ten-tactics-for-mastering-social-media-success/?utm_content=bufferae084&utm_medium=social&utm_source=twitter.com&utm_campaign=buffer)
* [Thunderclap](https://www.thunderclap.it/howitworks)

*Tips on engaging the media:*

* [PSD2016 Handbook](https://www.iapo.org.uk/sites/default/files/files/PSD2016_handbook_ENG(2).pdf) (p.14-15)
* [Communication Advisory](../Communication%20Advisory)
* What materials can the network produce to help spread the messages? E.g. thumbnails, graphics, leaflets, handouts, briefings, banners.
* Engage with IAPO communications and others in the pan-African IAPO network to pool resources.

*Seizing windows of opportunity: engage with the right people at the right time*

* Are there any events or meetings taking place that can be a good opportunity for meeting key stakeholders, promoting the network work, learning something useful or any anything else considered relevant for the implementation of the plan?

*Monitoring the action plan*

* Is the network following the action plan?
* If not, how are the changes affecting the implementation of the action plan?
* How will the changes affect the expected results?
* Are there any necessary adjustments that can be done to improve the initial plan and achieve the expected results?
* Report back to the other AMA Patient Champion Networks

## Phase 4 – Next steps

*Evaluating the action plan*

* Has the network achieved the expected results?
* What worked well and what can be improved next time?
* Have the network had ideas that couldn’t be put in practice? Why?

*Reporting back*

* Which member of the network is responsible for writing the final report on the plan?
* Which member of the network is responsible for elaborating the financial report to IAPO?
* What partners should receive the report (full or short-version)?

*Agreeing on the next move*

* What are the opportunities for the networks to keep advocating for the engagement of patients in the African Medicines Agency? E.g. Elaborating an engagement framework, creating a Pan-African working group.

Tip: Refer to [Framework on the interaction between EMA and patients and consumers organisations](http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/document_listing/document_listing_000235.jsp&mid=WC0b01ac05800aa3cb#section1)

*Building capacities for the next move*

* What skills the networks need to develop in order to work on the agreed next steps?
* Are there any potential partners that can help the networks build capacities for the next steps?

# 4. Milestones

A few key milestones (add to this throughout the campaign so that you can keep track of key dates)

|  |  |
| --- | --- |
| WHAT? | WHEN? |
| ‘3rd Biennial Scientific Conference on Medical Products Regulation in Africa’, Accra, Ghana | 27-28 November 2017 |
| STC Justice and Legal | November 2017 |
| Treaty passed |  |
|  |  |
|  |  |
|  |  |
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|  |  |
|  |  |

Please let us know about any events you add here. We will circulate the opportunities across the network to ensure other members can also engage.

# 5. Key resources

Here below, you’ll find a list of all resources referred to in this guide:

* [Margareth Ndomondo-Sigonga about AMRH and AMA](https://youtu.be/LBAbCVvsjcA)
* [IAPO Webinar ‘Making sense of evidence’ Handout - Fiona Morgan](../../../../../../Capacity%20Building/Webinar%20programme/2017%20webinars/Webinar%201%20-%20Patient%20Info/Fiona's%20docs/IAPO%20-%20Making%20sense%20of%20evidence_Fiona%20Morgan_Handout.pdf)
* [IAPO’s toolkit ‘Working with partners and stakeholders’](https://www.iapo.org.uk/sites/default/files/current/iapo_toolkit.html)
* [PSD2016 Handbook](https://www.iapo.org.uk/sites/default/files/files/PSD2016_handbook_ENG(2).pdf) (p.13)
* [Ten tactics for mastering social media success](https://powerfulpatients.org/2017/07/19/patient-advocacy-ten-tactics-for-mastering-social-media-success/?utm_content=bufferae084&utm_medium=social&utm_source=twitter.com&utm_campaign=buffer)
* [Thunderclap](https://www.thunderclap.it/howitworks)
* [PSD2016 Handbook](https://www.iapo.org.uk/sites/default/files/files/PSD2016_handbook_ENG(2).pdf) (p.14-15)
* [Communication Advisory](../Communication%20Advisory)
* [Framework on the interaction between EMA and patients and consumers organisations.](http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/document_listing/document_listing_000235.jsp&mid=WC0b01ac05800aa3cb#section1)

# Template documents

1. For example, 19.3 of the AMA Treaty (May 2017) says the Board may appoint to the Technical Working Groups (TWGs) “as consultants, additional experts from academia, research community, industry and consumer and *patient groups*.’ This commitment should be strengthened to *guarantee* the inclusion of patient groups in a specified number of TWGs. [↑](#footnote-ref-1)