

## PRESS RELEASE

### **Patients, product development partnerships and private health sector representatives call for the rapid ratification of the African Medicines Agency Treaty to speed up timelines to vaccines and medicines approval**

**London / Geneva, 5 February 2021** - On the eve of the 34<sup>th</sup> African Union Summit, two years after the Treaty to establish an African Medicines Agency was agreed, over 40 leading organizations who represent hundreds of thousands of patients, product development partnerships, youth groups, researchers and industry leaders, [are urging Heads of State and Government to ratify the Treaty](#) as a matter of priority. Delaying the establishment of an African Medicines Agency (AMA) undermines the timely access to effective, quality therapies, and vaccines for all patients across Africa.

The COVID-19 pandemic has highlighted the importance of regulatory harmonisation in the context of public health emergencies and the urgent need for a competent continent-wide regulatory authority to approve and monitor vaccines, repurposed medicines, innovative medicines and health technologies, in a timely manner.

Two years after African Union Heads of State and Government endorsed the treaty establishing the AMA, legal commitment from more countries remains to be secured for the continent-wide regulatory agency to become a reality. The Treaty has so far been signed by 19 countries<sup>1</sup>, and 8 out of the necessary 15 have already ratified it<sup>2</sup>.

The agency would follow a similar mandate to other global medicines regulatory agencies, such as the European Medicines Agency and the U.S. Food and Drug Administration. The AMA would provide an enabling environment for research and development, country participation in clinical research and other scientific development activities, as well as open more opportunities to boost local manufacturing capacities. Furthermore, the AMA would help effectively manage the prevalence of substandard and falsified medical products, currently inflicting severe pain and harm on patient's lives, due to porous borders and ineffective regulatory control.

*"The African Medicines Agency is the cornerstone of establishing a sustainable public health system in Africa", says Kawaldip Sehmi, CEO of the International Alliance of Patients Organizations (IAPO). "A number of leading countries have signed the treaty and close to half of them have so far transposed it into national law. Paradoxically, the ratification process has sometimes been delayed with attention shifting towards the COVID-19 response. That is precisely what the AMA's mission will be: to help African countries fight disease outbreaks by ensuring that only high-quality drugs, vaccines, and other health-related supplies reach the market and health systems from Cape to Cairo".*

*"There have been positive moves towards regulatory harmonization in Africa. However, the establishment of the African Medicines Agency is a critical next step to enable all patients in Africa to have timely access to quality medicines that are safe and effective", added Adam Aspinall, chair of the Fight the Fakes Alliance.*

*"Regulatory systems strengthening and harmonization efforts are key for optimizing sustainability in the supply and access of medical products and technologies for diseases disproportionately affecting Africa", said Karim Bendhaou, Head of Africa Affairs, Merck and IFPMA Chair, Africa Engagement Committee.*

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<sup>1</sup> Full list of signatories as of 2 February: Algeria, Benin, Burkina-Faso, Chad, Gabon, Ghana, Guinea, Madagascar, Mali, Morocco, Niger, Rwanda, Sahrawi Arab Democratic Republic, Senegal, Seychelles, Sierra Leone, Tunisia, DRC.

<sup>2</sup> Full list of countries who have ratified as of 2 February: Rwanda, Mali, Burkina Faso, Ghana, Seychelles, Guinea, Morocco, Namibia.

The following organizations support this call (in alphabetical order):

1. Action Group for Health, Human Rights and HIV and AIDS – AGHA
2. African Heart Network
3. African Liver Patients Association
4. African Research Network for NTDs –ARNTD
5. Association of Representatives of Ethical Pharmaceutical Industries - AREPI
6. Association pour la Lutte contre les Hépatites Virales "ALHV"
7. Centre for Initiative and Development - CFID Taraba
8. Coalition for Access to NCD Medicines and Products
9. Drugs for Neglected Diseases initiative – DNDi
10. Federation of African Pharmaceutical Manufacturers Associations - FAPMA
11. Fight the Fakes Alliance
12. Generic and Biosimilar Medicines of Southern Africa
13. German Medical Aid Organization action medeor e.V
14. Global Pharma Health Fund
15. Global Self-Care Federation
16. GS1
17. Heart and Stroke Foundation South Africa
18. Hepatitis Foundation of Ghana
19. International Alliance of Patients' Organizations - IAPO
20. International Federation of Pharmaceutical Manufacturers and Associations - IFPMA
21. Innovative Pharmaceutical Association South Africa – IPASA
22. International Pharmaceutical Students' Federation - IPSF
23. Kenya Association of the Pharmaceutical Industry- KAPI
24. Kenya Healthcare Federation
25. Les entreprises du médicament -LEEM
26. LiveWell Initiative - LWI
27. Management Sciences for Health
28. Medical Mission Institute Würzburg
29. Mental Health Society of Ghana – MEHSOG
30. Multiple Sclerosis South Africa
31. National Community of Women Living with HIV in Uganda – NACWOLA
32. NCD Alliance Ghana
33. NCD Alliance Kenya
34. Pan African Positive Women's Coalition
35. PATH
36. Patient and Community Welfare Foundation of Malawi - PAWEM
37. Pharmaceutical Society of Kenya
38. RTI International -Center for Global Noncommunicable Diseases
39. Sharecare Ghana
40. South African NCDs Alliance
41. Speak Up Africa
42. Stowelink Inc.
43. Thalassaemia International Federation
44. Uganda Alliance of Patient Organisations
45. Women in Hepatitis Africa
46. World Heart Federation

### **About the International Alliance of Patients' Organizations (IAPO)**

International Alliance of Patients' Organizations (IAPO) is a unique global alliance representing patients of all nationalities across all disease areas and promoting patient-centred healthcare around the world. Our full members are patients' organizations working at the international, regional, national and local levels to represent and support patients, their families and carers.

Through IAPO's 300 members we represent 52 disease areas and over 71 countries. Everything we do is focused on promoting patient-centred healthcare. We do this by being the global voice for



people who suffer from all diseases, and by being the focal point for patients' organizations around the world. We nurture relationships with members, partners and healthcare stakeholders, and build dialogue with decision-makers to promote our vision of patient-centred healthcare globally. Since our formation in 1999, we continue to get patient-centred healthcare firmly on the global health agenda. We aim to ensure that this remains front of mind for international policy makers such as the United Nations and the World Health Organization. Whilst we are based in central London, our voice, impact and sphere of influence is global. If you would like to get involved or learn more, visit our website [iapo.org.uk](http://iapo.org.uk) or send us an email to [info@iapo.org.uk](mailto:info@iapo.org.uk).