New Non-State Actors Alliance calls on behalf of patients, industry for urgent action to set up the African Medicines Agency by the end of 2021

22 June – Paris/Geneva/London – Ministers of Health from four African countries (Algeria, Democratic Republic of Congo, Egypt and Cabo Verde), representatives from international organizations, patient groups and the pharmaceutical industry reiterated today at a high-level roundtable event the urgency of establishing a regulatory authority across Africa, especially in the context of the COVID-19 pandemic. The current fragmented regulatory systems across the continent are making it difficult to mount an appropriate response.

Ministers of Health and roundtable participants outlined the first areas of work for the AMA and agreed that it has the unique opportunity to become one of the most efficient and modern regulatory systems in the world. Once established, it will perform a vital task in overseeing rapid and effective market authorisation of safe, quality, effective and accessible vaccines, medicines, and health devices to control and treat disease across Africa to robust regulatory standards. Crucially, it will foster reliance and regulatory harmonization across the continent. In practice, this means that national regulatory authorities will be able to build on the work done by counterparts in other countries, significantly cutting down the time it takes for medicines, vaccines or diagnostics to reach the market. For many countries, the AMA also holds the promise of driving industrial and economic growth, through encouraging the development of local pharmaceutical industry and the establishment of centres of excellence for research across the continent.

But while commitment to the AMA mission and vision is strong, it has not translated into concrete actions. A new cross-stakeholder alliance announced at the roundtable, the African Medicines Agency Treaty Alliance (AMATA), will seek to push for rapid ratification of the Treaty, as well as meaningful engagement with patients, industry and other relevant parties once the Agency becomes operational.

Michel Sidibé, Special Envoy of the African Union, said: "The delay in establishing the African Medicines Agency is hindering much-needed improvement of the regulation of medicines, medical products and technologies across the continent. I am heartened to see the launch of the African Medicines Agency Treaty Alliance, today and urge ministers of health who have not yet done so, to set the process in motion for the rapid ratification of the AMA".

Kawaldip Sehmi, CEO of IAPO, said: "The launch of the African Medicines Agency Treaty Alliance represents a key milestone in our campaign for patients' interest in Africa. Respecting the principle of 'nothing about us without us', we are stressing that the AMA needs to establish a particular framework and structure to engage with African patients and consumers like their European or American counterparts already do".

Karim Bendhaou, chair of the IFPMA Africa engagement committee echoed the new alliance's goals: "The African Medicines Agency will contribute to regulatory harmonization across Africa to enable collaboration, work-sharing and the use of reliance procedures, which will mean a win-win for national regulators, patients and industry. We hope we're reaching a tipping point on establishing the AMA and hope to see significant progress in the ratification process by the end of the year".

Philippe Lamoureux, Director general of Leem, said: “We are delighted to support this initiative and look forward to engaging with the AMA Treaty Alliance to achieve its goals for better patient access to medicines in Africa”.

Note to editors:

The African Medicines Agency will enter into force once ratified by fifteen African Union member states (out of 55). The African Medicines Agency Treaty Alliance was announced at a roundtable organized by the International Alliance of Patient Organization (IAPO), the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and the French Association of Pharmaceutical Companies (Leem), at the initiative of the Special Envoy of the African Union, Michel Sidibé.

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 the United Nations and the World Health Organization. Whilst we are based in central London, our voice, impact and sphere of influence is global.
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About the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
IFPMA represents research-based pharmaceutical companies and associations across the globe. The research-based pharmaceutical industry's 2 million employees research, develop and provide medicines and vaccines that improve the life of patients worldwide. Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community find solutions that improve global health.
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About Les Entreprises du Médicament (Leem)

Leem is the French industry association of drug companies operating in and from France. Leem has more than 260 member companies. It represents companies in the pharmaceutical sector carrying out research and development, manufacturing operation, distribution, or importing pharmaceutical specialties for human use. Its members are subsidiaries of large international groups as well as SMEs, and biotechs. Leem represents pharmaceutical companies to numerous national, European and international bodies. It is the main interlocutor of political decision-makers, and as such, the association plays a key role as intermediary, and as a source of proposals to promote the development of the industry, contribute to the development and promotion of research, innovation and production. The role of Leem is also to ensure the respect of the ethical rules of the profession, through an independent body (the “Codeem”), which ensures a mission of ethics watch, awareness, mediation and sanction, following a proactive self-regulation initiative on the part of drug companies.

On a daily basis, Leem deciphers the sector's environment and provides its members and public authorities with in-depth, quantified and reasoned studies and analyzes future challenges and current affairs in the sector. Leem is also a privileged place of exchange between companies, from which the debate and the construction of common sectoral positions emerge.

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