AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

AUDA-NEPAD COVID-19 SERIES

African Union Smart Safety Surveillance (AU-3S) and Coronavirus disease 2019 (COVID-19)

Volume 1

6 April 2020

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What are the safety challenges of COVID-19?

Generally, the safety of vaccines, medicines, medical devices and other medical products are monitored and managed to ensure their safety. The detection, assessment, understanding and prevention of adverse effects or any other medicine-related effect is to ensure that the medical products and other health technologies are safe throughout the product life cycle. It is an essential public health activity designed to ensure that interventions, including medical products and other health technologies, retain a favourable benefit-risk profile throughout their entire life cycle [1].

Clinical trials are undertaken in well-controlled environments, for short periods, and do not generally include special populations (such as pregnant women, children and the elderly) and often exclude participants with co-morbidities. Therefore, at the time of granting marketing authorization for real-world use of products, information on their safety and efficacy is limited, and post-market surveillance becomes key in collecting point of application data on any medical product and other health technology.

Hitherto, high-income countries (HICs) did the trials, collected the safety data, and LMICs relied on them, but this has changed. Increasingly, new medical products and other health technologies are being launched for the first time in Africa and many Lower/Middle-Income Countries (LMICs) to manage diseases that are endemic in these regions which are not of concern in the HICs. Safety data for Africa to rely on is significantly reduced, and Africa has the responsibility of collecting and managing her safety data.

COVID-19 pandemic, like many emergencies, brings an additional dimension to this difficulty. The shortening of the time and path to market for many interventions become even more justifiable. In the specific case of COVID-19, products like alcohol-based sanitizers, test kits, vaccines, medications and ancillary health products are needed to save human lives. The urgency, therefore, necessitates that processes, regulations will be relaxed or abridged to allow for products to be made available in a timely manner. These flexibilities have their inherent risks that may worsen the safety of the citizens of Africa.

What can AU-3S do for COVID-19?

There will be trials for new COVID-19 interventions and the registration of products that have gone through clinical trials elsewhere and urgency will be the prime focus. The safety of these products will be secondary. For African authorities to make informed decisions about the safety of these products, there is the need for an end-to-end system from clinical trials to post-registration and that this should be continental. Examples of products will include: Alcohol-based sanitizers, hydroxychloroquine, lopinavir, ritonavir and other COVID-19 related products

The African Union has called upon the AUDA-NEPAD to work with partners to ensure support for the acceleration of candidate drugs and vaccines so that African populations can access them in a timely manner and that they should be safe [2]. This call was especially emphasized during the period when the continent was confronted with the Ebola epidemic in West Africa.

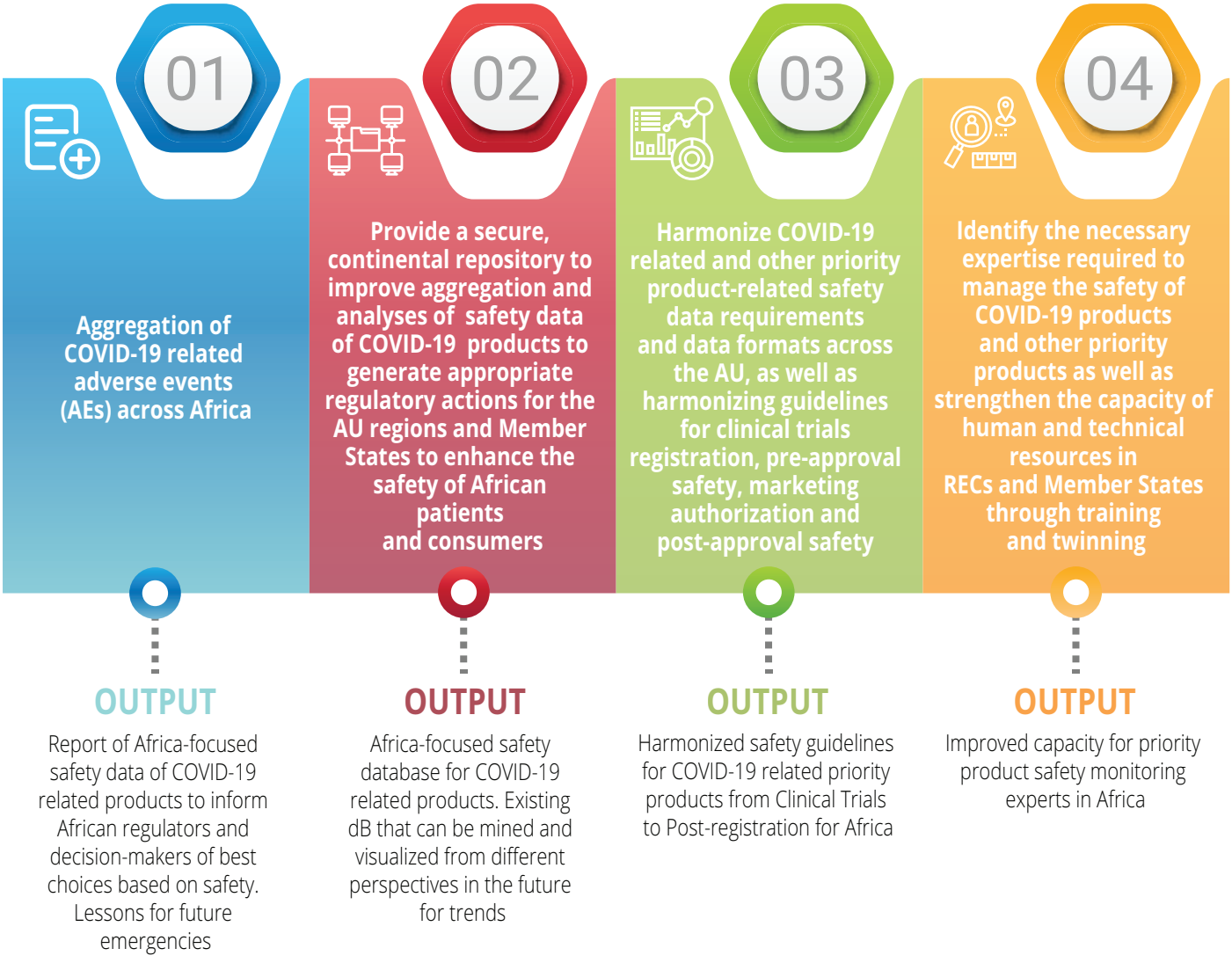
An Africa-wide effective and end-to-end safety surveillance system is necessary to support the safe launch of these products in Africa while tackling public health needs towards achieving the African Union Agenda 2063 Aspiration 1[3], Goals 1 & 3 and the Sustainable Development Goal 3[4] (SDGs). AU-3S fulfils this need by facilitating the introduction of innovation in a less risky environment for developers to invest in accelerated product development.

The system will cover the entire product life cycle from clinical trials through product approval to post-approval monitoring for safety and effectiveness. Public confidence in medical product and other health technology safety is ensured, supporting the uptake of public health interventions and enabling access to innovative treatments, thereby tackling significant public health challenges. It will also boost

developers' confidence to take the risk associated with accelerated product development for emergency responses.

AU-3S, therefore, serves as a safety net for the rapid development of intervention products for pandemics like COVID-19, epidemics like Ebola Virus Disease (EVD), and emergency response in the case of large-scale endemic diseases such as malaria, tuberculosis (TB), dengue fever and cholera. The reduction of development time during emergency response contributes to a limited safety data package. AU-3S, therefore, bridges this safety gap. These flexibilities underscore the need for a viable 3S programme in the continent as a critical contributor towards meeting emergency response needs as well as a confidence booster for developers to take the risk associated with accelerated product development.

AU-3S can provide the following for COVID-19



Schedule of Proposed Activities

Objective	Activities	Timelines immediate (1 to 6 months), ntermediate (6-12 months) and long term (1 year and beyond)	Deliverables	Engagement with Member States and other stakeholders
• Aggregation of Covid-19 therapy related Adverse Events across Africa	• Collect information on all products used in Covid-19 from a cross-section of MS.	Immediate to intermediate	Report of Africa-focused safety data of Covid-19 related products • to inform African regulators and decision-makers of best choices based on safety. • Lessons for future emergencies	liaise with MS to report all products used in Covid-19
	• collate Covid-19 related AEs from selected MS on all products in Covd-19			
	• Pool together safety data on on-going Clinical Trials			

Objective	Activities	Timelines immediate (1 to 6 months), ntermediate (6-12 months) and long term (1 year and beyond)	Deliverables	Engagement with Member States and other stakeholders
• Provide a secure, continental repository to improve aggregation and analyses of safety data of Covid-19 products to generate appropriate regulatory actions for RECs and Member States to enhance the safety of African patients and consumers.	• Landscape assessment for Covid-19 related data collection, storage and management conducted to determine baseline requirement, capability/ gaps and best practices at a continental level to identify already successful platforms • Enter Covid-19 related data into AfriVigilance • Create Covid-19 specific database within AfriVigilance for Covid specific vizualisation of dta from Clinical trials through product registration to post-market surveillance	intermediate to Long term	Africa-focused safety database for Covid-19 related products. Existing dB that can be mined and visualized from different perspectives in the future for trends	a pilot involving a cross-section of MS will be conducted

Objective	Activities	Timelines immediate (1 to 6 months), ntermediate (6-12 months) and long term (1 year and beyond)	Deliverables	Engagement with Member States and other stakeholders
• Harmonize Covid-19 related and other priority product related safety data requirements and data formats across the AU, as well as harmonizing guidelines for clinical trials registration, pre-approval safety, marketing authorization and post-approval safety	• Develop guidance on how to monitor the safety of promising Covid-19 products • Develop guidelines on how to monitor safety of new Covid-19 vaccines	intermediate to long term	Harmonized safety guidelines for Covid-19 related priority products from Clinical Trials to Post-registration for Africa	
• Identify the necessary expertise required to manage the safety of Covid-19 products and other priority products as well as strengthen the capacity of human and technical resources in RECs and Member States through training and twinning	• assessment of capacity gaps for the management of Covid-19 related data • development and implementation of capacity strengthening programme	intermediate term	Improved capacity for safety monitoring experts in Africa.	

About African Union Smart Safety Surveillance (AU-3S)

The AU-3S programme is a smart fit-for-purpose continental safety surveillance system (encompassing both passive and active surveillance approaches) for priority products that will support African Union Member States, at the continental level, to safeguard the health of their citizens. The system covers the entire product life cycle from clinical trials through product approval to post-approval monitoring for safety and effectiveness. Priority diseases such as Covid-19 will inform criteria and selection of products including innovative and emerging products/technologies and emergency response needs. The AU-3S programme is guided by the principles of an African continental approach, prioritization, reliance and sustainability. The programme employs an integrated approach that will define the required principles and structures that need to be in place for AU Member States to enable informed and appropriate decision making in the context of safety data collection, analysis, signal detection, and appropriate regulatory action. This also includes capacity strengthening that can enable appropriate regulatory actions that reflect the context of point of care bridged with the risk assessment analysis from wider data. The AU-3S programme will be implemented under three major priority areas, namely: an appropriate governance model; fit-for-purpose technologies; and adequate resourcing to ensure consistent normative standards drive the assessment, decision making and other pertinent aspects of the process. The AU-3S programme is underpinned by overarching AU policies facilitating and enabling medical product safety decisions for the continent where appropriate. The implementation of AU-3S embraces a risk-based prioritization of investment, work sharing, joint activities and reliance for maximum return on investment.

About Coronavirus disease 2019 (Covid-19)

Coronavirus disease 2019 (COVID-19) is a respiratory illness that can spread from person to person. The virus that causes COVID-19 is a novel coronavirus that was first identified during an investigation into an outbreak in Wuhan, China.[5]

In addition to the public health impact, the Coronavirus (COVID-19) has resulted in mass production shutdowns and supply chain disruptions due to port closures in China, causing global ripple effects across all economic sectors in a rare “twin supply-demand shock”. Africa is beginning to feel its full impact and plans to control and manage the humanitarian challenges of the virus are underway across the continent. Economically, the effects have already been felt - demand for Africa’s raw materials and commodities in China has declined and Africa’s access to industrial components and manufactured goods from the region has been hampered. This is causing further uncertainty in a continent already grappling with widespread geopolitical and economic instability.[6]

Endnotes

1 Mt-Isa, S., Ouwens, M., Robert, V., Gebel, M., Schacht, A., and Hirsch, I. (2016) Structured Benefit–risk assessment: a review of key publications and initiatives on frameworks and methodologies. Pharmaceut. Statist., 15: 324–332. doi: 10.1002/pst.1690.

2 Decision on the Report of Heads of State and Government Orientation Committee (Hsgoc) on NEPAD Doc. Assembly/AU/10(XXIV) 30 - 31 January 2015 Addis Ababa, ETHIOPIA https://au.int/sites/default/files/decisions/9665-assembly_au_dec_546_-_568_xxiv_e.pdf

3 A prosperous Africa based on inclusive growth and sustainable development

4 Ensure healthy lives and promote well-being for all at all ages

5 "Coronavirus Disease 2019 (COVID-19) | CDC." https://www.cdc.gov/coronavirus/2019-ncov/index.html.

6 The Impact of COVID-19 on Key African Sectors. https://www.bakermckenzie.com/en/insight/publications/2020/03/the-impact-of-covid19-on-key-african-sectors

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