Africa hopes to speed up medicine approval systems

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Bringing a new medicine to market in Africa requires 54 separate applications to each country on the continent, a time-intensive process that could be costing lives. African leaders are now trying to move toward a regional and eventually continentwide approach to speed the process.

Africa could see a continentwide equivalent of the Food and Drug Administration in a decade, depending on the success of regional initiatives, said Margareth Ndomondo-Sigonda, a former director of Tanzania's Food and Drugs Authority. African leaders are first working through regional economic communities to "harmonize" the regulation of medicines on the continent.

Because of medical regulations that vary from country to country, Ndomondo-Sigonda said that an application for a drug approval submitted to Tanzania might take two years, for example. But an application submitted to neighbors Uganda or Kenya could take far longer, depriving patients there of care.

Unni Karunakara, the international president of the French group Doctors Without Borders, said his group has seen patients in Africa suffer because they didn't have the right treatment available to them. He said today the medical community is able to dream of the day of eliminating diseases in many parts of Africa, though he noted that providing treatment in the 10 to 15 percent of the continent ravaged by conflict will remain difficult.

More than 400 scientists, ministry of health officials and other experts met in Nairobi this week to push for more funding and research in Africa. The meeting was sponsored by the Drugs for Neglected Diseases initiative, a body that works to improve drug research for neglected diseases often seen only in Africa.

The first regional harmonization effort was launched in March of 2012 in the East Africa Community, which includes Kenya, Tanzania, Uganda, Rwanda and Burundi. Hiiti Sillo, director general of the Tanzania Food and Drugs Authority, said the project, which is funded by the Bill and Melinda Gates Foundation, will help drug manufacturers to prepare one set of technical documents instead of dozens for the continent.

"The net benefit is that the capacity to regulate quality and safe medicines in Africa is built and patients are assured that medicines are safe, quality and effective and that these products are made available to the patients as quickly as possible," Sillo said. "This is similar to what is happening at the European Union level. This is the future and it will have a lot of benefits."

Marcel Tanner, the director of the Swiss Tropical and Public Health Institute and chair of the board of directors of the Drugs for Neglected Diseases initiative, said that if African leaders can create an equivalent to the FDA or the European Medicines Agency it "would be enormously helpful to bring new products to the people."

"Traditionally you have very bad registration authorities or weak ones, and you have all these different standards," he said of African regulatory bodies.

This week's conference saw medical leaders call for African governments to dedicate more money to medical research. Many of the

world's most intractable diseases continue to trouble the largely impoverished continent.

"I think it's time Africa spent a lot more time and resources on home-grown research," said James Macharia, the secretary of Kenya's Ministry of Health. "Africa ranks very high in terms of disease, so we have to have home-grown solutions."