International Federation
of Pharmaceutical
Manufacturers & Associations

event highlights

IFPMA

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DIA, *Fondation* Chirac, the World Bank Group, and IFPMA hosted a roundtable for media from Africa and Senegal on 28 April in Dakar, a special press event of the 4th African Regulatory Conference. Find out what key speakers had to say about the Africa regulatory roadmap for improving access to quality medicines.

WHAT'S NEEDED TO ACCELERATE ACCESS TO SAFE AND QUALITY MEDICINES AND VACCINES IN AFRICA?

This media roundtable event was organized at the margins of the 4th African Regulatory Conference (ARC) that took place in Dakar from 27 to 28 April and preceded the day-long Counterfeit Medicine's Workshop on 29 April 2015. The event was organized to highlight the key outcomes emanating from ARC and lay out the main components that the workshop on counterfeit would address.

Professor Amadou M. Dieye, Director of the Pharmacy and Medicines Directorate of Senegal, inaugurated the event and introduced the Senegalese Authority's proposed solutions on increasing access to quality medicines. He welcomed the idea of setting-up a centralized agency that oversees medicines registration in Africa, starting with such a mechanism being in place within West Africa. He also described the different tactics that his country, Senegal, adopted to effectively curb counterfeit medicines. These tactics included strengthening the legislative framework, fostering collaboration between sectors, and leading special field operations such as the one undertaken in 2014 which mobilized different state agencies and led to the arrest of 42 people involved in this illicit trade.

Dr Vincent Ahonkhai, Senior Advisor, Global Health, Bill and Melinda Gates Foundation and co Chair of 2015 ARC, set the scene for the media roundtable.

He started by reemphasizing the vision of the Foundation that every person deserves to live a healthy and productive life. Access to good, quality medicines that are safe and can be made available to poorer countries and communities of the world is a key part of meeting that vision. As Africa happens to be one large geographic area where these poorer communities exist and where medicines are used to treat and prevent deadly diseases, ensuring that these medicines are safe and effective is very much dependent upon a well-functioning regulatory system. The affordability component is also being examined by aid organizations and other stakeholders, in particular for malaria, HIV, TB and other infectious diseases. He pointed out that today all stakeholders are left with no choice but to cooperate and attend to regulatory issues in a methodical way. Recognizing that this is not an easy task, he optimistically welcomed the genuine progress that could be observed in some regions of the continent.

The moderator, ***Radio France Internationale* (RFI)'s Ms Claire Hedon**, then opened the debate, engaging with the panellists through various questions such as what's needed to accelerate access to quality medicines and curb the threat of counterfeit medicines.

Dr Mercè Caturla, Global Access Regulatory Lead at Janssen, the pharmaceutical companies of Johnson & Johnson, and Chair of IFPMA's Africa Regulatory Network, underlined the crucial role of regulatory harmonization in Africa, not only for industry, but for all stakeholders involved in facilitating access to medicines. She explained that today, the process for both the registration and regulatory maintenance of medical products throughout their life-cycle is lengthy in comparison to other regions. The reason being that each of Africa's 54 countries were currently requesting many different regulatory requirements, rendering the whole process very complex, which ultimately impacts patient access to needed medicines. In developing regional harmonization within Africa, sharing resources and competencies amid regulatory authorities is key. The removal of regulatory hurdles would help to create a harmonized regulatory framework with faster approvals thereby bringing benefits for all, including patients in Africa.

She concluded that Africa needed to see more trust developed between neighbouring countries. For example, one entity could approve regulatory submission dossiers and undertake Good Manufacturing Practices (GMP) inspections. This would help to confirm the quality of medicines, avoid redundancy, and pave the way for the development of regional guidelines. If not done collaboratively, harmonization will be lost at the expense of patients.

Dr Corneille Traoré, Director of Health, Social Protection and Mutual Insurance of the Commission of the West African Economic and Monetary Union (WAEMU) and co-Chair of 2015 ARC, summarized the key elements debated during the two day conference stating that "Convergence is built when countries come together and are conscious that harmonization will put together the competence needed for the approval of medicines. If all have the same requirements, they will be able to process the submitted files and shorten delays for patients to get those quality medicines. Beyond willingness, we need to reinforce and strengthen the capacity of such countries, so that they can reach that objective and have the necessary autonomy to evaluate fully the quality, safety, and efficacy of a medicine. This can be improved and we now have examples from East Africa where a coherent process has been initiated bringing a unique solution for the region. This is inspiring for other regions as well."

Turning to counterfeit medicines, the debate evolved with West Africa Health Organization (WAHO)'s perspective reflected in the intervention made by **Ms Sybil Ossei-Agyeman-Yeboah**, WAHO's Professional Officer, Essential Medicines and Vaccines. She explained that counterfeiters are not sleeping, they have a very lucrative business, and they come with products that have detrimental effects and they can kill people. For example, fake antimalarials kill people and real lives are put at great risk. In response to the specific question on whether countries were observing their international obligations, **Ms Ossei-Agyeman-Yeboah** confirmed that governments indeed made commitments. However, given the porosity of countries' borders and lack of security, there was a need to look at the problem globally and apply actions that are common amid the regions. "What we need is an anti-counterfeit action plan and a regional law developed and validated to control and fight this plight. We know this isn't an easy task to curb medicines' counterfeiters, but together we'll make it."

Professor Marc Gentilini, Fondation Chirac, reminded the audience that counterfeiters are criminals and governments and policy makers must do what it takes to end impunity in this area. "Different stakeholders have a role to play in this fight, working in silos doesn't help. Collaboration between and within countries is required and strong regulatory and legislative systems are paramount to achieve this goal," he added.

The Medicrime Convention

Professor Gentilini explained that "Today we have a legal framework at our disposal. In fact, the Medicrime Convention is the first international legal instrument criminalizing counterfeiting which is open to signature and ratification by all states – members or not - of the Council of Europe. It offers an opportunity to establish international cooperation, which has been sorely lacking in the fight against counterfeiting of medicine, and currently counts 23 signatory states, including three that are not members of the Council of Europe (two of which are from Africa: Guinea and Morocco). Only one more signatory state must ratify in order to bring the convention into force, which will certainly renew mobilization. Regional initiatives are also essential, because they involve responsible parties, elected officials and individuals closer to the reality in the field. Like the European Union, which armed itself with a directive along these lines in 2011, the African states should also invest in harmonizing their regulations. In Africa, authorities and professionals are expressing increasing interest in being better informed on the regulations and initiatives that may be transposed into their health systems."

Q & A

Q. ***In the ARC press release***, you mentioned that in Africa, it could take up to five years longer for medicines to be available for patients than for those in other parts of the world. Why is that?

A. Dr Mercè Caturla: "It is indeed lengthy because there is no consistent process in place to get timely approvals. Yet we are seeing progress when these processes are in place. Things are indeed changing step by step, so we remain positive."

A. Ms Sybil Ossei-Agyeman-Yeboah: "The process of harmonization is to ensure quicker availability of these medicines for patients. To expedite the process, a common dossier assessment will shorten the time spent on its evaluation without compromising the quality of the evaluation itself."

A. Dr Vincent Ahonkhai: "Access to medicines is going by one speed, the other is affordability. We must be frank about this. Some medicines remain unaffordable for the vast majority of the African population. A multi-stakeholder approach to adequately address this aspect is also one of the avenues we should explore."

A. Professor Dieye: "I disagree with this information. We do everything possible, at least, at the level of the Senegalese Authority to ensure that patients get the therapies they need, including the most innovative ones as fast as possible, very often in granting special temporary approvals."

Q. What is your perspective on the use of traditional medicines in Africa?

A. Ms Sybil Ossei-Agyeman-Yeboah: "Within WAHO, we have adopted measures where traditional practitioners are integrated and work together in a formalized way in a hospital structure. We are aware that traditional medicines may create kidney failure, so the best is to assert their benefits for common use."

Q. Are we talking too much instead of acting on the issues related to good governance?

A. Dr Corneille Traoré: "It is true that the procedures are lengthy. Yet good governance is indeed needed. But at same token, we need our leaders to have an accelerated formula for their population to access vital drugs when necessary – and expedite the process when needed."

Q. If we de-localize – develop medicines locally in Africa - would that improve access to medicines?

A. Dr Mercè Caturla: "It can be done in practice, but at same time you also need to innovate. Basically, there is space for everyone as long as they produce quality medicines: innovators, local and international generic manufacturers."

Q. What are the potential risks of buying medicines on the internet?

A. Professor Marc Gentilini: "Simply because, on the internet, it is difficult to know the origin of the drugs. We don't have means to control the quality of medicines. I would also like to stress that traditional medicines are an ambiguous term. We should not fight counterfeits, then propose another danger derived from phytotherapy that are not based on scientific practice. We should not make poor people think that this is safe to buy treatments outside of the legal supply chain."

Conclusion & Summary Remarks

Dr Andreas Seiter, Senior Health Specialist, Pharmaceuticals, the World Bank Group, concluded by providing a wider perspective on the issue. He re-emphasized the engagement of the World Bank to fight poverty, addressing the challenges from a health perspective where most of the out of pocket money goes to medicines expenditure. He illustrated his point with the example of buying bad medicines, for instance antimalarial medicines with no active ingredient. "You spend money on something that is useless. Instead of buying clothes or food, you end up with a double burden: a health and economic tragedy." To conclude he shared the World Bank's philosophy on harmonization by saying "we think that collaboration, division of labor within sectors, will not only bring up the standards but avoid repeating what has been done by others. It is essential and we back it fully."

Program

Opening

Professor Amadou M.DIEYE,
Director of the Pharmacy and Medicines Directorate of Senegal

Setting the Scene

Introduction – Global Health Community Engagement

Dr Vincent AHONKHAI, Senior Advisor, Global Health, Bill & Melinda Gates Foundation

The Debate

Moderator

Ms Claire HEDON, Journalist at Radio France Internationale (RFI)

The Regulatory Framework in Place

Dr Mercè CATURLA, Global Access Regulatory Lead at Janssen, the pharmaceutical companies of Johnson & Johnson, Chair of IFPMA African Regulatory Network (ARN)

The African Context

Dr Corneille TRAORÉ, Director of Health, Social Protection and Mutual Insurance of the Commission of the West African Economic and Monetary Union (WAEMU)

Addressing Counterfeiting from a Governmental Organization Perspective

Ms Sybil OSSEI-AGYEMAN-YEBOAH, Professional Officer, Essential Medicines and Vaccines, West Africa Health Organization

Impact of Counterfeiting from a Civil Society View

Professor Marc GENTILINI, General Delegate, *Fondation* Chirac

Closing Remarks

Dr Andreas SEITER, Senior Health Specialist – Pharmaceuticals The World Bank Group

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