Overcoming regulatory challenges in Sub-Saharan Africa

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Agenda – Overcoming regulatory challenges in Sub-Saharan Africa

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Speakers

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Senior Science Editor

- Ph.D. (Molecular Biology), Belgium
- Vaccines for infectious diseases

Stephen DuPraw,  
Managing Editor, Content Operations

- The Incidence and Prevalence Database
- Disease Forecasts and Disease Briefings

John Cleverley,  
Product Manager, Cortellis CMC Intelligence

- 15 years of industry experience
- Senior editor & manager, Cortellis CI forecast drugs content database
Healthcare challenges in Sub-Saharan Africa

Are we doing enough?
August 2018 – Ebola outbreak in Democratic Republic of Congo

- 494 reported cases; 283 fatalities; 140 recoveries
- bat reservoir
- rVSV-ZEBOV vaccine in 39,000 people
- single shot/ring vaccination
- chAd3-EBO-Z vaccine PREVAIL I
- 160 patients treated with four experimental therapies:
  - Zmapp
  - Remdesivir
  - REGN3470-3471-3479
  - Favipiravir

Transmission electron micrograph of a Ebola virus virion. Created by CDC/Cynthia Goldsmith
Other deadly diseases:
- Diabetes mellitus
- Hypertensive heart disease
- Diarrheal diseases
- Respiratory tract infections
- Tuberculosis
- African trypanosomiasis
- Schistosomiasis
- Malaria
- Lymphatic filariasis
- Human papilloma virus

HIV/AIDS
- Aim: 90-90-90 goal
- 90% of people with HIV know their status
- 90% of these are on antiretroviral therapy (ART)
- 90% of those on ART achieve viral suppression by 2020

Top 20 sponsors for HIV clinical trials in South Africa.
Source: Cortellis Clinical Trials Intelligence, Clarivate Analytics, May 31, 2018.
- Sub-Saharan Africa (SSA)
  - No orphan drug policy
  - No rare disease registry
- South Africa
  - 613 rare diseases
  - 1 in 10 persons affected = 3.6 million
- Most common rare diseases
- Less common
  - Nodding disease

**Rare Disease Societies (RDSA)**
- promote awareness, advocacy, research, intervention
- offer treatment advise and supportive care
Healthcare challenges – Regulatory environment

- **Economic considerations**
  - 200% increase in Africa’s foreign trade since 2000
  - 10-fold increase in foreign investment in SSA since 2005
  - Largest economies: Nigeria, South Africa
  - Only 30% to 35% of medicines produced locally (Nigeria)
  - Healthcare companies not among top 70 (SSA)

- **Priorities**
  - access to market (harmonization across countries)
  - safety (counterfeit drug trade)
  - cost (over-regulation)
Healthcare challenges – Industry response

○ Initiatives
  □ African Medicines Agency (AMA)
  □ African Medicines Regulatory Harmonization (AMRH) Initiative

○ Selected interventions
  □ research, marketing and community education
  □ pharmaceutical response
    • HIV, TB, HPV
    • Ebola and malaria
    • nodding syndrome
Current regulatory environment
Regulatory diversity and difficulties in bringing a drug to market in Sub-Saharan Africa

Delays in marketing and clinical trials authorization

- Many low and middle income countries (LMICs) experience delays in the granting of access authorization
- For medical products these delays can range from 4 to 7 years

Sub-Saharan Africa comprises 46 distinct markets

- Requirements can often vary significantly among LMICs
- Difficult for organizations to develop the same drug for different countries
- Approval mechanisms between countries can lack integration

Enforcement of requirements is challenging

- Different levels of regulatory maturity and consistency
- Wide gaps between countries in market size, growth trajectory, macroeconomic landscape, legal structure and political complexities

Different LMICs may have different requirements for demonstrating stability

- SSA comprises three climatic zones:
  - II, IVa and IVb
- Companies may only account for the climatic zone of the first release wave
  - Repeat studies are required to address differing requirements
- Lack of upfront visibility for required stability requirements can push back launch by at least 6 months
Access to CMC requirements

Accessing requirements can highlight a range of variations

- Availability of requirements
- Format of requirements
- Format of documentation
- Native language documentation
How are CMC requirements currently captured?

No single public source of CMC requirement information

• There is no single source that offers a harmonized approach to capturing requirements

Companies use different approaches

• Internally maintained databases and resources
• Review of regulatory authority websites
• Consultant development partners and subject matter experts
• Hire local staff with relevant expertise
The importance of access to accurate and up to date CMC information

- Knowledge of requirements and enforcement is fundamental to the production of quality healthcare products
- Lack of access to regulations and of consistent interpretation increases time and costs

50% of first new drug applications filed between 2000 and 2012 were rejected
11.3% of which were due to Chemistry, Manufacturing and Control (CMC) issues
18.3% of resubmitted applications were delayed again due to CMC issues
Cortellis CMC Intelligence

Cortellis
Powering Life Sciences Innovation
Introduction to Cortellis CMC Intelligence

Setting out with the challenge of enabling drug developers to bring more life-saving medicines to the people who need it the most, Clarivate Analytics has developed* a comprehensive CMC database to simplify the drug submission process and increase the chances of an optimal health authority review.

Cortellis CMC Intelligence is a granular collection of CMC data requirements for small-molecule drugs around the world

With Cortellis CMC Intelligence, you can:

- Efficiently track CMC requirements in countries of interest to ensure compliance with evolving regulations
- Select countries that best fit your capabilities by understanding specific regional requirements for manufacturing, trials or distribution
- Choose the optimal path to market by pinpointing potential approval pathways
- Develop CMC strategies to balance cost, time and quality risk
- Fully understand requirements around testing and manufacturing before deciding with whom to partner

*Developed with the support of a grant from the Bill & Melinda Gates Foundation

Cortellis
Powering Life Sciences Innovation
Summary
How Cortellis CMC Intelligence can help

CMC data come from official regulatory documents and are curated with local-market expert guidance and editorial insight

Cortellis CMC Intelligence also contains information on local practices, which is provided by local consultants

Content is compiled and curated by a dedicated team of experts with more than 20 years of regulatory experience, as well as long-term partnerships with local regulatory consultants

Access to CMC requirements by country, as well as multi-country and climate-zone comparisons – at both a summary and a detailed level – to help users decide on the best manufacturing approach to penetrate multiple markets

The end result is increased confidence that when you submit your clinical trial and registration applications, whether it’s to one country or to the world, you won’t have to do so again
Summary – Opportunity, Challenge, Solution

Opportunity
Alleviate:
• Burden of rare and prevalent disease

Challenge
Penetrate:
• Uneven regulatory landscape

Solution
Implement:
• Cortellis CMC Intelligence by Clarivate Analytics