SAHPRA
South African Health Products Regulatory Authority

BILL & MELINDA GATES foundation

Fundisa
African Academy of Medicines Development

The Innovation in Regulatory Sciences Capacity Development in Africa Meeting

30 June 2020

REPORT

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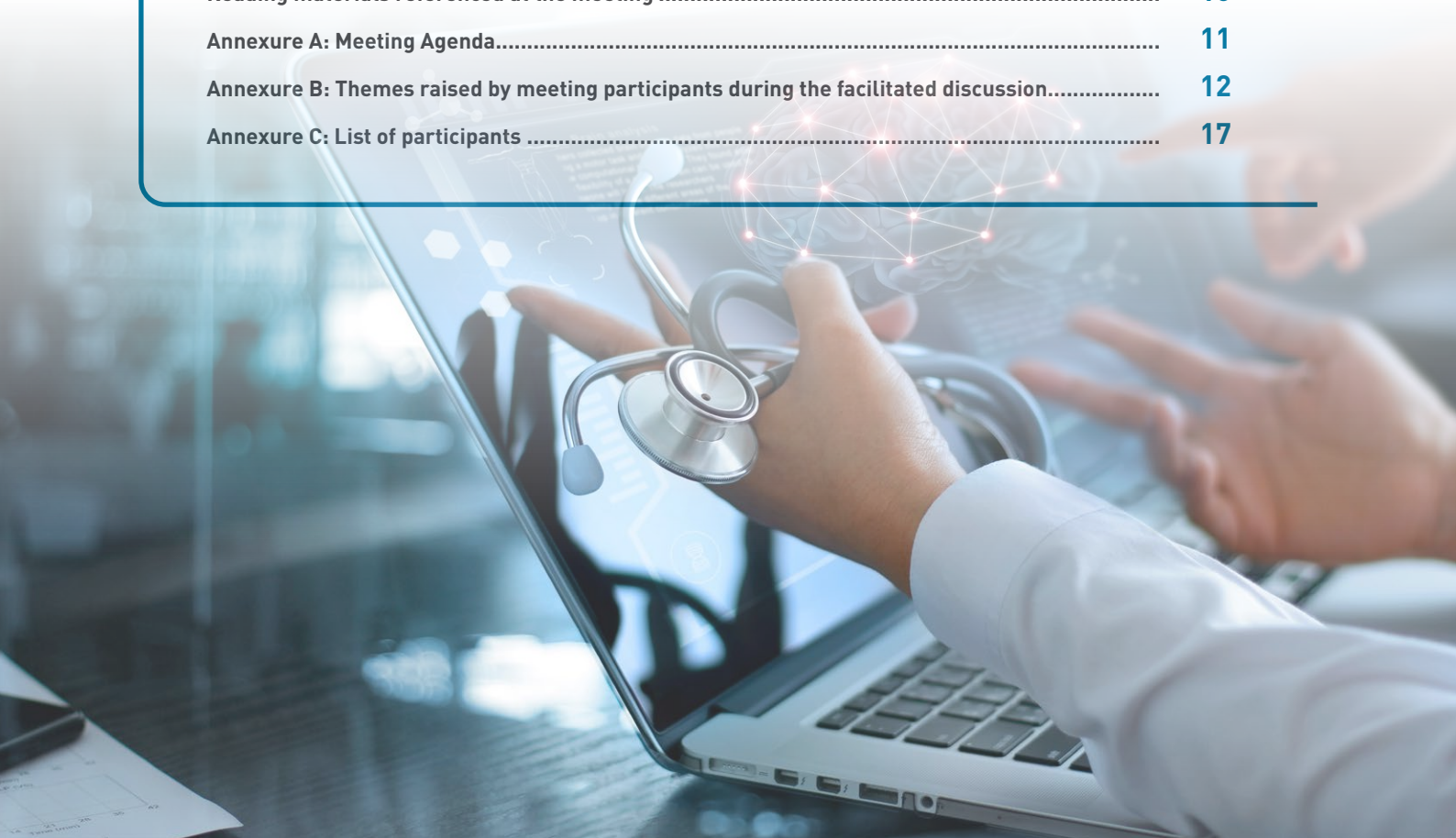


EXECUTIVE SUMMARY

There is a critical skills gap on the African continent in the regulatory sciences, and an acknowledged need to develop a long-term strategy for training and professional development of African regulatory personnel.

A virtual meeting of 40 senior level participants from regional African agencies, African regulatory authorities, international regulatory authorities, the WHO, AUDA-NEPAD and academia from across Africa, Europe, the UK and the USA came together to discuss this topic. The meeting was convened by the South African Health Products Regulatory Authority (SAHPRA) in collaboration with the Bill & Melinda Gates Foundation (BMGF), CP+ Associates GmbH and Fundisa African Academy of Medicines Development in collaboration with several experienced African regulators.

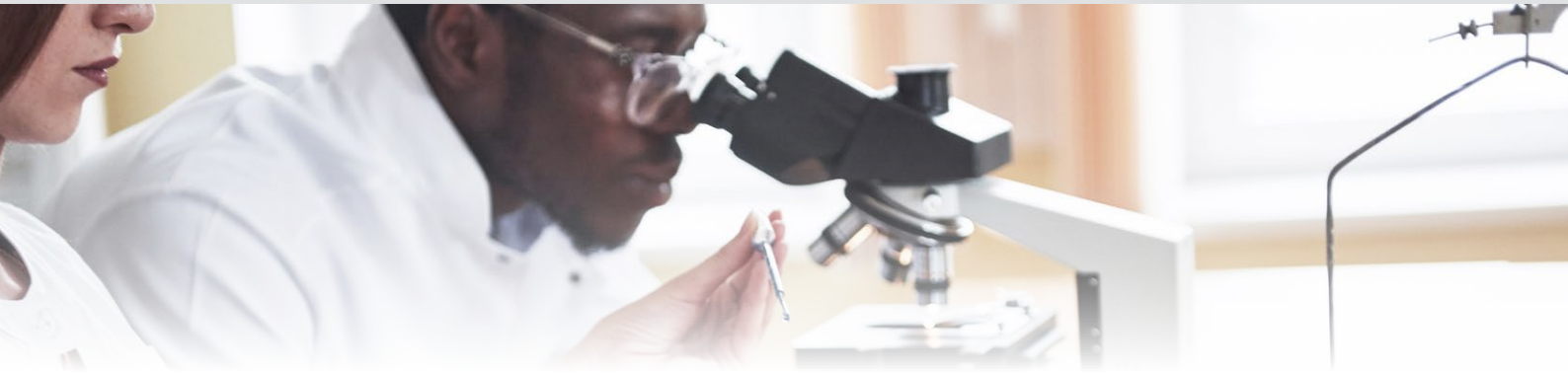
Recognizing the strong baseline of efforts that has already been implemented on the continent across various regulatory authorities, the objectives of the meeting were to share experiences, inspire regulators, build networks and develop a program of action on the development of capacity and capabilities in African regulatory agencies.

Following a few short contextual presentations by regulatory experts and academics, an open discussion ensued.

This report summarises the talks, key themes from the discussion session and ends with recommendations.

INTRODUCTION

This report summarizes the outcomes of an expert virtual meeting held on 30 June 2020 to discuss Innovation in Regulatory Sciences Capacity Development in Africa. The meeting was convened by the South African Health Products Regulatory Authority (SAHPRA) in collaboration with the Bill & Melinda Gates Foundation (BMGF), CP+ Associates GmbH and Fundisa African Academy of Medicines Development with several other African regulators.



BACKGROUND AND RATIONALE

DR BOITUMELO SEMETE-MAKOKOTLELA, DR COLIN PILLAI AND DR DAVID MUKANGA

This was the first meeting to discuss the topic of increasing competencies in regulatory science in the African region, with the purpose of developing a longer-term strategy for training and professional development of African regulatory personnel.

There is a critical skills gap on the African continent in regulatory sciences[1] that has also been articulated by many African regulatory authorities, the World Health Organisation, African Medicines Regulatory Harmonisation (AMRH) initiative and the BMGF. Under the auspices of the AMRH initiative and together with the WHO, the BMGF continues to seek avenues to partner with regulators across Africa to support building efficient fit-for-purpose authorities, with the required capabilities, as well as a network of agencies.

Due to a shortage of expertise as well as limited size of the key industries in the African continent, clinical pharmacology and regulatory sciences skills and expertise are extremely underutilized in Africa. There is an incredibly good and strong baseline of efforts that has already been implemented on the continent across various regulatory authorities. The critical objectives of the virtual meeting were to share experiences, inspire regulators, build networks and take action on the development of capacity and capabilities in African regulatory agencies.

[1] Wilson et al., Sci. Transl. Med. 12, eaax2550 (2020) 29 July 2020

OBJECTIVES – DR BOITUMELO SEMETE-MAKOKOTLELA

The purpose of the meeting was to achieve the following objectives:

- Consult with, seek alignment and consensus from regulatory leadership on the continent on various aspects of regulatory science capacity development.
- Explore existing programs and options to build capacity in regulatory agencies in Africa.
- Determine tools that would be put in place to assess/grade the level of capacity developed.
- Explore approaches to increase capabilities in regulatory agencies to review clinical data in dossiers.
- Initiate a process to develop a roadmap for Pan-African capacity development.

PARTICIPATION

The meeting was attended by 40 senior level participants from regional African agencies, African regulatory authorities, international regulatory authorities, the WHO and AUDA-NEPAD, academia from across Africa, Europe, the UK and the USA.

OUTCOMES

The meeting was the first of its kind, in that it had varied participants with a core focus on discussing the topic of increasing capacity and capabilities to benefit regulatory sciences in the African region. Furthermore, the purpose of developing a longer-term training programme for professional development for African regulators was a key discussion point.

PRESENTATION SUMMARIES AND ABSTRACTS

INTRODUCTION AND CONTEXT AND MEETING OBJECTIVES
Dr Boitumelo Semete-Makokotlela, Dr Colin Pillai and Dr David Mukanga

These are summarized above.

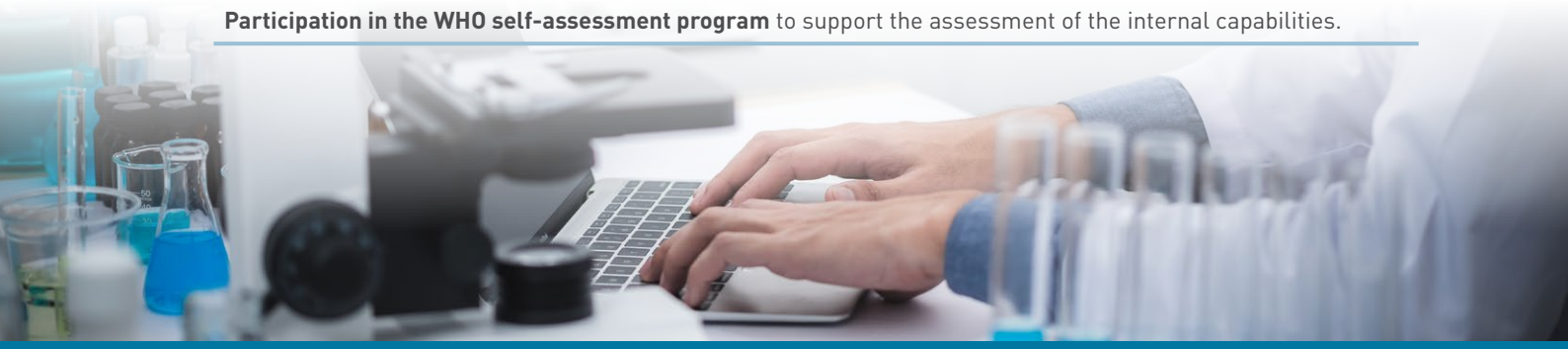
INNOVATION IN REGULATORY SCIENCES CAPACITY DEVELOPMENT
Ms Gugu Mahlangu, MCAZ Zimbabwe

The Medicines Control Authority of Zimbabwe (MCAZ) has provided training to regulators on the continent over a number of years, supported by various donors and WHO to develop modular programmes.

Programmes focused on giving regulators **hands-on experience** with courses offered to regulators ONLY or to regulators and industry combined, such as Bioequivalence, Biosimilars, Special (Non-oral) Dosage Forms, GMP Considerations for Assessors and Advanced Drug Delivery Systems (online).

The programs offered are varied, including but not limited to:

- **Partnership with universities** in own country and internationally to provide accredited courses.
- **Fellowship program** for the MCAZ staff with stronger regulators and with the WHO.
- **Participation in the WHO self-assessment program** to support the assessment of the internal capabilities.



The innovation in regulatory sciences capacity development in Africa meeting

Working with regulators in Africa MCAZ identified the following gaps;

Limited capacity to assess new medicines, primarily clinical evaluation. The AVAREF joint review program has been critical in bridging the capacity gap. The ZAZIBONA model has on the other hand supported capability in quality reviews.

No research ongoing in regulatory science due to lack of research skills.

ZAZIBONA Approach: one of the goals of the ZAZIBONA initiative since inception in 2013 was to build **assessor capacity** in the region, with 16 training sessions being conducted to date during ZAZIBONA assessment sessions.

REGULATORY SCIENCE AND GOVERNANCE-REQUIREMENTS FOR SUCCESSFUL IMPLEMENTATION AND CAPACITY BUILDING

Ms Precious Matsoso

The growing burden of disease due to colliding epidemics of communicable and non-communicable diseases coupled with emerging disease outbreaks (SARS, Ebola, Zika, Lassa fever, coronaviruses etc) are posing a major threat to African countries. The WHO typology of diseases highlights this succinctly. Type I diseases are those that equally affect both developed and developing countries, Type II diseases affect both but disproportionately, with developing countries carrying the higher burden and Type III diseases are predominantly in the developing countries[1].

In recent years we have experienced new developments with the increase in new biotechnological products aimed at addressing these problems. The Medicine regulatory authorities ('regulators') have been challenged to deal with these new developments, that have progressed at such unprecedented speed, bringing about a paradigm shift. The exponential growth of these complex products has brought about a shift in understanding the development, manufacture as well as the use of these products in clinical settings e.g. 3D printing, gene therapy, gene editing, stem cells therapy. In addition to this are advances in medical device technology and changes in the digital health landscape such as artificial intelligence, wearable technologies etc. They have posed a challenge on how they should be accessed and approved. As they are needed to treat certain diseases how can they be made available whilst ensuring their safety? How to respond in those countries where there is a high burden of disease. These scientific developments have challenged Regulators on how best to keep up with these changes, how best to respond, amend regulations and adjust regulatory processes. They present a new environment that requires the understanding of the regulatory environment to ensure effective and responsive regulation and avoid under-regulation and / or over-regulation[2]. It requires better oversight on self regulation and avoidance of co-regulation. Each regulatory process presents risks and undermines the very essence of medicines' regulation.

Effective and responsive regulation that avoids any pitfalls should be within the context of a well-designed regulatory ecosystem. Success in achieving effective and responsive regulation, should be based on good governance, supported by risk-based approaches. There must be sufficient resources to generate evidence with an aim to support medicinal product efficacy and safety. OECD countries have introduced regulatory reform measures based on good regulatory policies that safeguard public interest whist stimulating economic growth. This has resulted in reduced costs and some of these countries include, Netherlands, Belgium, Germany, Greece[3]. Principles of good regulatory policies must be upheld to ensure policy coherence and avoid inconsistencies. This will require that laws, regulations and policies be formulated based on evidence. Regulatory reviews must be subject to scientific rigor and the regulatory system must be "fit for purpose".

[1] WHO Report of The Commission on Public Health Innovation and Intellectual Property Report, 2006
[2] Aeres I., Braithwaite J., Responsive regulation: Transcending the deregulation debate, 1992
[3] OECD Regulatory Policy Outlook, 2018

PRESENTATION SUMMARIES AND ABSTRACTS (CONTINUED)

WHO COMPETENCY FRAMEWORK INCLUDING WHO PRE-QUALIFICATION

Dr. Luther Gwaza

The WHO competency framework aims to support a systematic approach to capacity building in the context of organizational performance improvement. The framework is flexible to allow individual regulatory authorities to adopt it based on their needs and local context. The draft has been piloted in Botswana and Southern Africa Development Community's (SADC) regional joint activities. Key lessons from the pilot are discussed as follows. Any training intervention should be based on needs assessment, supported by evidence from learning science and performance improvement, and includes both training and non-training interventions. We should consider optimizing existing opportunities and creating new opportunities, as necessary. For example, the WHO Prequalification of Medicine includes a significant number of assessors from African countries. Also, the regional joint activities and harmonization projects are an opportunity to build the necessary capacity. How can countries maximise these and other existing opportunities to build the necessary capacity? How can countries ensure effective and efficient transfer of the skills at the institutional level? In conclusion, any proposed intervention should consider a collaborative approach between the learning context (academic and training institutions) and the performance context (regulatory authorities and industry) in designing and delivering learning in regulatory science to address current and future needs.

INNOVATIVE METHODS FOR CAPACITY BUILDING – THE ACADEMIC PERSPECTIVE

Prof. Bernd Rosenkranz

Training of Specialists in Medicines Regulation involves vocational and experiential learning defined as "training that emphasizes skills and knowledge required for a particular job function" and "developing personal understanding, knowledge, skills and attitudes through the analysis of, and reflection on, activity (workplace learning by doing)". Successful completion of a training programme may lead to professional licensure or higher degree of specialisation, or an academic or other professional higher degree certification, or a basic certificate.

Clear educational policies and appropriate tools must be developed to meet labour market needs and to support career development. This includes mentoring of effective teachers and trainers. An example is the well established "dual system" in Germany which provides accredited vocational education and training together with full- or part-time workplace exposure. In South Africa, the specific personal, economic and cultural context must be taken into account.

Regulatory science encompasses a major part of the value chain of medicines development and market access, with various diverse competencies and role players. Training of competent medicines regulatory professionals must be based on pre-defined, standardised competencies, including knowledge (academic programmes or accredited courses), skills (workplace training), and attitudes (professional mentoring). Examples for standardised programmes for industry experts in medicines development and regulation are the UK Faculty of Pharmaceutical Medicine PMST Programme (Pharmaceutical Medicine Specialty Training, 57 defined core competencies), or the PharmaTrain Masters of Regulatory Affairs standard syllabus.

Development of innovative and relevant teaching and training approaches is recommended, as recommended in the Innovative Practice Framework (UNESCO-UNEVOC Report, 2019). Accredited academic programmes offered by African Universities and other institutions should be integrated, as appropriate.

The innovation in regulatory sciences capacity development in Africa meeting

INNOVATIVE AND INTEGRATIVE TRAINING APPROACHES: GHANA FDA

Mrs Mimi Darko

The skills gaps are higher among regulators with limited budgets. Most regulators depend on their Ministry of Health and Ministry of Finance for funding and are often under-resourced given competing budget priorities.

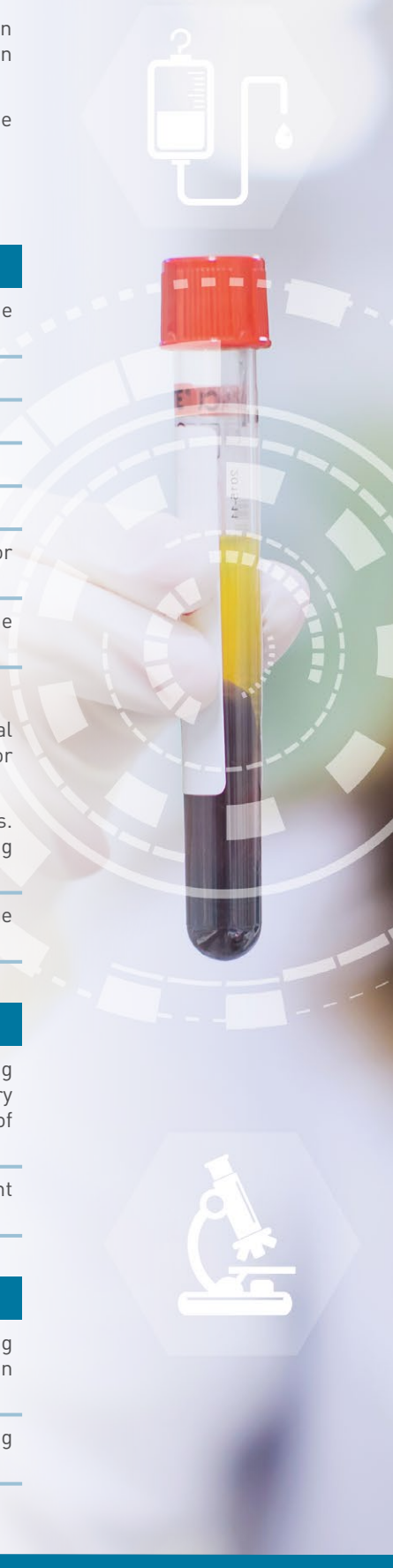
These funding constraints result in limited training budgets. Thus, regulators need to raise funding for specific programs.

Recommendations/Input

REQUIREMENTS FOR TRAINING
Agencies must make sure that the 'scheme of service' is open to all disciplines to attract some skills like Clinicians and Chemists.
Engineering skills are critical for GMP inspections.
Retention of skills is critical in capacity building.
Regulatory science in Africa should be developed within the context of PUBLIC HEALTH.
Collaboration between the academic, training institutions and regulators for learning.
There will be a need for an accreditation or certification scheme, with preference for establishment of an own accreditation platform for Africa.
Training on Reliance, especially since it is becoming a key lever that all regulators across the world will be utilizing.
Assessment tools will be an important part of the successful implementation: • WHO Competency Framework provides the opportunity to establish the current technical skill base of the regulatory teams and help design a career development pathway for regulators. • For this to work, the regulatory agencies must train the trainers rather than the universities. Most universities do not have the capacity and flexibility to offer Work Integrated Learning (WIL) which is part of competence training.
Implement incentives (not necessarily monetary) to attract and retain young scientists in the field of regulatory science.

ECOSYSTEM TO SUPPORT THE HEALTH SECTOR
The idea of a regulatory ecosystem that engages and partners with other stakeholders including academia, CROs and NGOs will mean that expertise in the ever-expanding field of regulatory science filters into teaching and research in a symbiotic way. The challenge will be that of managing conflicts of interest where industry is involved.
The consideration of patient involvement is critical for establishment of an efficient and relevant ecosystem.

INTEGRATION
More transparency and sharing of review reports and evaluations between regulators, including international regulatory authorities to enable building a culture of information sharing between mature and less mature regulators. This will also facilitate sharing of best practices.
Alignment and consensus from regulatory leadership on the continent will be key to achieving success.



FACILITATED DISCUSSION – PROF PETER STONIER

A vibrant discussion followed the contextual presentations. The following themes emerged from this discussion. Refer to Annex B for related thematic discussion points.

Feedback by representatives from international regulatory agencies (USA, Germany, United Kingdom, The Netherlands) indicated that the topics discussed were not unique to Africa. These colleagues provided reassurance that the gaps outlined by speakers and discussants were also experienced outside Africa.

The size of the African market correlates with the resources that would be made available (e.g. by pharmaceutical product sponsors) to finance efforts to build capacity and capability of regulators. It was noted that regulatory agencies in larger markets are able to charge fees that could be channeled towards building staff capacity and capabilities, but this might not be easily implementable in Africa.

One contributor briefly reiterated that regulators play an important role in enabling access to medicines on the continent.

A short discussion addressed the importance of governments in this topic, particularly their dominant effect on creating an enabling environment for regulatory capacity development. Government departments should avoid working in silos and seek complementarity in the interests of their communities e.g. the ministries of science and technology, health, finance and trade could work together to create business environments that could attract multinational pharmaceutical companies.

Multiple commentators discussed the topic of "Regulatory Reliance" as a mechanism to increase efficiency. Regulatory reliance is defined by the WHO as *"The act whereby the regulatory authority in one jurisdiction may take into account and give significant weight to – i.e. totally or partially rely upon – evaluations performed by another regulatory authority or trusted institution in reaching its own decision. The relying authority remains responsible and accountable for decisions taken, even when it relies on the decisions and information of others."*

There was a reverberating message that training efforts and training resources should consider that a baseline exists – with both international, regional and local programs that are already at a sophisticated level of development.

One discussant highlighted that a challenge is that historically, low and middle income countries have not been involved in the actual decision-making around the creation and the building of guidelines. This is a way to build capacity in that expertise is cultivated when one is engaging with the thought processes of how to develop standards.

Suggestion that regulatory training should be done at post-graduate level. At the same time, there was a strong call for the training to be contextual i.e. on-the-job/vocational/experiential. This should be coupled with mentorship programs.

Regarding on-the-job training, local and international (especially UK) regulators highlighted that often they hired subject matter experts (e.g. clinical specialists) into their agencies who then need to use the on-the-job learning to become au fait with regulation and regulatory processes.

Instruments for training should be tailored towards the objective and the target regulatory role e.g. training for a clinical assessor might be very different to that of someone looking at the quality aspects of a biological.

Call for establishing a structure e.g. competency framework along the lines of that set up by the WHO, but with an African flavour. This should allow for different levels of competency and/or capacity for different roles as well as establishment of benchmarking tools.

There is a need to conduct contextual research into regulatory science, but there is limited to no time for existing regulatory staff, and a need for capacity and skills development to fulfil this research role.

In this regard, there was the suggestion that a Regional Institute (or Academy) of Regulatory Sciences in Africa with inclusive membership might be a home base for such a competency framework. Inclusivity should allow for minimal compromise of the sovereignty of regulatory agencies in African member states and should ensure involvement of academia for post-graduate accreditation.

FACILITATED DISCUSSION – PROF PETER STONIER (CONTINUED)

A call for patient/public engagement by the regulators i.e. "educate the community they serve".

One discussant highlighted the need to be more holistic and consider traditional medicines – given their importance in the African context. This discussion extended into nutritional products.

Colleagues from international agencies outlined the importance of monitoring and evaluation of any program that might be started – this should cover output, outcome and impact which represents increasing levels of change management.

Finally there were multiple warm compliments to the organizing committee for arranging this convening as a timely effort given the increasing complexity of the role that African regulatory assessors need to play e.g. beyond traditional expectations of bioequivalence assessment, to cover gene therapies and complex biological healthcare agents.

RECOMMENDATIONS

1. Develop a long-term strategic plan for strengthening African regulatory sciences and capabilities, including standard-setting for competency domains, learning outcomes and syllabus, creating an enabling workplace to encourage training and mentoring, and assessments. This might involve compiling an inventory of available education and training programs / platforms that already operate in Africa.
2. Rapidly execute at least one training event, that fills an urgent need and that could also illustrate aspects of the longer-term plan.
3. Compile a detailed gap analysis using multiple sources of information including published reports, feedback from African agency staff, industry and other stakeholders of the African regulatory ecosystem. Strive for Africa-centricity in terms of local needs, training content and faculty. Avoid duplication by incorporating existing programs that have been set up to strengthen regulatory capacity in Africa or by including existing content or lessons learnt.
4. Develop plans for establishment of an African accreditation platform.
5. Select and recommend modern methods of vocational education and training, especially those that use technology to increase efficiency and flexibility for educating professionals who are in full-time employment.
6. Establish a quality assurance (QA) process for courses and training centres and a monitoring and evaluation program for all interventions envisaged under this program using metrics / tools that have been established for assessing similar programs.
7. Set up a close working relationship between regulatory agencies and academia that could simultaneously provide local accreditation and higher qualifications to agency staff who acquire advanced skills to execute their roles. This will naturally feed into the system of **Regulatory Reliance** where agencies depend on each other's assessments. Consider regular e.g. bi-monthly formal (virtual) meetings between the key stakeholders.
8. Implement additional, non-monetary incentives such as an African research agenda for the regulatory sciences to attract and retain young scientists into the field.
9. Seek out, align with, and form collaborations with other global initiatives that have similar objectives.
10. Advocate for attracting additional academic disciplines e.g. engineering and allied quantitative sciences, in addition to pharmacy and the clinical sciences that have traditionally attracted regulatory professionals.

NEXT STEPS

- Convene a working group drawn from meeting participants and other interested stakeholders.
- Prepare a peer-reviewed publication that will invite collaborations to execute on prioritized capacity development programs.
- Compose, plan and conduct a short-course training program on how to evaluate clinical sections of regulatory dossiers.
- Compose a longer term strategic plan.

READING MATERIALS REFERENCED AT THE MEETING

Ghana FDA, IAVI, NEPAD, University of Ghana, 2016. Clinical Trials Training Manual: *for capacity building in Regional Centres of Regulatory Excellence (RCOREs)and other training institutions.*

Keyter, A., Banoo, S., Salek, S. and Walker, S. *The South African Regulatory System: Past, Present and Future.* (2018). Front. Pharmacol. 9:1407. Doi:10.3389/fphar.2018.01407.

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WHO Regulatory News, 2019. WHO Drug Information: WHO Towards a global competency framework for regulators of medical products. Vol 33, No. 1.

WHO, 2010. WHO Assessment of medicines regulatory systems in sub-Saharan African countries: *An overview of findings from 26 assessment reports.*

Wilson et al., Sci. Transl. Med. 12, eaax2550 (2020) 29 July 2020.

UNESCO, 2019. UNEVOC International Centre for Technical and Vocational Education and Training: *Trend Mapping and Innovation in TvET*

ANNEXURE A: MEETING AGENDA

PROGRAMME

TIME	ITEM	PRESENTER
12:00-12:05	Opening remarks	Chairperson: Dr Boitumelo Semete-Makokotlela CEO – SAHPRA
12:05-12:15	Introductions of participants	
12:15-12:20	Remarks and Objectives of the day	Dr Colin Pillai CEO Pharmacometrics Africa
Presentations		
12:20-12:30	Current status of training programmes in Africa including requirements for successful implementation	Mrs Mimi Darko CEO, Ghana FDA
12:30-12:40		Innovation in Regulatory Sciences Capacity Development Ms Gugu Mahlangu DG, MCAZ Zimbabwe
12:40-12:50		Ms Precious Matsoso Director: Health Regulatory Science Platform
12:50-13:00	WHO Competency Framework including WHO Pre-Qualification	Dr Luther Gwaza Technical Officer: WHO
13:00-13:10	Innovative methods for capacity building – the academic perspective	Prof Bernd Rosenkranz President: FAAMD
Discussions		Facilitator: Prof Peter Stonier Director E&T, Faculty of Pharmaceutical Medicine, Royal Colleges of Physicians UK
13:10-13:35	Facilitated discussion around innovative and integrative training approaches	All
13:35-15:15	Roadmap: what format would the training take? Institute of Regulatory Sciences? Long-term plan on how we embed these into vocational training/ professional development (academic, employer offered training, vocational)	All
15:15-15:30		Break
15:30-16:00		Summary and Closure • What is the aspirational goal? • What do we want done in the next 6-12 months? • Have we achieved the objectives for the day?

ANNEXURE B: THEMES RAISED BY MEETING PARTICIPANTS DURING THE FACILITATED DISCUSSION

FACTORS AFFECTING THE APPROACH TO SETTING UP CAPACITY BUILDING PROGRAMS

THE ISSUES WHERE LIMITED CAPACITY PREVAILS

There is limited present capacity available to deploy to even assess new needs.

Gap analysis needs to be ongoing to identify, label then recognize the gaps that need to be filled.

Real gaps are not being addressed e.g. attracting, training, retaining appropriately qualified and orientated young professionals to regulatory / regulatory science.

No research in regulatory science, due to lack of skills (thus attractiveness of the field is not enhanced for newcomers).

Growing burden of disease engages regulatory time and resource, limiting capacity further.

Regulatory requirements for complex medicines / new molecules / advanced therapy medicinal products (ATMPs) again limits capacity further.

These are intrinsic issues with compounding elements (positive feedback loops) built in. Need for a dynamic and ongoing effort to even stand still, then greater and sustained effort to start to grow and develop capacity.

SOME APPROACHES TO THE SOLUTION

Recognition that 'one size does not fit all'.

- Recognition of multidimensional approach to capacity building e.g. money, resources, education & training, sustainability, sharing, 'Reliance'.
- Different emphasis on factors in different countries and their national regulatory agencies (NRAs).
- Different strengths in different NRAs.

Risk-based approach e.g. Proportionality.

Regional perspective / umbrella concept.

Competency framework – an essential component of any E&T solution.

FACTORS AFFECTING THE ENVIRONMENT FOR CAPACITY BUILDING

POSSIBLE BARRIERS

Limited enabling working environment: the environment is largely dictated by governments, but there is some enabling support from WHO. Because of balance of prevailing forces, this can lead to:

- a non-receptive environment for capacity-building solutions;
- constant need for more investment / more money / recognition of fiscal elements in addressing issues such a capacity development.

Resources (money and infrastructure resource): it is widely understood and accepted that the African continent is comprised of LMICs (low-middle income countries). This can lead to:

persistent lack of resource, limited money;

lack of resource to address new challenges e.g. Gene and cell therapies, ATMPs;

risk of inability to address current and standard regulatory issues better / more efficiently.

ANNEXURE B: THEMES RAISED BY MEETING PARTICIPANTS DURING THE FACILITATED DISCUSSION (CONTINUED)

SOME APPROACHES TO THE SOLUTION OF ENVIRONMENT / RESOURCE ISSUES

Realisation that Demand from R&D companies results in subsequent resources. So, create a (research/clinical trial) environment which is attractive to international R&D (standards, practices, accountabilities, transparency, patient engagement/informed consent [all ethical considerations]).

Need Ecosystem concept – broad regulatory landscape – Regulatory model (Vision within which to work and grow).

Need Framework for regulatory function – common structure (between NRAs) within which to work.

Both Ecosystem and Framework concepts to be Continent- / Region-wide. These concepts would be a major contribution to an enabling environment.

The profession (Regulatory) understands what needs to be done (but is there a broader knowledge/understanding and consensus?).

These environment / resource considerations would/could lead to:

1. attracting and welcoming young professionals to regulatory science and embark on a career-defining training program;
2. recognition of strengths and opportunities of regional approach; recognition of work-sharing, 'Reliance', global benchmarking and that 'one size does not fit all'.

FACTORS AFFECTING REGULATORY SCIENCE

The Discipline and Profession

SOME INHIBITORY FACTORS

Regulatory Science (or Regulatory Affairs) not well or widely understood or appreciated, thus:
- not an attractive choice for a career discipline or function;
- low recruitment, low retention, short career development.

Said that there is a focus on the career path of one profession, viz. pharmacy; thus e.g. chemists, biologists, life scientists, nurses can feel neglected / unwanted / unsupported. This reality (or perception) needs addressing, so that the discipline (regulatory science) is welcoming to people of a multi-disciplinary background.

SOME APPROACHES TO THE SOLUTION

The problems are recognised amongst Regulators.

Support needed for appreciation of global benchmarking.

There is a history of involvement in certain countries/NRAs of global leadership / advisory, with a strict directive/ mandate for local development, management and leadership - "Think global, Act local".

Regulatory science – must be progressive, innovative, research-based, evidence-based, adaptive pathways (e.g. routes for accelerated registration, rare diseases, paediatrics), patient-centric, patient engagement, RWD/RWE versus RCTs.

ANNEXURE B: THEMES RAISED BY MEETING PARTICIPANTS DURING THE FACILITATED DISCUSSION (CONTINUED)

People and Professional Resource

SOME INHIBITORY FACTORS
Do not have the numbers (of people).
Do not have the experience (staff).
Do not have appropriate competencies (inappropriate training / need for gap analysis).
Lack of attraction for regulatory staff with appropriate skill-sets (competencies).
Length of time to train to Competent level (working without supervision) is longer than recognised / provided / possible (time/finance).

SOME APPROACHES TO A SOLUTION
Conglomerate the continent / region; create a one-stop shop.
Regulatory mandate Does see trends in new (product) developments for increased work and Can create capacity availability. But this needs to be a broad view of the Entire Value Chain, not a narrow view of e.g. Dossier completion (metrics: numbers / time).
Size of Regulatory mandate – with time it is strengthening the scope of regulatory functions and creating capacity to complete work, and at the same time to develop and grow.
Recognition and development of work-sharing and various work-sharing initiatives.
Consideration of Regional level of organisation (e.g. work-sharing: pockets of expertise are not all in one NRA).
Engage with global environment, encourage global support as appropriate but within continental powers of principles, priorities, programs and management/leadership.
Emphasis for the solution is about Formalised education and training: vocational (fitness for the work) rather than academic (degrees): competency/capability/competence-based.
Multifactorial approach to solutions in Regulatory Science issues: broad not narrow.
Focus on: • pre-licensing: Continue developing Dossier critical review, notably Clinical Dossier review; • post-licensing (new focus for better performance in post-licence area): e.g. Pharmacovigilance; Promotion scrutiny.

Education and Training

SOME INHIBITORY FACTORS
Supply side insufficient.
Said that Universities (alone) should not train. Evidence of a mismatch between academic output and regulatory / industry needs to do the jobs. Inappropriate Academic focus can be countered by introduction and growth of Outcomes-based / Competency-based vocational education and training (E&T).

ANNEXURE B: THEMES RAISED BY MEETING PARTICIPANTS DURING THE FACILITATED DISCUSSION (CONTINUED)

SOME FACTORS ADDRESSING SOLUTIONS
Training fellowships were/are a successful innovation (had goals / had metrics).
A focus could be the E&T of Specialists in Medicines Regulation.
WHO Global Competency Framework (Regulatory Science) is detailed and a work in progress (piloting).
Define broadly what is required (A Career Pathway model).
Consider what is on offer internationally for postgraduate professional E&T e.g. German model of Academic and Vocational E&T.
This all fits in with a tri-partite career pathway approach of Academic base, Vocational (fit for work/regulatory), Experiential (scope of work / breadth of opportunity within regulatory science / pharmaceutical medicine / medicines development (including clinical trials).
Vocational competency-based training (outcomes-based), mentored in-work programs. (Adult) learner-centric, not a teacher-centric / syllabus-driven 'tick box' exercise. The outcomes are: • capability-centred (Entrustable to do the job – without supervision); • competency-centred (acquired competencies which make up the capabilities); • competent – a rounded, capable professional fit to do the job at a moment in time / career with capacity to develop.
Ongoing training concepts (CPD, re-certification, life-long-learning).
Needs for Certification (of people) / Accreditation (of institutions / courses) to international benchmarks / standards – applied regionally: for standards, quality, personal recognition and growth, international acceptance, assurance, professionalism.
Would these needs lead to a central structural/functional organisation? – Institution, Faculty, Professional body e.g. TOPRA principle – to set and deliver standards, quality, certification and accreditation.
Or lead to a decentralized regional (NRA) approach, with recognition of a centre (Hub and Spoke approach).
One example of a Regulatory E&T strategy and approach: • Consider size of Regulatory Authority / Consider size of market. • Need to train for Role-Purpose. • Consider what sort of people needed: • Diverse range of people (inter-disciplinary) including clinical experience. • Allocation of mentor. • Recognition of Competency development framework. • Training: Regulatory principles (Process); General or Specialist /Subspecialist (Expert) therapy area (Content). • Recognition of long-term investment in people.
Africa is not the only region with capacity issues, and examples were given of low capacity in Europe (at stage of early maturity and poor investment. This led to: • structured environment / frameworks; • training & education initiatives; • work-sharing and joint assessment initiatives.

ANNEXURE B: THEMES RAISED BY MEETING PARTICIPANTS DURING THE FACILITATED DISCUSSION (CONTINUED)

General considerations

1. Consider regional institute for Regulatory Science.
2. Build future on what has happened in the past; no need to re-invent the wheel.
3. Recognise limitations of resources (and money).

BRING TOGETHER INITIATIVES:

Reliance*, ZAZIBONA**, WHO, Individual NRAs (work-sharing);

opportunities for regional approach.

'NRAs strive to improve regulatory performance and accelerate approval times; however, many continue to face challenges due to resource constraints. Increasing workloads, advancing technologies, and limited expertise require NRAs to leverage regulatory convergence initiatives, collaborative registration procedures, and functional regional, continental and international networks to fulfil regulatory mandates. Recommendations for the implementation of an abridged review process and a framework for GRelP have been made with a view to optimise regulatory review processes in South Africa.' Ref: Keyter, A., Banoo, S., Salek, S. and Walker, S. The South African Regulatory System: Past, Present and Future. (2018). Front.Pharmacol. 9:1407. Doi:10.3389/fphar.2018.01407

**ZAZIBONA is a collaborative procedure for 14 Southern African Development Community (SADC) countries in which national regulatory authorities jointly assess medicines for registration purposes.

ANNEXURE C: LIST OF PARTICIPANTS

NO	NAME	ORGANISATION
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2	Prof S Banoo	Board member, SAHPRA
3	Dr U Mehta	Board member, SAHPRA
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5	Mrs D M Darko	Chief Executive Officer, Ghana FDA
6	Ms G N Mahlangu	Medicines Control Authority of Zimbabwe MCAZ Director-General, MCAZ
7	Dr S E Kern	Bill & Melinda Gates Foundation (BMGF)- Deputy Director, Quantitative Sciences Global Health – Integrated Development
8	Dr D Mukanga	Bill & Melinda Gates Foundation (BMGF)
9	Dr I Hudson	Bill & Melinda Gates Foundation (BMGF) Senior Advisor - Integrated Development, Global Health
10	Prof B Rosenkranz	Fundisa African Academy of Medicines Development
11	Dr. L Gwaza	World Health Organization, Technical Officer, Regulation and Safety Unit (REG), Regulation and Prequalification Department (RPQ, Access to Medicines and Health Products Division (MHP), Geneva, Switzerland
12	Ms P Matsoso	Director: Health Regulatory Science Platform
13	Mrs P Nkambule	Chief Regulatory Officer: SAHPRA
14	Prof P Stonier	Clinician consultant in pharmaceutical medicine (Kings College London and UK Faculty of Pharmaceutical Medicine)
15	Prof H Reuter	Stellenbosch University
16	Prof M Blockmann	University of Cape Town
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19	Dr A Dube	University of Western Cape
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21	Dr S Ghanie	HOA, BOMRA

ANNEXURE C: LIST OF PARTICIPANTS (CONTINUED)

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28	Prof N Nyazema	Clinical Pharmacologist
29	Prof Stuart Walker	Centre for Innovation in Regulatory Science (CIRS)
30	Ms M Mphidi	SAHPRA
31	Ms S Munbodh	SAHPRA
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35	Dr M Lumpkin	Bill & Melinda Gates Foundation (BMGF)
36	Mr Y Gounden	SAHPRA
37	Mrs M Pajewska	European Medicines Agency (EMA)
38	Ms E M Gonzalez	European Medicines Agency (EMA)
39	Ms S Padayachee	SAHPRA
40	Mr T Sehloho	SAHPRA
41	Dr J Gobburu	University of Maryland, USA