

# ***IFPMA Africa Regulatory Network (ARN)***

*SAPRAA Meeting – Friday, 7 April 2017*

*Merle Scher (Merck) & Marianne Zenon (Pfizer) on behalf  
of IFPMA*

# ***IFPMA in Brief***



## **WHO WE ARE**

**We are the leading global association representing the research-based biopharmaceutical companies, and regional and national associations across the world.**



## **WHAT WE DO**

**We advocate policies and practices that encourage the discovery of and access to life-saving and life-enhancing medicines and vaccines, for people everywhere.**



## **HOW WE WORK**

**We promote dialogue and sharing of expertise to reach common positions within our industry to represent the sector's public policy interests to UN bodies responsible for public health, trade and intellectual property.**



## **WHY IFPMA**

**We are an informed and credible voice, engaging with the global public health, trade and intellectual property community and advocating for sustainable health policies to meet global needs.**

# GENEVA

*home to unique synergies  
for health, innovation  
and trade*



IFPMA

# Geneva, Home to Unique Synergies for Health



## INTERNATIONAL ORGANIZATIONS

representing national members engaged in the critical interface between public health, innovation and trade.



## NATIONAL GOVERNMENTS

to drive their agendas through their Permanent Missions to the United Nations for more than 140 countries.



## INTERNATIONAL POLICIES & STANDARDS

for innovation, intellectual property and trade, health systems and access to medicines, regulatory, and disease-specific issues.



## GLOBAL STRATEGIES

that shape national governments' policies and impact the biopharmaceutical industry's business on the ground.

# ***We are the industry interlocutor & partner for intergovernmental organizations***



IFPMA has a consultative status with the United Nations and specialized agencies, including:

- World Health Organization (WHO)
- UNAIDS, the Joint United Nations Program on HIV/AIDS
- World Intellectual Property Organization (WIPO)
- United Nations Children's Fund (UNICEF)
- United Nations Conference on Trade and Development (UNCTAD)
- United Nations Economic and Social Council (ECOSOC)
- United Nations Industrial Development Organization (UNIDO)
- International Telecommunication Union (ITU)

and a formal relationship with:

- World Bank
- World Trade Organization (WTO)



***Engaging with stakeholders***

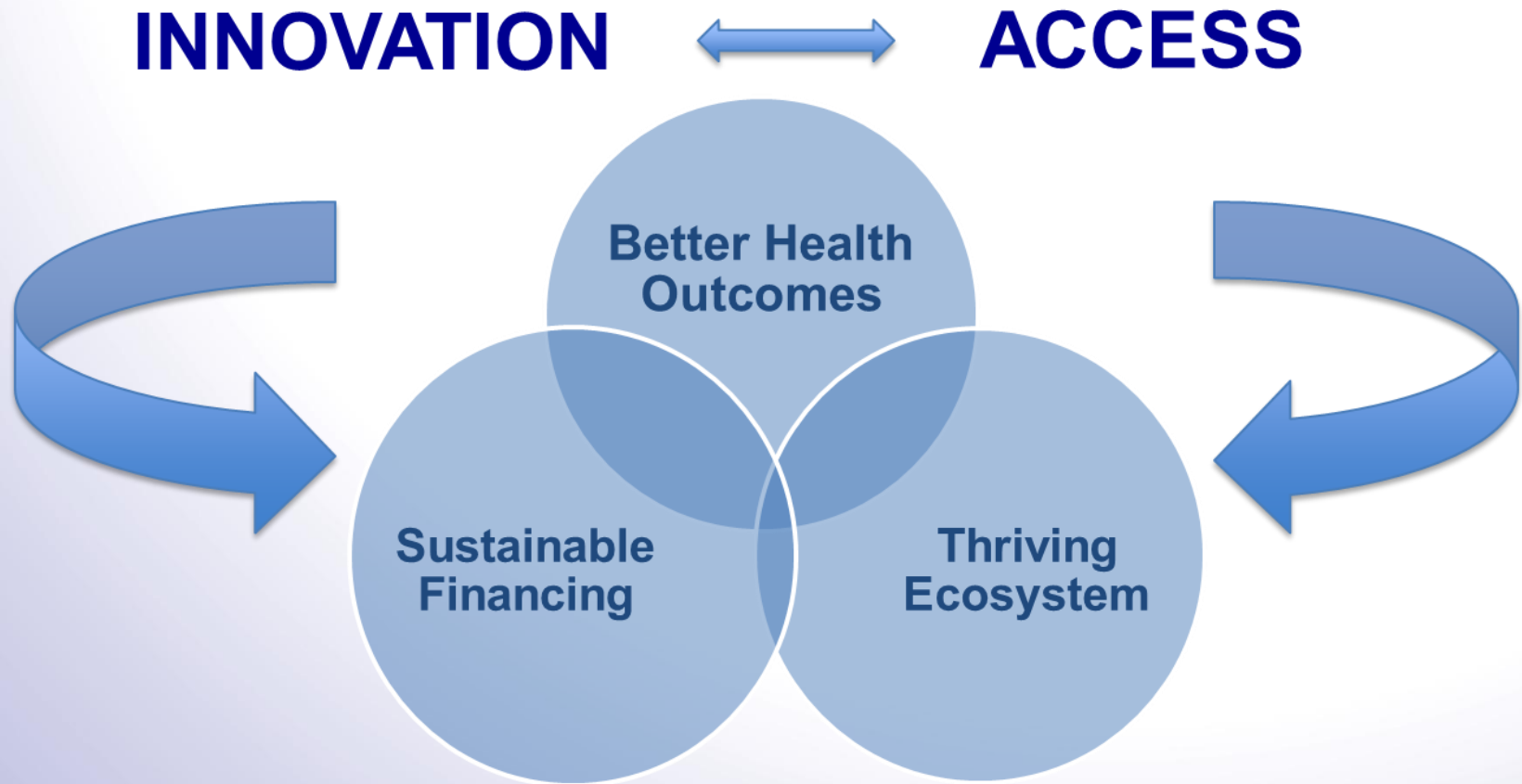
# ***Our members provide a wealth of experience & expertise***



- Over 30 leading international companies
- About 50 national and regional associations across the globe
- And many organizations who are supportive of our industry's goals

***Who we are***

# *Goals and Societal Expectations*



*Committed to a healthier future*

# Our Regulatory Policy



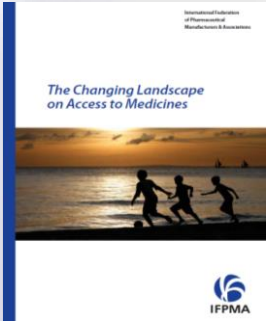
1. Promote Global and Regional Convergence of Standards (e.g. AMRH)



2. Focus on Biotherapeutics (e.g. non-comparable BTPs, INN BQ)



5. Promote cooperation & exchange of information between NRAs



3. Progress new policies & approaches with WHO's normative work (e.g. GMP, EML, INNs, lifecycle management)



4. Support efficient & expedited regulatory pathways (e.g. PQ, good review practices)



One of our four focus areas: Regulatory



# Africa Regulatory Network (ARN)

A green banner with a white ribbon icon on the left. The text reads 'STRENGTHENING REGULATORY SYSTEMS' and 'The Africa Regulatory Network (ARN)'. On the right, there are icons for email, Twitter, a plus sign, and Facebook.

STRENGTHENING  
REGULATORY SYSTEMS

The Africa Regulatory Network (ARN)

A central graphic with a white background and a pattern of light green hexagons. The central hexagon contains the text 'THE AFRICA REGULATORY NETWORK (ARN)'. Surrounding it are five other hexagons with the text: 'WHO WE ARE', 'WHAT WE DO', 'WHY WE DO IT', 'HOW WE DO IT', and 'RESOURCES'. There are also four images: a microscope, a laboratory flask with yellow liquid, a smiling young girl, and two men in white lab coats.

HEALTHCARE  
QUALITY PRODUCTS  
GUIDELINES  
COLLABORATION  
AFRICAN REGULATORY NETWORK

WHO WE ARE

THE AFRICA REGULATORY NETWORK (ARN)

WHAT WE DO

WHY WE DO IT

HOW WE DO IT

RESOURCES

*About ARN*

# ***Our Objectives***

Emphasize WHO Resolution on Regulatory System Strengthening (RSS)

Build evidence on how a strong commitment to RSS addresses gaps in expertise

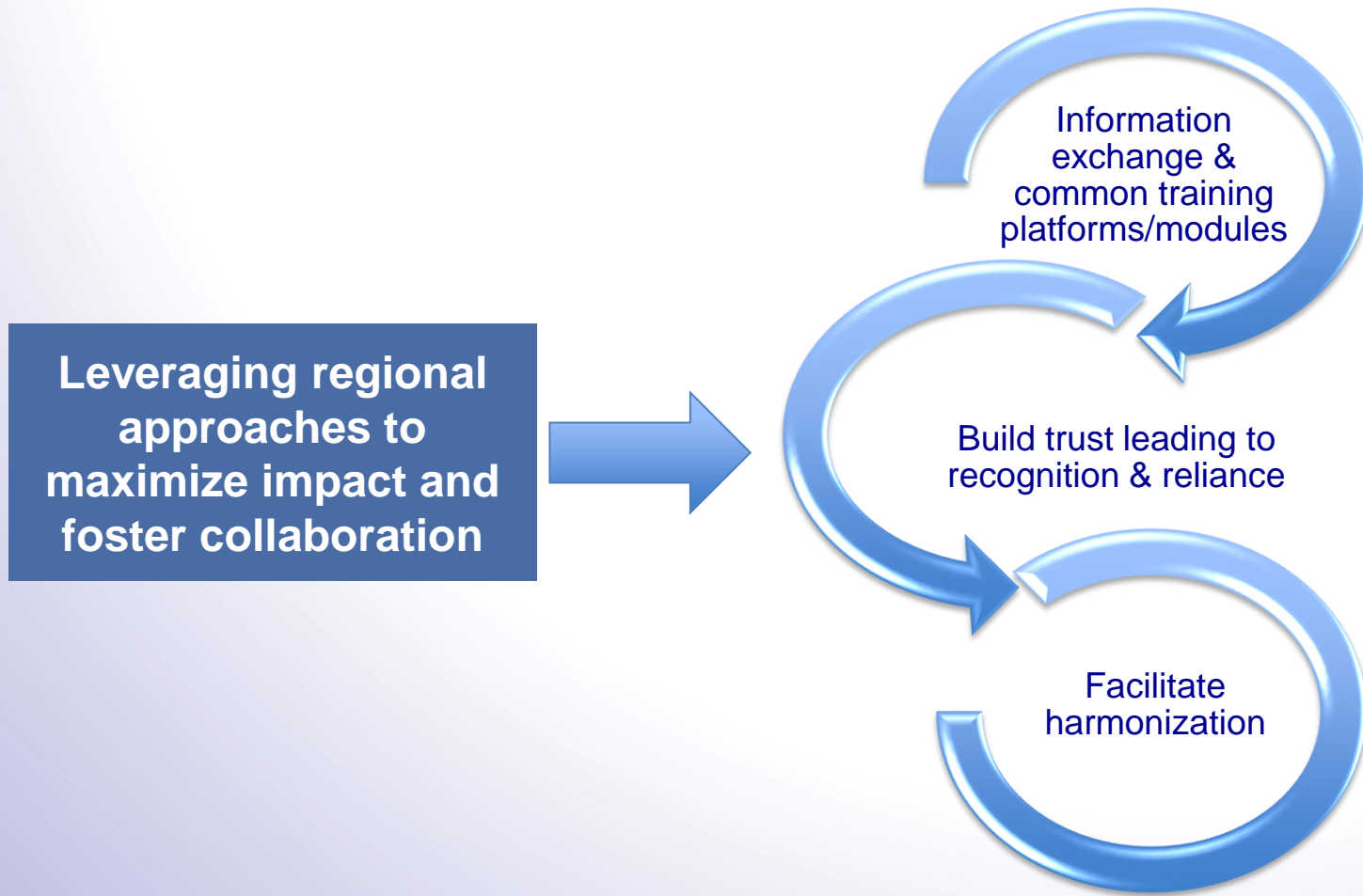
Highlight industry as key player in RSS

Raise awareness on regulatory challenges facing our industry

Share best practices and harmonization efforts

Demonstrate how global initiatives & innovation can promote convergence

# *Regulatory Convergence*



*Why we do it*

# Regulatory System Strengthening

## Regulatory Policy and Technical Standards (RPTS)

### Biotherapeutics

### Vaccines

### Counterfeit

- African Regulatory Network (ARN)
- Certificate of Pharmaceutical Product Network (CPPN)
- Regional capacity-building platforms
- Norms & Standards – *Medicines*
- PQ & Regulatory pathways (incl. pilots) – *Medicines*
- Essential medicines policies
- Clinical trials
- ICH
  
- Norms & Standards - *Biotherapeutics*
- Biosimilars
- Pharmacovigilance
  
- Norms & Standards - *Vaccines*
- PQ & Regulatory pathways – *Vaccines*
  
- Norms & Standards – *Anti-Counterfeiting*
- Legislation

*What are the technical expertise we bring*

# Regulatory Platforms

## Africa



## Asia



*How we do it: Capacity building to put regulatory in synchronization through the 6Cs*



**IFPMA**

# ***The 6 Cs***



**COOPERATION**



**COLLEGIALITY**



**CAPACITY**



**COMMITMENT**



**COMMUNICATION**



**CONVERGENCE**

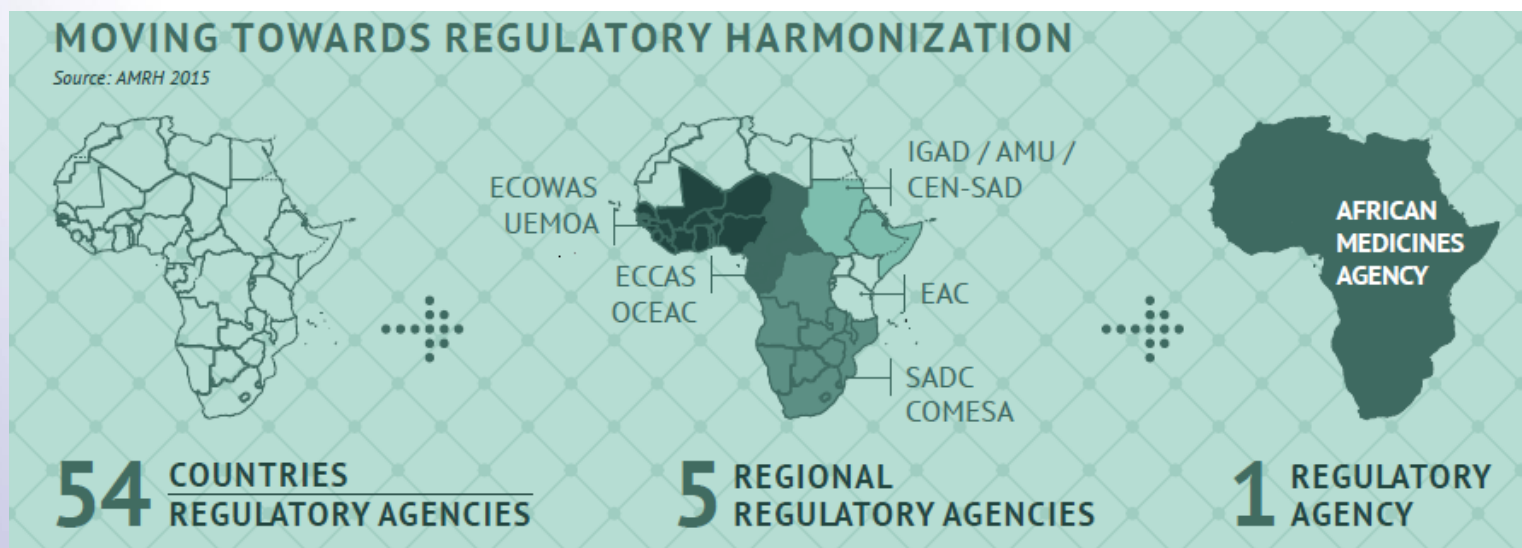
***How we do it***

## ***ARN Regional Focus Subgroups:***



## *To conclude,*

- Provide platforms for exchange of ideas and information*
- Offer technical expertise to support local capacity building*
- Contribute to develop innovative regulatory pathways*



*The way forward together*



# ***IFPMA ARN F2F Meeting in Geneva 13-14 March 2017***



1. Delegates from companies active throughout Africa
2. Key focus areas of the meeting:
  - Discussion on upcoming NEPAD 3<sup>rd</sup> Scientific Conference: 27-29 November 2017, Abijan (Ivory Coast) – “Sustaining the Momentum for Regulatory Harmonization in Africa”
  - Presentation by Swissmedic – introduced members to Swissmedic’s Market Authorization for Global Health Products (MAGHP) registration process and its potential role in Africa
  - Advocacy efforts in Geneva, Switzerland

***Learn more and stay connected!***



**IFPMA**

[www.ifpma.org](http://www.ifpma.org)

