Ensuring Medical Products We Can Trust: COVID-19, Supply Chain Transparency and Regulatory Systems

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Network Strategies for Health

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- COVID-19: Unprecedented urgency to ensure access to safe, efficacious, quality medical products for all
- The complexity of globalized medical product access and regulation
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  - SF definitions
  - Current status of reports
  - Potential drivers
- What more needs to be done to assure medicines we can trust?
  - Supply chain transparency
  - Post-market surveillance and reporting
  - Procurement, labeling and distribution
  - Join the movement

Unprecedented urgency for equitable access to safe, quality, efficacious medical products…

THE NATION

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EDITORIAL FORUM

There's fake COVID-19 drugs, say WHO, NAFDAC

June 4, 2020 in News, News Update

US-, CHINA- AND EU-FIRST NATIONALISM AND COVID-19 TECHNOLOGY HOARDING PUSH THE REST OF THE WORLD TO THE END OF THE LINE

Posted by Brook Baker | Jun 8, 2020 | Coronavirus, Domestic Policies

HEALTH

WHO, partners unveil ambitious plan to deliver 2 billion doses of Covid-19 vaccine to high-risk populations

By HELEN BRANSWELL @HelenBranswell / JUNE 26, 2020

Reprints

Hospitals in Covid-19 hotspots are running out of remdesivir

By Elizabeth Cohen, CNN Senior Medical Correspondent

Updated 2008 GMT (0408 HKT) July 12, 2020

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Global Opinions

The international community must guarantee equal global access to a covid-19 vaccine

new vaccines and therapies to respond to the escalating COVID-19 pandemic, the world's big
onalistic policies, racing to the front of the line with sweetheart deals to fund research and
preferential access to life-saving health products. These same countries (along with others)
ecessary export controls limiting supply of needed health supplies to other countries.[1] This
nked with a broken, profit-driven pharmaceutical system risks obstructing access to life-savin
ould be a moment for transformative, systemic change, but instead of an innovative respons

nature

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NEWS FEATURE · 09 APRIL 2020

If a coronavirus vaccine arrives, can the world make enough?

Researchers warn production constraints and hoarding could limit SARS-CoV-2 vaccine supplies.

Roxanne Khamsi

RW COVID-19 page: Find latest updates on global humanitarian responses

World

Countries in the Americas pool efforts to ensure access to COVID-19 vaccines

Source: PAHO · Posted: 15 Jul 2020 · Originally published: 14 Jul 2020 · Origin: View original

© PAHO

Primary country: World

Source: Pan American Health Organiz

Format: News and Press Release

Theme: Health

Disaster type: Epidemic

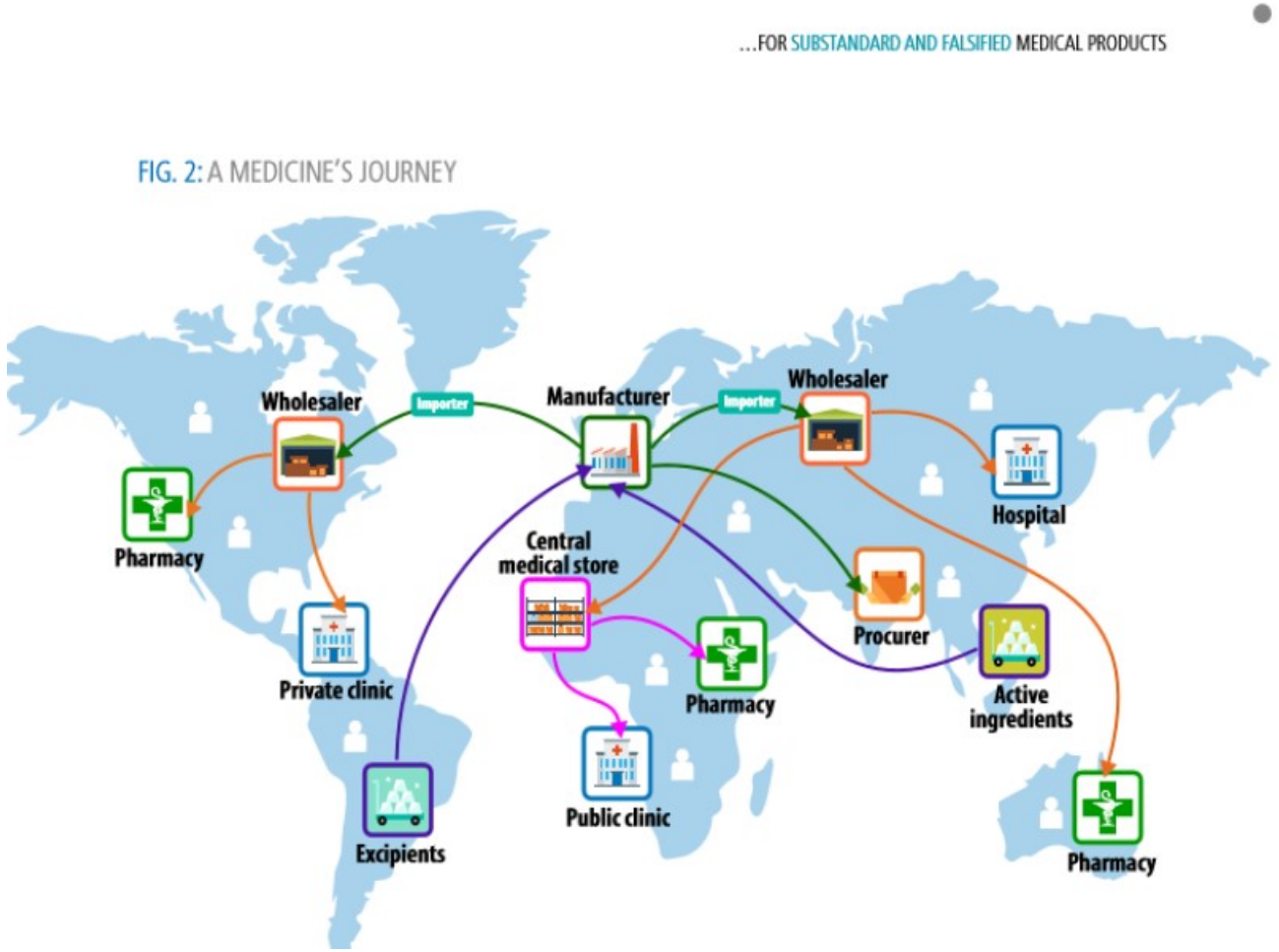
Language: English

Washington, D.C., July 14, 2020 (PAHO) — Countries in the Americas are pooling their efforts to ensure

…in the face of shortages, supply chain disruptions, false claims, harmful products

What makes this a global issue?

- 80% of ingredients in medicines from overseas
  - Ingredients from China
  - Manufacturing in India
- Complex supply chains cross jurisdictions
- Substandard and falsified medicines fail to treat and can cause harm
- Drug resistant pathogens cross borders
- People behave and act on information from around the world



https://apps.who.int/iris/bitstream/handle/10665/326708/9789241513425-eng.pdf?ua=1

Complex systems and processes are required to assure equitable market access…

Ensuring quality, safety and efficacy of health products

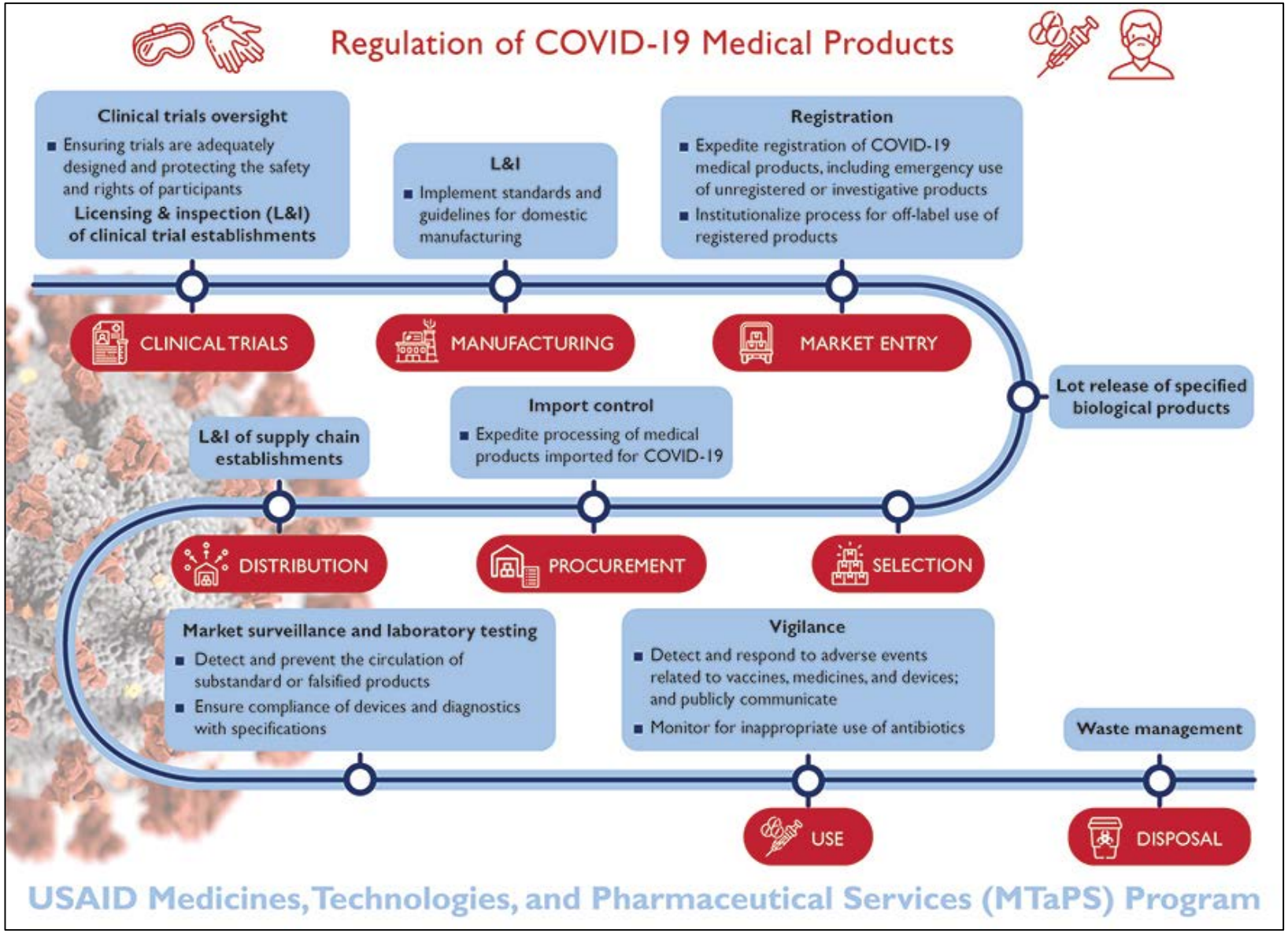
- Regulatory system strengthening
- Assessment of the quality, safety and efficacy/performance of health products through prequalification
- Market surveillance of quality, safety and performance

Improving equitable access

- Research and development that meets public health needs and improves access to health products
- Application and management of intellectual property to contribute to innovation and promote public health
- Evidence-based selection and fair and affordable pricing
- Procurement and supply chain management
- Appropriate prescribing, dispensing and rational use

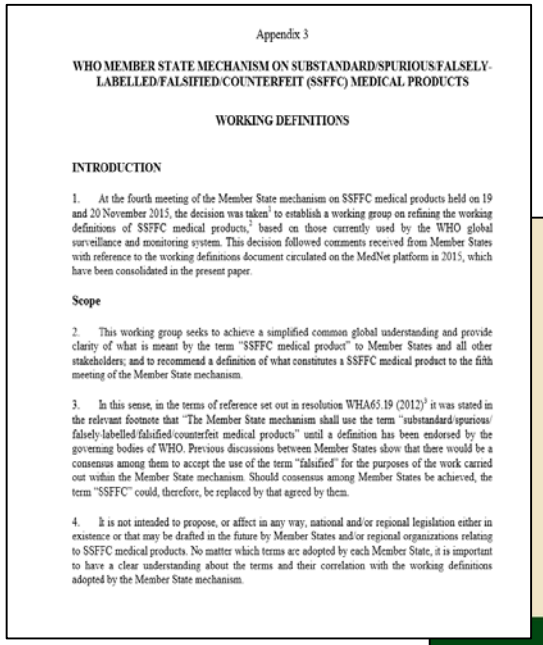
Roadmap for Access to Medicines, Vaccines and Other Health Products, WHO, 2019-2023, https://apps.who.int/iris/bitstream/handle/10665/330145/9789241517034-eng.pdf?sequence=1&isAllowed=y

…but only 1/3 of world's regulatory bodies can fulfill basic functions of ensuring product safety, efficacy and quality



Regulating COVID-19 Medical Products: An Urgent Need, MTaPS, 2020: https://mtapsprogram.org/blog/regulating-covid-19-medical-products-urgent-need

Substandard and Falsified Medicines: A threat to patients and the public health



Appendix 3

WHO MEMBER STATE MECHANISM ON SUBSTANDARD/SPURIOUS/FALSELY-LABELLED/FALSIFIED/COUNTERFEIT (SSFFC) MEDICAL PRODUCTS

WORKING DEFINITIONS

INTRODUCTION

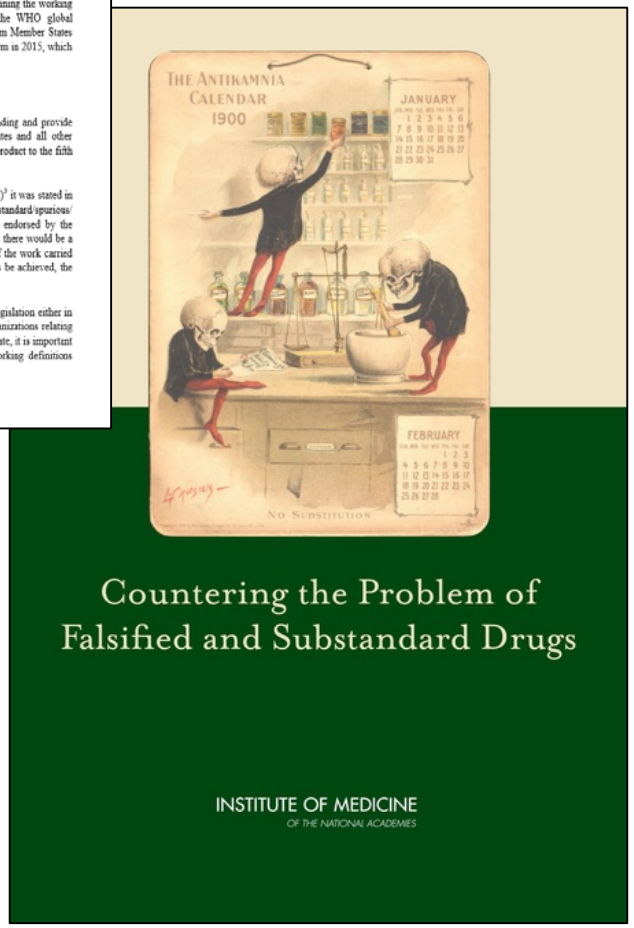
1. At the fourth meeting of the Member State mechanism on SSFFC medical products held on 19 and 20 November 2015, the decision was taken[1] to establish a working group on refining the working definitions of SSFFC medical products,[2] based on those currently used by the WHO global surveillance and monitoring system. This decision followed comments received from Member States with reference to the working definitions document circulated on the MedNet platform in 2015, which have been consolidated in the present paper.

Scope

2. This working group seeks to achieve a simplified common global understanding and provide clarity of what is meant by the term "SSFFC medical product" to Member States and all other stakeholders; and to recommend a definition of what constitutes a SSFFC medical product to the fifth meeting of the Member State mechanism.

3. In this sense, in the terms of reference set out in resolution WHA65.19 (2012)[3] it was stated in the relevant footnote that "The Member State mechanism shall use the term "substandard/spurious/falsely-labelled/falsified/counterfeit medical products" until a definition has been endorsed by the governing bodies of WHO. Previous discussions between Member States show that there would be a consensus among them to accept the use of the term "falsified" for the purposes of the work carried out within the Member State mechanism. Should consensus among Member States be achieved, the term "SSFFC" could, therefore, be replaced by that agreed by them.

4. It is not intended to propose, or affect in any way, national and/or regional legislation either in existence or that may be drafted in the future by Member States and/or regional organizations relating to SSFFC medical products. No matter which terms are adopted by each Member State, it is important to have a clear understanding about the terms and their correlation with the working definitions adopted by the Member State mechanism.



https://www.who.int/medicines/regulation/ssffc/A70_23-en1.pdf?ua=1

Substandard: Also called "out of specification", these are authorized medical products that fail to meet either their quality standards or specifications, or both.

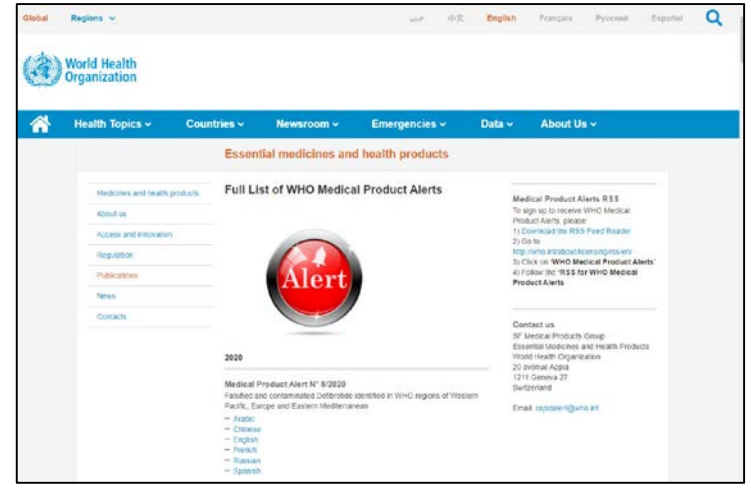
Unregistered/unlicensed: Medical products that have not undergone evaluation and/or approval by the National or Regional Regulatory Authority (NRRA) for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.

Falsified: Medical products that deliberately/fraudulently misrepresent their identity, composition or source.

Update on SF product reports

- Between January – September 2020, over 300 articles (lay and scientific literature) from 56 countries (www.iddo.org, Oxford University)
- SF COVID19 related products identified:
  - Diagnostic tests
  - Hand sanitizers, masks
  - Hydroxychloroquine
  - Dexamethasone
  - Remdesivir
  - Falsified COVID19 vaccines
- COVID19 presents a challenge to all essential medical products.

https://www.iddo.org/mqmglobe/



https://www.who.int/medicines/publications/drugalerts/en/

What do we know about drivers of SF medicines?

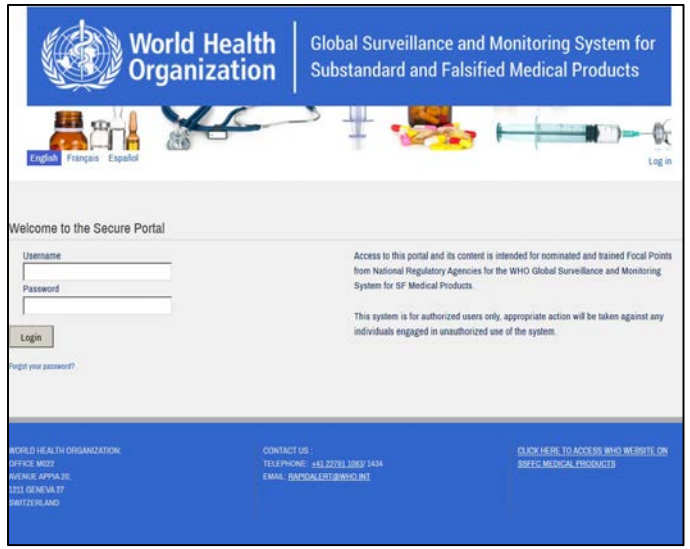
- Shocks (event-based) and vulnerabilities (underlying weaknesses) in supply chain
- Shortages
  - Increased demand can lead to shortages, price pressures
  - Unpredictable spikes in demand and insufficient demand forecasting
  - Limited sources of active pharmaceutical ingredients and excipients; rising cost of ingredients
- Environmental regulation and import restrictions
- Price: affordability and availability in relation to local market context and need
- Limited or weakened regulatory oversight

Improve supply chain transparency

- Transparency across ingredients suppliers, manufacturers, distributors
- Information sharing
  - by industry (traceability, planned or unplanned changes, expected impact)
  - Information sharing between regulators (increasing line of sight, removing statutory barriers to cooperation)
  - From prescribers (understand demand, improve forecasting and planning)
- Moving from voluntary to mandatory reporting

https://www.usp.org/sites/default/files/usp/document/about/public-policy/increasing-transparency-medicine-supply-chain.pdf

Strengthen national and global reporting:
The WHO Global Surveillance and Monitoring System



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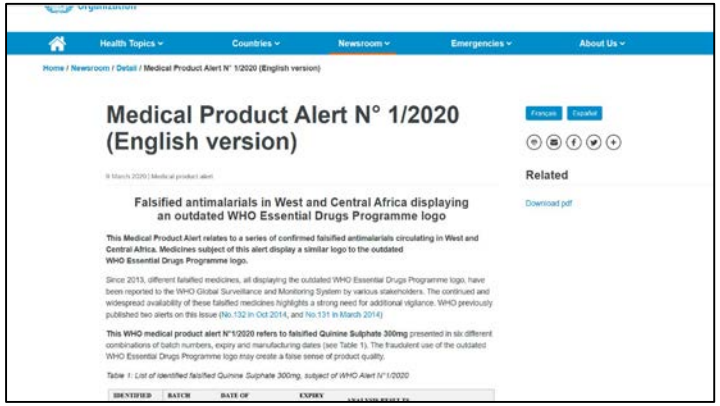
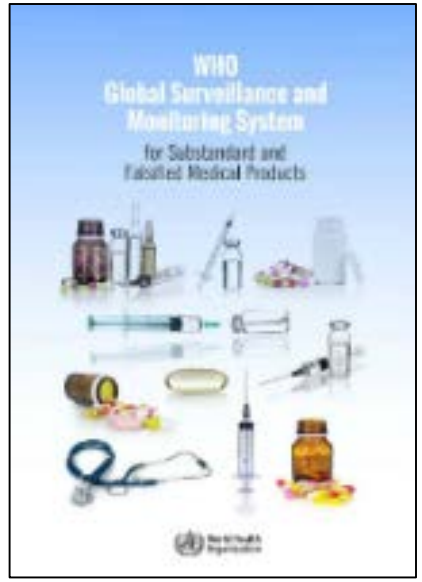
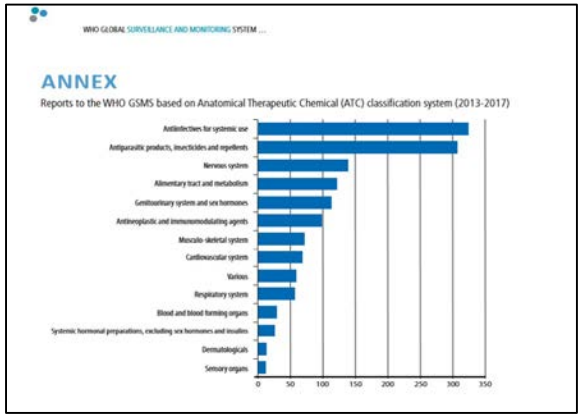


https://www.who.int/news-room/detail/09-03-2020-medical-product-alert-n-1-2020-english-version





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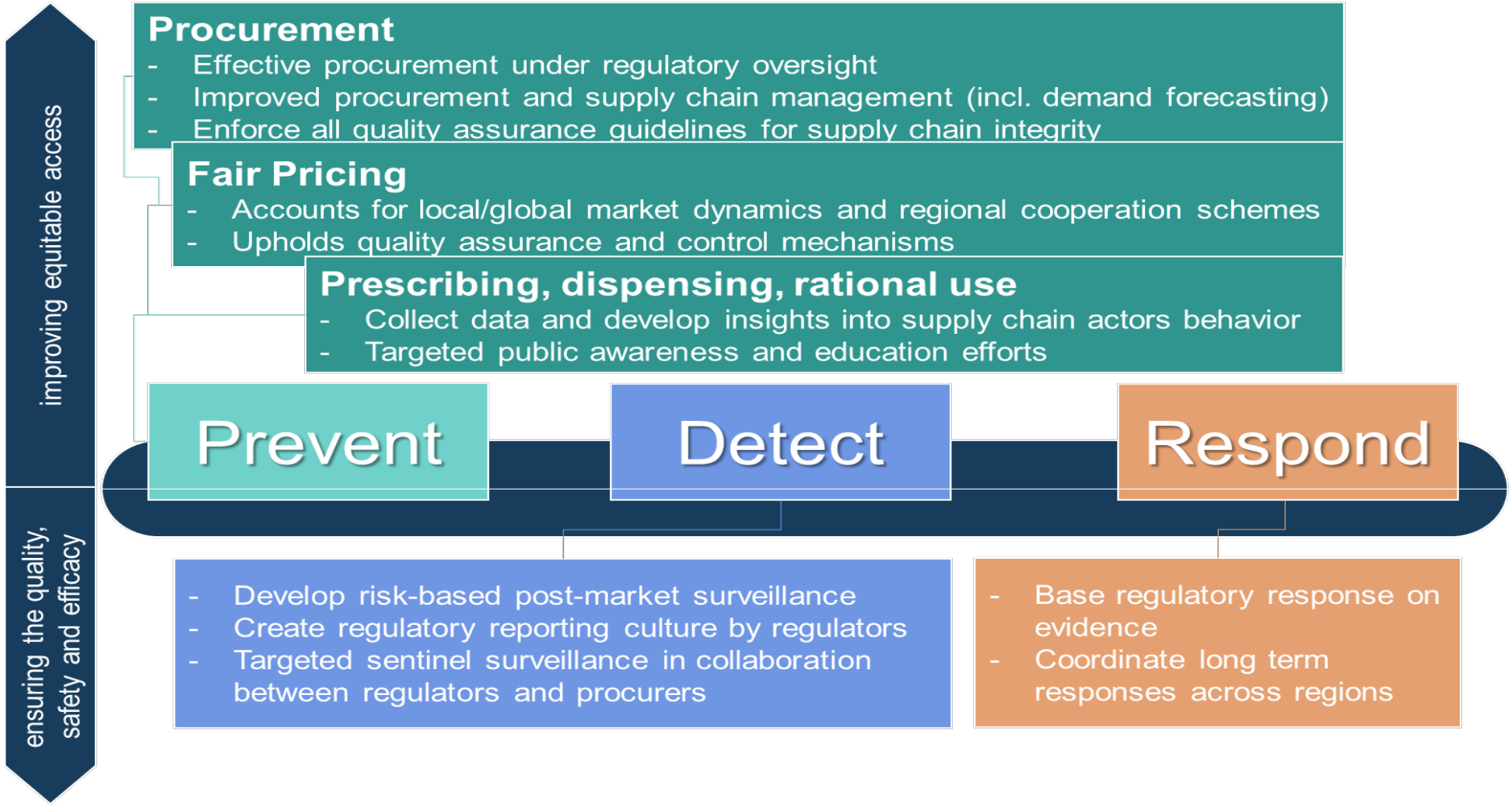
What more needs to be done?



Source: https://apps.who.int/gb/SF/pdf_files/MSM9/A_MSM9_6-en.pdf

https://medswecantrust.org/

Medicines We Can Trust

Join the Movement

The Issue | The Campaign | The Evidence | Events | Raise Awareness

Everyone should have access to medicines they can trust.

Through our network of 300+ partners, the Medicines We Can Trust campaign is galvanizing communities around the importance of medicine quality and the impact poor-quality medicines have on people's lives.

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