MARKETS FOR QUALITY-ASSURED PRODUCTS

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Innovation, Access and Use
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WHO
Objectives

- Indicate market needs for medicines and diagnostics
- Provide case examples of trends in markets for priority programmes
- Provide sources of useful market-related information
- Provide an overview of related activity at WHO
- Solicit feedback from manufacturers on priorities for WHO and partners
- Discuss how industry can work with global health community/countries to shape market initiatives
Health markets respond to health needs

Disease Ranking by DALY per 100,000. All population

<table>
<thead>
<tr>
<th>High SDI</th>
<th>Low-middle SDI</th>
<th>Low SDI</th>
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<tbody>
<tr>
<td>1 Neoplasms</td>
<td>1 Diarrhea/LRI/other</td>
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<tr>
<td>2 Cardiovascular diseases</td>
<td>2 Cardiovascular diseases</td>
<td>2 Neonatal disorders</td>
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<tr>
<td>3 Musculoskeletal disorders</td>
<td>3 Neonatal disorders</td>
<td>3 NTDs &amp; malaria</td>
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<tr>
<td>4 Mental &amp; substance use</td>
<td>4 Other non-communicable</td>
<td>4 HIV/AIDS &amp; tuberculosis</td>
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<td>6 HIV/AIDS &amp; tuberculosis</td>
<td>6 Other non-communicable</td>
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<tr>
<td>7 Diabetes/urog/blood/endo</td>
<td>7 Neoplasms</td>
<td>7 Nutritional deficiencies</td>
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<td>8 Unintentional Inj</td>
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<tr>
<td>9 Chronic respiratory</td>
<td>9 Unintentional inj</td>
<td>9 Mental &amp; substance use</td>
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<td>10 Self-harm &amp; violence</td>
<td>10 Chronic respiratory</td>
<td>10 Neoplasms</td>
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<tr>
<td>11 Diarrhea/LRI/other</td>
<td>11 NTDs &amp; malaria</td>
<td>11 Diabetes/urog/blood/endo</td>
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<td>12 Transport injuries</td>
<td>12 Musculoskeletal disorders</td>
<td>12 Other group I</td>
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<td>13 Cirrhosis</td>
<td>13 Nutritional deficiencies</td>
<td>13 Musculoskeletal disorders</td>
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<td>14 Digestive diseases</td>
<td>14 Neurological disorders</td>
<td>14 Transport injuries</td>
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<td>17 Maternal disorders</td>
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<td>18 Other group I</td>
<td>18 Digestive diseases</td>
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<tr>
<td>19 Maternal disorders</td>
<td>19 Other group I</td>
<td>19 Self-harm &amp; violence</td>
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<tr>
<td>20 War &amp; disaster</td>
<td>20 Maternal disorders</td>
<td>20 War &amp; disaster</td>
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<tr>
<td>21 NTDs &amp; malaria</td>
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<td>21 Cirrhosis</td>
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Communicable, maternal, neonatal, and nutritional diseases
Non-communicable diseases
Injuries

Source: https://vizhub.healthdata.org/gbd-compare
Downloaded 10 Sep 2017

Copenhagen, Denmark  18-21 September 2017
PQ enables a core market of ~$3.1 billion with the majority coming from vaccines

Sales of PQ products (PQ-enabled sales)
US$ M, 2014

Large donors and procurers (based on detailed PQ market sizing by each disease area and procurer)
Sales: ~$3,085M²

~$71M
~$1,971M
~$1,043M

National markets
(based on LMIC market estimation for each disease area and manufacturer perspective on access enabled by PQ)

Private market
Minimal benefit of PQ approval on private markets (except Rx Malaria)

1 Includes all product streams for HIV, TB, malaria, and reproductive health; products were PQ-approved or PQ+SRA approved; 2 $1M difference from components due to rounding; 3 Refers only to Low and Middle income markets

SOURCE: Market sizing analysis using GPRM, Global Fund PQR transaction database; RH Interchange database; UNITAID market landscape reports; UNITAID vaccine supply, UNICEF demand and supply outlook, UNICEF procurement data; WHO World Malaria Report; PEPFAR Latest Results Fact Sheet; Clinton Health Access Initiative ARV Market Report
Healthy markets: key characteristics

• Availability: appropriate products exits to meet needs
• Quality: ensured efficacy and safety
• Affordability: fair prices that allow access
• Security: sufficient capacity to meet demand
• Transparency: information on demand and supply to reduce uncertainties and risks
• Sustainability: for health systems and manufacturers

Engagement of all stakeholders
Availability:

Essential Medicines List Updated 2017

- TOTAL = 433 medicines
- Adults = 30 new
- Children = 25 new

- NEW Classification system for antibiotics AWARE

- Essential Diagnostics List in development

Availability: innovation

• Support for development process of medicines and diagnostics that target priority diseases for developing countries.

• Collaboration to identify target products, appropriate planning to secure regulatory approval and sufficient manufacturing capacity to meet demand:
  • Inter Agency Task Team Paediatric Working Group
  • Amodiaquine+SP for Seasonal Malaria Chemoprophylaxis

• WHO Priority Pathogens List and Clinical Pipeline report to be launched imminently
WHO Prequalification Programme and a number of initiatives by regulatory agencies (e.g. US, Canada, EU) provide regulatory pathway for medicines and diagnostics needed to address public health challenges.

Strengthening capacity of National Regulatory Authorities, fostering regulatory harmonization and cooperation among countries are priorities to increase efficiency in the system and address resource challenges in an increasingly demanding environment, e.g.

- WHO Global Benchmarking Tool for Regulatory Authorities
- East African Community Medicines Regulatory Harmonization (EAC MRH)
- Interest in expansion of collaborative models, including creation of African Regulatory Authority
Affordability: how to engage industry?

WHO advocates that the price paid for medicines must be fair to all – affordable to countries working towards Universal Health Coverage and sufficient to ensure a sustainable industry to produce them.

Industry has a key role in building a fair pricing model to enable access to new products.

Key activities supported by WHO and partners include strengthening procurement capacity of countries and working toward markets that allow fair competition.

Large funders and procurement agencies are also developing Procurement Strategies that consider market interventions aimed at increasing affordability and also sustainability (e.g. UNITAID Ped HIV and DR TB, Global Fund strategies for HIV and Malaria)
Supply Security

- Global Forecasts
  - ACTs, ARVs, Vaccines

- Enabling diversification of supplier base
  - Consideration of split awards and long term agreements
  - Licensing of IP - Medicine Patent Pool

- Procurement strategies for vulnerable supplies (e.g. low demand, complex market)
  - Paediatric ARV Procurement Working Group

- Mitigating impact of shortages
  - Assessment of the nature and magnitude of the problem.
  - Global shortage reporting mechanisms
Transparency

• A number of efforts to make transaction data available
• Standards and completeness still vary widely
• Difficult to obtain comprehensive information

• What else can be done?
• What does industry need?
Sources of Market Information

HIV

- **WHO/AMDS** Global Price Reporting Mechanism
- **WHO and partners** Combined global demand forecasts for antiretroviral medicines and HIV diagnostics in low- and middle-income countries from 2015 to 2020 (Sep 16)
- **Global Fund** Procurement and Quality Reporting and ARV Procurement Working Group documents. Manufacturers Meetings.
- **CHAI** ARV Market Report: The State of the Antiretroviral Drug Market in Low and Middle-Income Countries, 2015-2020 (last October 2016)
- **UNITAID** Landscape for HIV rapid diagnostic tests for HIV self-testing – 3rd edition – 2017
Sources of Market Information

Malaria

• **Global Fund** Procurement and Quality Reporting. Manufacturers Meetings.
• **UNICEF** Seasonal Malaria Chemoprophylaxis, Market Update September 2017
• **UNITAID** Malaria diagnostics technology and market landscape: 3rd edition – July 2016

TB

• **Stop-TB/GDF** Product List
• **UNITAID** Tuberculosis diagnostics technology landscape – 5th edition (July 2017)
Sources of Market Information

Reproductive Health

• Reproductive Health Supply Coalition Supply Interchange
• UNFPA catalogue and reports

General

• UNICEF Supply Division homepage
• MSH Price Indicator Guide
HIV: Demand

- 36.7 million people living with HIV at end of 2016
- 1.8 million new cases
- 19.5 million people living with HIV were receiving ART
  - 54% of adults
  - 43% of children
- 76% of pregnant women living with HIV had access to antiretroviral medicines to prevent transmission of HIV to their babies
- Approximately 30 per cent of people with HIV remained unaware of their status

- Major milestones being met but more testing required
- Still unmet meet and more funding required

UNAIDS estimates USD 26.2b 2020

WHO website, 2017; UNAIDS Global Aids Update 2017 and factsheet 2017
HIV: Market trends

2015 USD 1.4 Billion estimate but better data needed
Source: WHO Global Price Reporting Mechanisms
HIV: Market trends

Characteristic market behaviour
• Increasing volumes and manufacturers
• Decrease in unit price

Source: WHO Global Price Reporting Mechanisms
HIV: Market trends. Diagnostics

- Demand for HIV diagnostics is expected to continue growing driven by programme scale up.

- Rapid Diagnostic Tests represent largest expenditure in Global Pricing Reporting Mechanism and Global Fund Price Quality Reporting Mechanism.

- The market dominated by a few manufacturers - one company concentrating 1/3rd of orders in 2015.

- New guidelines Early Infant Diagnostic testing and HIV self-testing are expected to drive increase in demand.
Demand: Malaria

212 million cases in 2015, 90% in Africa

Incidence rate fell by 21% between 2010 and 2015

More and more children are tested in Africa (51% presenting with fever tested)

Five-fold increase in coverage of preventive treatment in pregnant women from 2010 to 2015

One third of target for Seasonal Malaria Chemoprevention reached in 2016

Decline in the burden of malaria but still more to do

Source: 2016 World Malaria Report, WHO; UNICEF
Malaria: Market trends Artemisin Combination Therapy ACTs

Shipment data, based on data provided by 10 companies eligible for procurement by WHO/UNICEF

Copenhagen, Denmark | 18-21 September 2017
Malaria: Market trends Artemisinin Combination Therapy ACTs

- Expansion of ACTS through private sector will increase coverage
- UNITAID forecast: no significant changes
- Price of ACT remained relatively stable.
Malaria: Seasonal Malaria Chemoprophylaxis (SMC)

50 percent of the global SMC target is unmet.

Scale up of SMC programmes is largely constrained by limited sources of quality-assured medicines.

- Listed in WHO Expression of Interest (EOIs) since 2012.
- Expert Review Panel approval since 2013
- 1 WHO PQ: 20 Oct 2014
- 3 ERP approved
- 2 products under assessment
Volumes RCTs linked to funding and penetration in private sector
UNITAID forecast
- No dramatic changes expected
- Prices have declined which may make market unattractive
Demand: Tuberculosis

2.3 billion people infected with TB

10.4 million new cases each year

480,000 new cases of multidrug resistant TB (MDR-TB) in 2015

only 20% started on MDR-TB treatment

Increasing uptake of molecular diagnostics and shorter MDR-TB regimes

- This is a big market AND more is needed
- International donors finance 90% national TB programmes in low-income countries

Copenhagen, Denmark | 18-21 September 2017
Tuberculosis: Market trends (from Global Drug Facility)

GDF Orders Placed with Suppliers - Value and Volume over time

Source: GDF
GDF MDR Treatment Regimen Price Trends

Standard Regimen (20 months)
8 Months Kanamycin, Pyrazinamide, Levofloxacin, Ethionamide, Cycloserine/
12 Months Pyrazinamide, Levofloxacin, Ethionamide, Cycloserine

*Note: New Shorter Regimens (9 months) estimated price is approximately $700
Tuberculosis: Market trends

**Medicines under assessment**

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<tr>
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<th>FPPs</th>
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<td>1st line</td>
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<tr>
<td>2nd line</td>
<td>34</td>
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<tr>
<td>Pediatric (1st and 2nd)</td>
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**Manufacturers with products prequalified**

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<tbody>
<tr>
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<tr>
<td>2nd line</td>
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<tr>
<td>1st &amp; 2nd</td>
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<td>3</td>
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<tr>
<td>Total</td>
<td>6</td>
<td>14</td>
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Demand: Reproductive Health

Use of modern contraception has risen only slightly, from 54% in 1990 to 57.4% in 2015

214 million women in developing countries who want to avoid pregnancy are not using a modern contraceptive method

Each year, 357 million new infections with 1 of 4 STIs: chlamydia, gonorrhoea, syphilis and trichomoniasis

Postpartum Haemorrhage is the primary cause of one quarter of all maternal deaths globally
Reproductive Health: Market trends

2015 (by value)
- Implants 33%
- Injectables 24%
- Male condoms 23%

UNFPA and USAID managed majority of the procurement (90% of value)

Source: RHInterchange
Reproductive Health: Benzathine benzinpenicillin

- Benzathine benzinpenicillin or benzathine penicillin G (BPG) is the only recommended treatment for syphilis in pregnant women to prevent mother to child transmission of congenital syphilis.

- Limited sources of quality assured BPG and shortages in recent times have impacted UN agencies ability to supply it.

- Plans to scale up screening and treatment of pregnant women hampered by lack of quality assured products.

- Added to WHO PQ programme in Jan 2017.
- Engagement with UN Agencies and submissions to WHO PQ needed.
Thank You