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Pharmaceutical R&D for Reproductive, Maternal, Newborn & Child Health:

**Is there a role for
investors to rectify
this market failure?**

Presentation Outline

- Background
- Challenges to Pharmaceutical Business Model
- RMNCH Pharmaceutical Pipelines ?
- Incentive structures
- Role of investors ?
- Questions

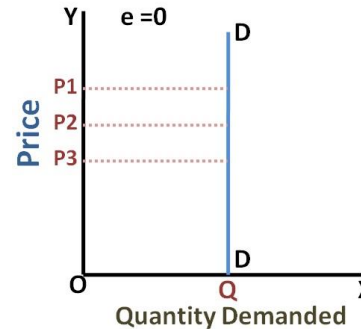
Pharmaceuticals: Commodity or Right

What's the Dilemma ?


- Inelastic demand for health.
- Most powerful 'commodity' on Earth !
- Health is a Human Right !
- Pharmaceuticals = Global Public Goods

• • •

- Private sector provision. (IP based)
- Free market economics ?
- Very lucrative industry
- No one size fits all!



First expression of the right to health:
The **WHO Constitution** (1946)



The Universal Declaration of Human Rights

The universal right to health

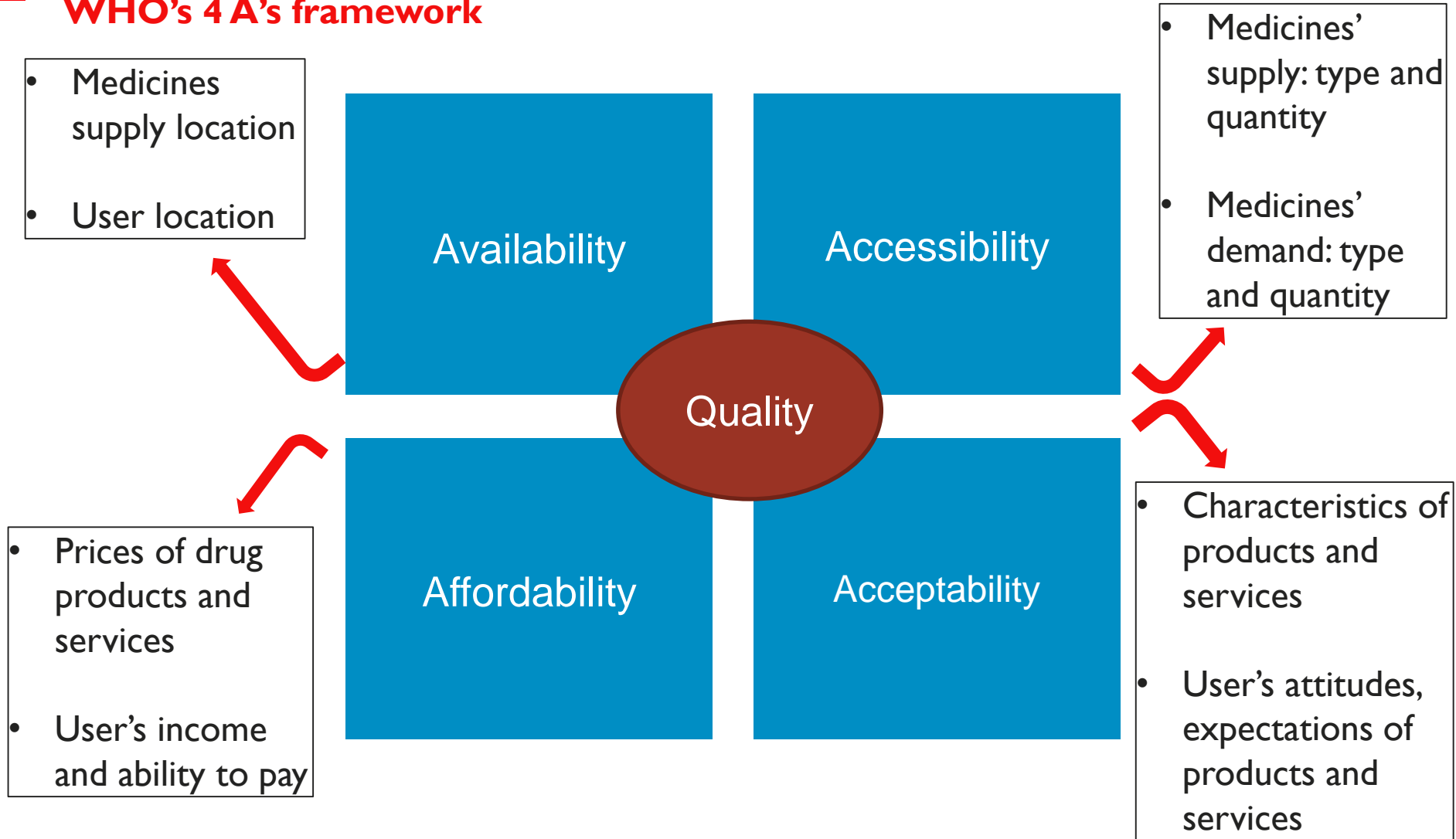
International Covenant on Economic, Social and Cultural Rights (Art 12)

"The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."

Health Policy V.s. Industrial Policy

Access to Medicine's & LMIC's

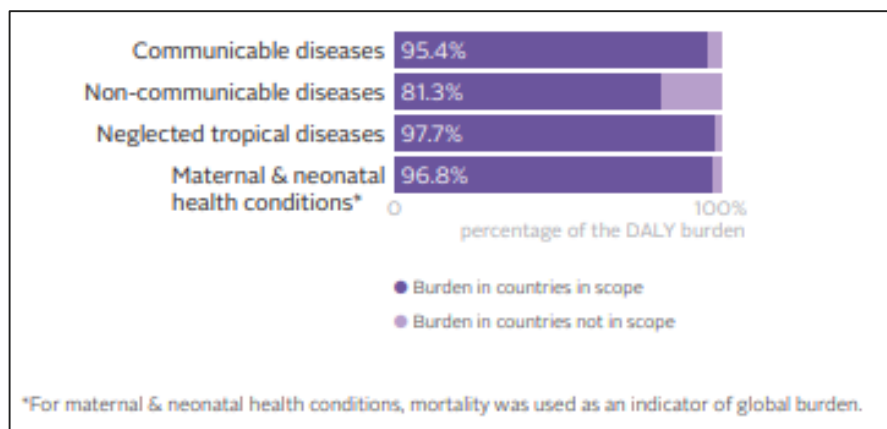
WHO's 4 A's framework



Reproductive, Maternal, Newborn & Child Health

Maternal Mortality

- 810 women die daily from preventable causes related to pregnancy and childbirth.
- 94% of all maternal deaths occur in low and middle income countries.
- Sub-Saharan Africa (SSA) and Southern Asia accounted for approximately 86% (254 000)
- SSA alone accounted for roughly two-thirds (196 000) of maternal deaths.



***75% of ALL Maternal Deaths ***

- severe bleeding (mostly bleeding after childbirth)
- infections (usually after childbirth)
- high blood pressure during pregnancy (pre-eclamps)
- complications from delivery
- unsafe abortion.

United Nations Commission
on Life-Saving Commodities



10 Recommendation = ↑ 13 lifesaving commodities

Rep

lth

Morta

- 810
- 94%
- Sub
- SSA

Commodity by life stage	Examples of key barriers	Recommendations	Potential 5-year impact
Maternal health commodities			
1. Oxytocin – post-partum haemorrhage (PPH)	Often poor quality	1, 4, 5	15,000 maternal lives saved
2. Misoprostol – post-partum haemorrhage	Not included in national essential medicine lists	5	
3. Magnesium sulfate – eclampsia and severe pre-eclampsia	Lack of demand by health workers	1, 9, 10	55,000 maternal lives saved
Newborn health commodities			
4. Injectable antibiotics – newborn sepsis	Poor compliance by health workers	1, 9, 10	1.22 million neonatal lives saved
5. Antenatal corticosteroids (ANCs) – preterm respiratory distress syndrome	Low awareness of product and impact	9	466,000 neonatal lives saved
6. Chlorhexidine – newborn cord care	Limited awareness and demand	2, 5	422,000 neonatal lives saved
7. Resuscitation devices – newborn asphyxia	Requires trained health workers	1, 9, 10	336,000 neonatal lives saved
Child health commodities			
8. Amoxicillin – pneumonia	Limited availability of child-friendly product	2, 7, 9, 10	1.56 million lives saved
9. Oral rehydration salts (ORS) – diarrhoea	Poor understanding of products by mothers/ caregivers	2, 5, 7, 9, 10	1.89 million lives saved
10. Zinc – diarrhoea			
Reproductive health commodities			
11. Female condoms	Low awareness among women and health workers	1, 7	Almost 230,000 maternal deaths averted
12. Contraceptive implants – family planning/ contraception	High cost	1, 7	
13. Emergency contraception – family planning/ contraception	Low awareness among women	2, 7	

*For matern

Unit
on Li

Save the Children

Pharmaceutical R&D for RMNCH

16th June 2020

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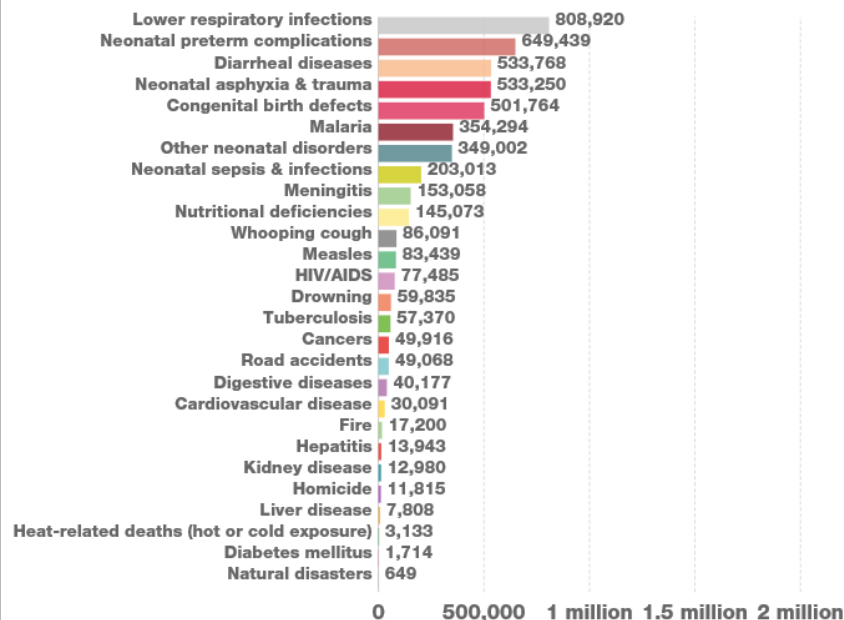
Reproductive, Maternal, Newborn & Child Health

Newborn & Child Mortality

- In 2018 an estimated 6.2 million children and adolescents under the age of 15 years died, mostly from preventable causes.
- Of these, 5.3 million occurred in the first 5 years, with almost half of these in the first month of life.
- 2.5 million children died in the first month of life in 2018.

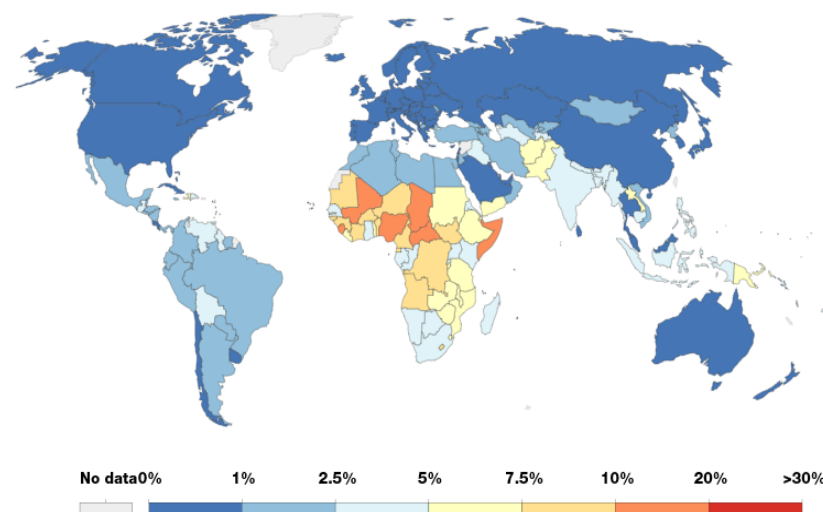
Causes of death in under-5s, World, 2017

Annual number of deaths by leading causes in children under 5 years old.



Child mortality rate, 2017

The share of newborns who die before reaching the age of five.



Source: UN Inter-agency Group for Child Mortality Estimation

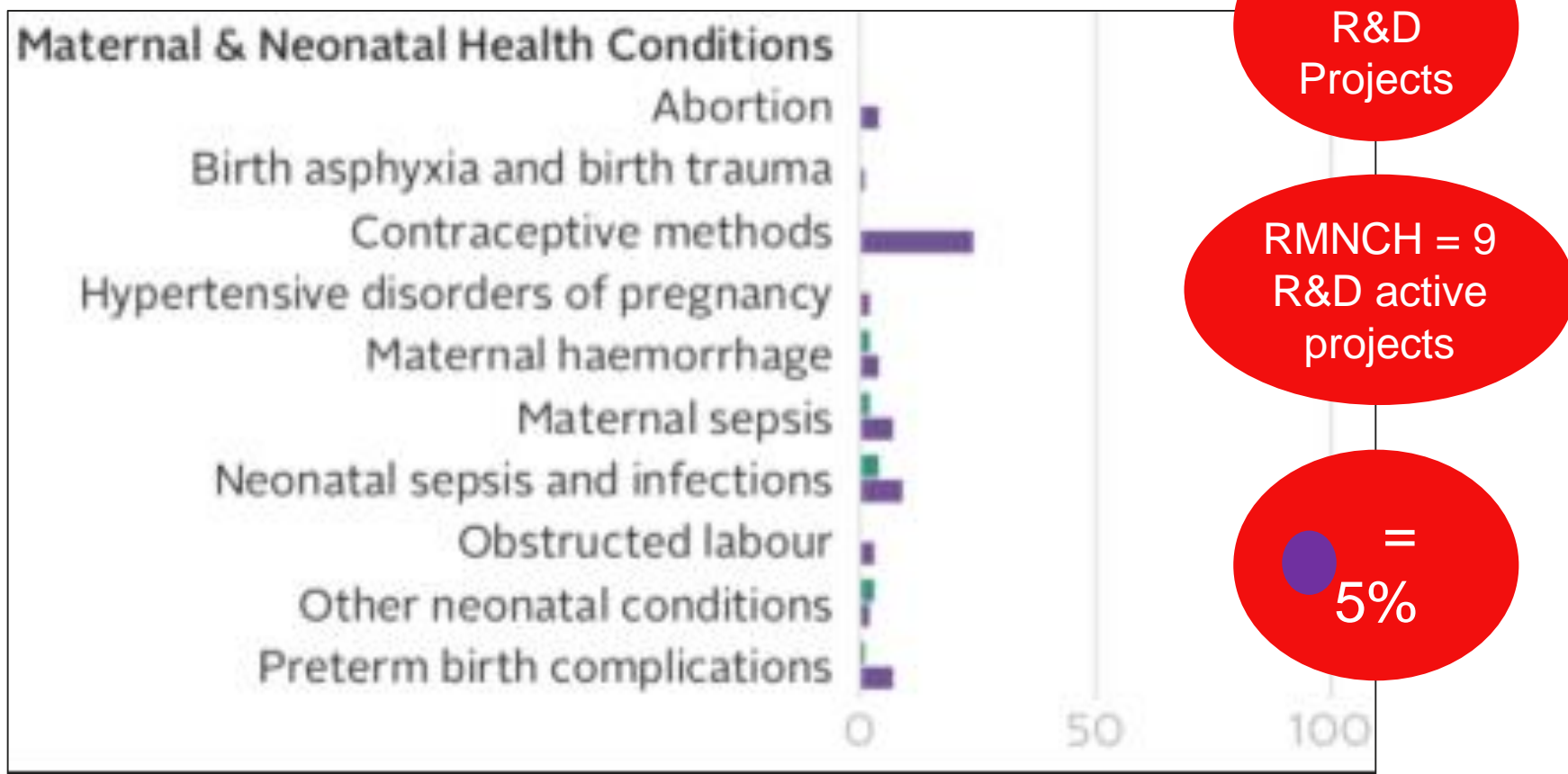
OurWorldInData.org/child-mortality • CC

Note: The child mortality rate expresses the probability of a child born in a specific year or period dying before reaching the age of five, subject to age-specific mortality rates of that period. This is given as the share of live births.



Pharmaceutical Pipelines ?

Maternal & Neonatal Conditions



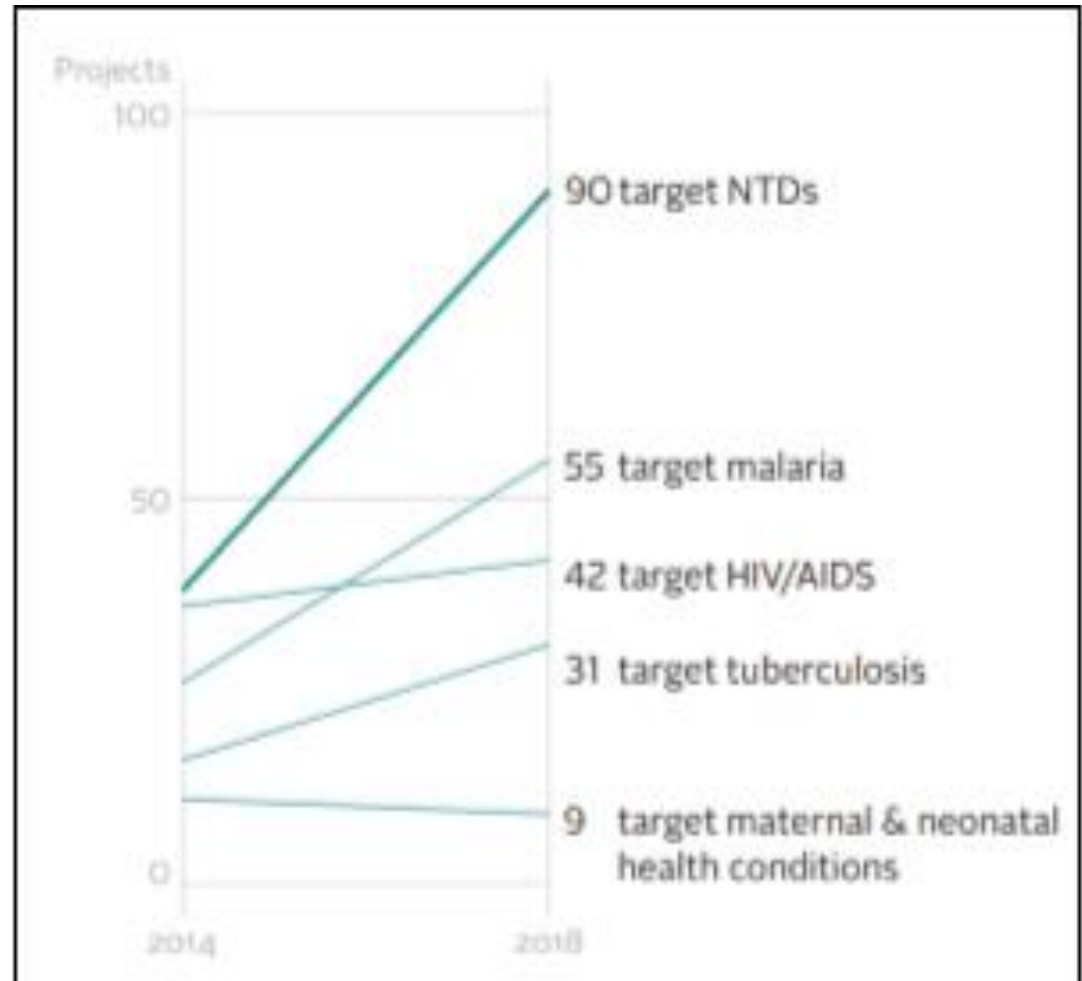
Source: 2018 Access to Medicine Index

Pharmaceutical Pipelines ?

A Cause for Concern

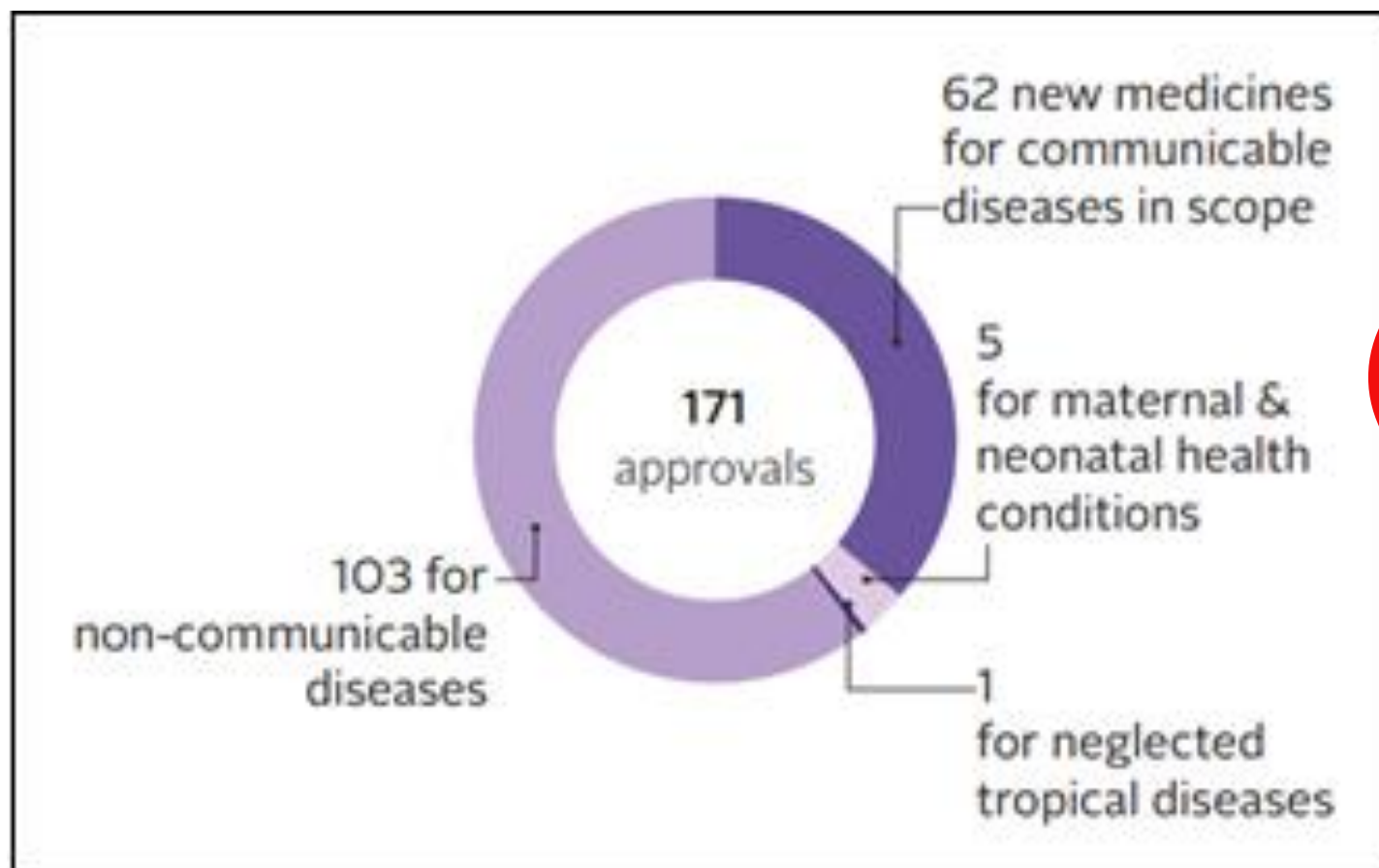
- Symptom of low political priority afforded to Women and Children
- Incentives ! Incentives ! Incentives !
- Role of Global Health Community/ Donors ?
- Need for a new business model?

R&D pipelines for key diseases Since 2014



Pharmaceutical Pipelines ?

New drug approvals since 2008



< 3
%

Pharmaceutical Pipelines ?

Medicines for Children



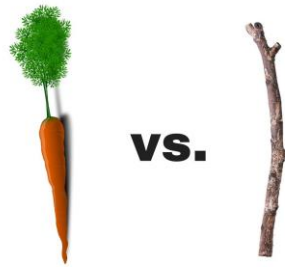
GSK,
J&J,
Sanofi

21/
29

Incentive Structures ?

Medicines for Women & Children = Unique Challenges

- Clinical Trial: Ethics, Technicality & Cost
- Small market size relative to adult market
- Market Failure !



Incentives V.s Legislation

- Lego-regulatory mechanisms.
- European Medicines Agencies' (EMA) 2007 paediatric regulation framework **PIP**
- Inclusion of paediatric data = 6 Month IP extension (*2 years when orphan drug)
- Financial Incentives ? ...Push V.s Pull
- Success Story : **Advanced Market Commitment for PCV (Childhood Pneumonia Vaccine)**

Role for Investors ?

Investment ethos/appetite

Tools: Informed investments

Investor Influence: 'Money Talks'



A role for investors ?

High ROI & SRI = not mutually exclusive

The screenshot shows the Financial Times website. At the top, there is a search bar and the 'FINANCIAL TIMES' logo. Below the logo, a navigation bar lists various sections: WORLD, US, COMPANIES, TECH, MARKETS, GRAPHICS, OPINION, WORK & CAREERS, LIFE & ARTS, and HOW TO SPEND IT. A large banner on the left encourages becoming an FT subscriber. The main headline reads 'Companies with strong ESG scores outperform, study finds'. To the right of this headline is a decorative image of a horn. Below the main headline, there is a section titled 'Sustainable Funds Fell Less During the Selloff' with a sub-headline stating 'It is only a short period, but ESG funds held up a bit better than the overall market during the coronavirus-fueled stock drop'. The article is by Maitane Sardon and was updated on May 3, 2020. It includes a 'PRINT' button and a 'TEXT' button. The article text begins with 'Most stock funds saw declines due to coronavirus- and energy-related selling during the first quarter, but "do good" funds saw smaller declines than most other types. Funds that practice sustainable, also referred to as ESG, strategies typically base investments on environmental, social and governance criteria. Some exclude specific products or sectors—such as tobacco, arms, fossil fuels or gambling—while others invest in companies that take actions to protect the environment or their workers. The most sophisticated ones include...'. On the right side of the article, there is a 'WSJ PRO CYBERSECURITY' advertisement for a 'Special Report: Keeping Your Workforce Secure Remotely' with a 'Free Download' button. At the bottom right, there is a 'FROM THE EXPERTS' link.

FINANCIAL TIMES

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Companies with strong ESG scores outperform, study finds

MARKETS | JOURNAL REPORTS: FUND/ETFS

Sustainable Funds Fell Less During the Selloff

It is only a short period, but ESG funds held up a bit better than the overall market during the coronavirus-fueled stock drop

By Maitane Sardon
Updated May 3, 2020 10:13 pm ET

PRINT TEXT

Most stock funds saw declines due to coronavirus- and energy-related selling during the first quarter, but "do good" funds saw smaller declines than most other types.

Funds that practice sustainable, also referred to as ESG, strategies typically base investments on environmental, social and governance criteria. Some exclude specific products or sectors—such as tobacco, arms, fossil fuels or gambling—while others invest in companies that take actions to protect the environment or their workers. The most sophisticated ones include...

WSJ PRO CYBERSECURITY

Special Report: Keeping Your Workforce Secure Remotely

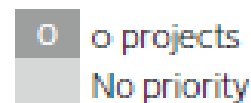
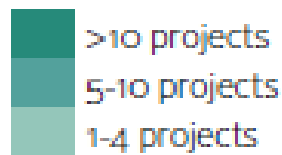
Free Download

FROM THE EXPERTS

Many priority product gaps go unaddressed

The table shows which products are urgently needed by people living in low- and middle-income countries, as identified by WHO and Policy Cures Research. Diseases with the most unaddressed gaps are at the top. The zeroes represent gaps that receive no attention from companies in scope. A total of 91 of the 139 gaps are unaddressed.

Figure 5



Diseases, conditions and pathogens	Gaps Remaining	Product types						
		Medicines	Vaccines (Preventive)	Vaccines (Therapeutic)	Diagnostics	Microbicides	Vector Control Products	Devices (Reproductive Only)
Crimean-Congo haemorrhagic fever (CCHF)	5	0	0	0	0		0	
Rift Valley fever (RVF)	5	0	0	0	0		0	
Severe fever w thrombocytopenia syndr. (SFTS)	5	0	0	0	0		0	
Arenaviral haemorrhagic fevers (incl. Lassa fever)	4	0	0	0	0			
Coronaviruses**	4	0	0	0	0			
Nipah	4	0	0	0	0			
Buruli ulcer	3	0	0		0			
Leishmaniasis	3	13	0	0	0			
Marburg	3	0	1	0	0			

● Communicable diseases ● Neglected tropical diseases
● Maternal & neonatal health conditions

5. [Takeda Pharmaceutical Co., Ltd.](#)

THANK YOU



Save the Children

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