Ensuring Quality in Manufacturing and Importing Pharmaceutical Products: Opportunities for South-to-South Collaboration

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1. Increasing need for drugs and devices
2. Limited resources
3. What is limiting South-to-South trade?
4. Results of the Partners survey
5. Why generic drugs?
6. Getting to quality assurance
7. Suggested solutions.

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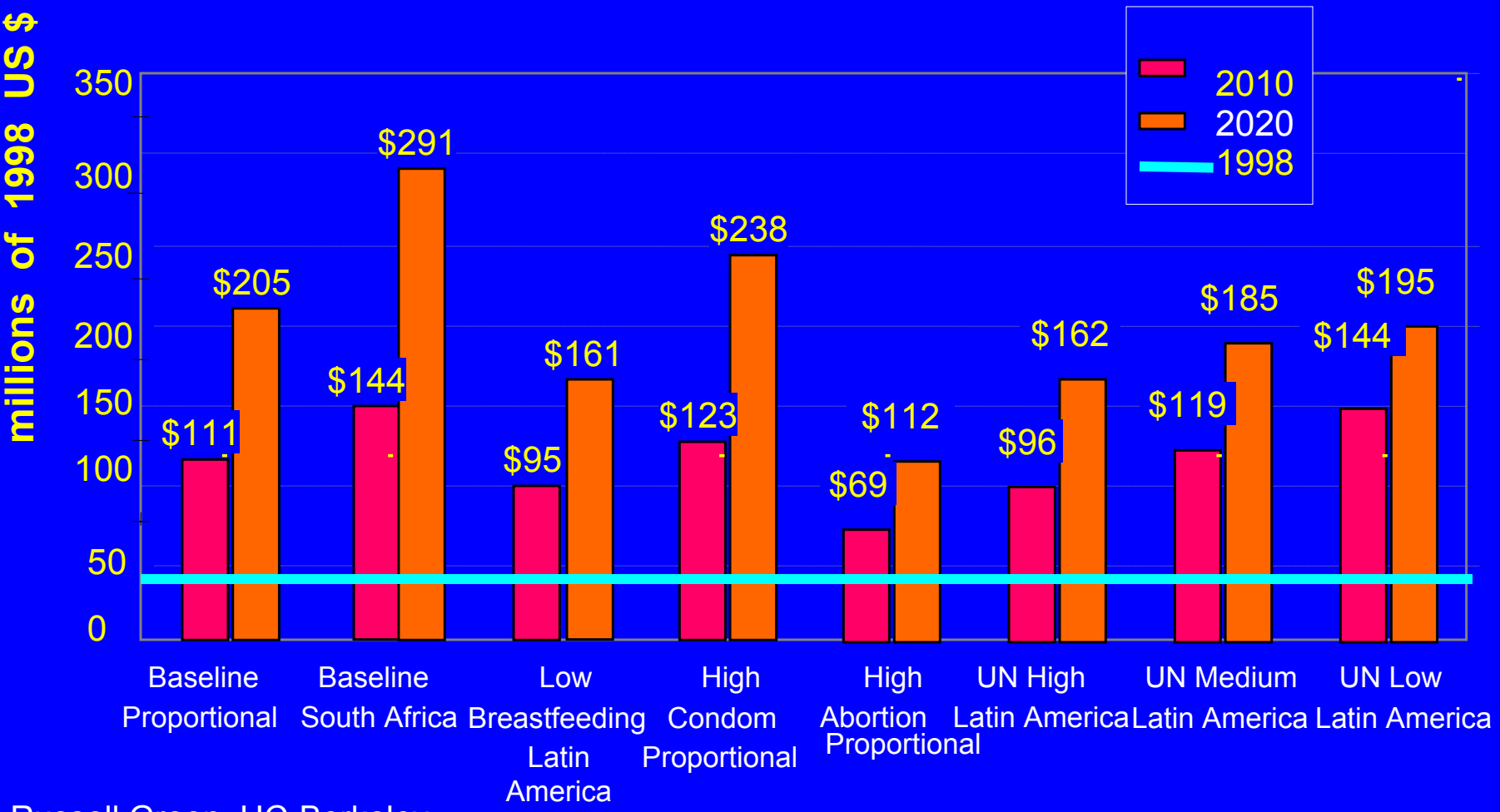
Sub-Saharan commodity costs in years 1998 (line), 2010, 2020



Russell Green, UC-Berkeley

Percent of Population Who Can Afford the Full Cost of of Family Planning

Assuming the 'one percent rule'

Sub-Saharan Africa	**3 %**
Arab States/ E. Europe	**29 %**
Latin America	**49 %**
Asia	**7 %**
All aid-dependent nations	**16 %**

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Financing commodities

- **Donor agencies**
- **Government procurement from tax base**
- **Commercial market import and distribution**

Per capita annual health expenditures by Partner country governments

12 Partner countries **≤ $27**

7 Partner countries **≤ $6**

at international exchange rates

Data source: WHO, 2000

In 14 Partner countries:

Out-of-pocket health expenditures per capita exceed governments' spending for health per capita.

How can we ensure that there are high quality, low cost products for the consumer to buy?

Why is market distribution important?

- Efficiency: Market distribution can grow rapidly to large scale.

- Reduce the burden on government ministries – allowing public services to focus on the most vulnerable people.

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What limits South-to-South pharmaceutical trade?

One key reason:

Regulatory processes to approve import varies from country to country. Working through them can be time-consuming and costly for the manufacturer.

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Test required for approval of off-patent pharmaceutical products

	Yes	No
Are physical tests of composition required?	**8**	**0**
Are stability tests required?	**7**	**1**
Are bioequivalence tests required for some products?	**7**	**1**

Wide variation in costs in Partner countries

Cost of physical composition tests	**$60 to $1000 USD**
Cost of bioequivalence tests	**$6,000 to $20,000**

Accept tests from other countries?

Are results of tests conducted for drug registration in other countries ever accepted in your country?

Yes - 8

No - 0

Drug regulation offices in Partner countries

	Yes	No
Are all the posts in the regulatory office filled by appropriately qualified personnel?	4	4
Are staff easy to recruit and retain?	4	4

Would your country welcome Partners' setting up a system whereby off-patent pharmaceutical products made in the South can undergo the required chemical tests, to facilitate swift regulatory approval for importing off-patent products into many countries?

Yes - 7

No - 1

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Off patent drugs: an immediate opportunity

- Gro Harlem Brundtland
- Expanding in the U.S.
- Many of the pharmaceutical products needed in the developing world are off patent.

Examples of off-patent FP and RH products

- Monophasic oral contraceptives
- Depomedroxyprogesterone acetate (Depo Provera) – injectable contraceptive
- Misoprostol (brand name: *Cytotec*)
- Mifepristone (off patent soon)

…and more off-patent products. These are needed & hard to get.

- PAS
- Streptomycin
- Isoniazid
- Penavalent antimony (Pentoshan)
- Spectinomycin HCl (Trobicin, Togamycin)
- Clindamycin phosphate/clindamycin HCl (Dalacin)

Microbicides - a special case

- Vaginal microbicides - can protect women from HIV infection and STIs
- Not generic, but license arrangement can be obtained
- Moving slowly through US FDA route
- ***Should be a South-to-South product***

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Quality Assurance

Similar questions in manufacturing and import approval.

Precisely defined protocols
Physical and chemical tests of

- raw materials
- intermediate stages
- final products.

GMP...Filters...Procedures...Controlling the manufacturing environment...Shelf life... Packaging and labeling...

Quality assurance for approving generic drugs

For products off patent:

- Showing that the generic drug is essentially the same as the original drug
- Assurance of manufacturing procedures and controls

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Suggestion #1

a Partners testing certificate

Subcontract tests on generic drugs out to laboratories - -

- physical and chemical quality of the product
- stability
- bioavailability, where needed.

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Decide: *which labs --- which products*

--- frequency of tests ---

Opportunity to consider: Testing a product 3 times over 6 years may result in higher product quality at lower cost than every country's own testing a single time.

Suggestion #2

"Partners common market" approach

- Share information among countries on approvals of pharmaceutical products.

- If a product is approved by one member country, that approval could be extended to all member countries.

Suggested principles

1. Be cautious about harmonization, which might constrain trade.

2. Collaboration can be ***enabling*** -

to make drug approval ***faster***

and trade ***easier.***

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