

Access to medicines – a requirement for peace, health and medical work



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Peace, Health and Medical Work
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Access

- “Access to essential drugs of assured quality is one of the key indicators of equity and social justice”

Dr Brundtland, 2000



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Access components

- Research and development of medicines - priorities
- Patents
- Prices
- Availability
- Quality



Access to essential medicines is fundamental to human rights

- The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition
- Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services
- Governments and the international community have an obligation to see the right to health progressively realised, which includes the responsibility for prevention, treatment and control of disease, and the creation of conditions to ensure access to health, facilities, goods and services
- Access to goods and services include – of course – the provision of essential medicines necessary for the prevention and treatment of prevalent diseases

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Key facts and figures

- A third of the world's people lack access to the medicines they need - rising to 50% in parts of Asia and Africa
- Up to 50% of medicines are inappropriately prescribed, dispensed or sold, leading to wasted resources and potentially resulting in patient harm
- Patients improperly use up to 50% of medicines, resulting in reduced treatment efficacy and potentially leading to resistance
- In developing countries, medicines account for 60% - 90% of household expenditures on health. Inappropriate prescription, high prices, low quality and improper use mean that the poor often receive little health benefit for their spending on drugs

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Essential medicines

- Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness.
- Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.
- The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations, exactly which medicines are regarded as essential remains a national responsibility.

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Research on medicines

- By pharmaceutical companies
- By universities etc.
- Usually, if universities find a new medicine, patent rights are sold to companies which then do clinical trials if necessary, apply for registration and market the product
- Example: Publicly funded (National Institute of Health (NIH) in USA has found and done clinical trials for e.g. most of the cancer medicines. Then sold rights to multinationals which increases price tremendously. American taxpayers thus pay twice!

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The pharmaceutical industry

- Multinationals (also called research-based), e.g. Pfizer, Lilly, Merck, GSK. Develop and patent medicines, but often has a generic division or a contract with a generics company to produce copies after patent expiry. Power increased through mergers. Charges the highest price a market is willing to bear.
- Generic manufacturers which manufacture copies after patent expiry. They comprise large international companies, national companies, branches of multinationals. Some of them are not-for-profit suppliers to public sector in developing countries

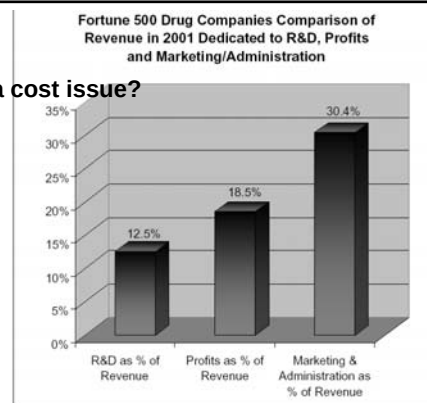
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What are the research priorities?

- From 1975 to 1999 1393 New Chemical Entities (NCE) was granted market authorisation, mainly for diseases affecting patients in high-income countries. This was especially pronounced for infectious and parasitic diseases which account for 1/3 of disease burden worldwide, but only for 5% in high-income countries.*
- Main focus is on high-income countries and on
 - developing 'me-too' medicines
 - evergreening of patents
 - making trivial problems diseases, often called 'lifestyle medicines' or disease-mongering'.

*Trouiller P et al. Drug development for neglected diseases: a deficient market and a public-health failure. Lancet 2002;359:2188-94 9

Is it a cost issue?



Source: Public Citizen analysis of company annual reports; Fortune magazine, April 2002; Fortune 500 (www.fortune.com)

Neglected (orphan) diseases

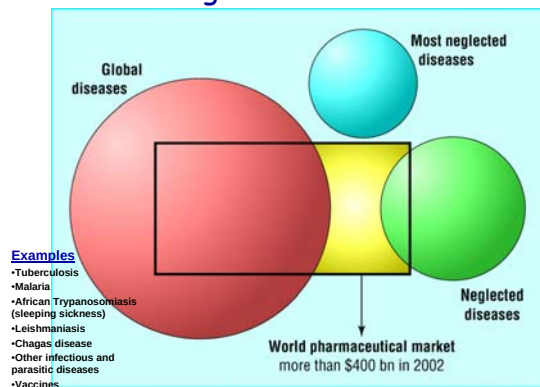
- Diseases affecting a limited number of people, i.e. small market, but high purchasing power
- Tropical diseases affecting a large number of people, i.e. a large market, but poor people

If any of the two receives attention at all, which one will it most likely be?

"It takes much less effort and imagination to grow rich by selling expensive products to a small number of people than by selling cheap products to a large number of people"

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Neglected diseases



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Current barriers to drug development for neglected diseases

- Cost of Research and Development (R&D)
- Regulatory barriers
- Protection of intellectual property



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Are orphan drugs being researched?

- Companies finding and producing drugs for orphan diseases for small patient groups in rich countries receive special regulatory advantages and research grants
- Tropical diseases receive little attention unless specific contracts on e.g. price is being reached

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Patents

- Patents protect *inventions*, for both products and processes, i.e. gives the owner a monopoly over the invention, usually for 20 years
- In all fields of technology
- Patent criteria: novelty, inventive step, industrial application (TRIPS Art.27)
- For pharmaceuticals, the invention is often a new molecule or family of molecules for the treatment (or prevention) of a particular disease (protected by what is known as a 'product' or 'substance' patent, or
- - a method of producing a drug (protected by what is known as a 'process' or 'methods' patent)

→ there can be more than one patent for a single medicine!!

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Why patents?

- Stimulate innovation – a debate over this concept
- Publication of patents: dissemination of information, technical knowledge
- Grant a monopoly – preventing others from using, making, selling, and marketing the product for a time-limited period

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The TRIPS agreement

Trade Related Aspects of Intellectual Property Rights

- a World Trade Organisation (WTO) agreement aimed at strengthening and harmonising aspects of the protection of intellectual property at the global level. It includes trademarks and patents as well as other forms of intellectual property
- Minimum standards for protection of patent rights and copyright
- minimum 20 years patent protection (EU, USA, Japan and Australia have 24-25 years)
- covers both process and product patents
- deadlines for national implementation:
 - 1996 industrialised countries
 - 2000 developing countries
 - 2006 the poorest 49 countries (2016 after DOHA)

Medicines are only a small part of the agreement

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Government use of exemptions: Compulsory licence

Article 31 TRIPS - other use without authorisation of the Right Holder

- "Public non-commercial use"
- Government grant of licence to 3rd party to use patent without consent of patent holder
- Right to determine grounds for compulsory licence
- NOT just for emergencies
- Conditions for grant: prior negotiations, compensation to patent holder, appeals process
- After DOHA: permission to import if the country has no production capacity

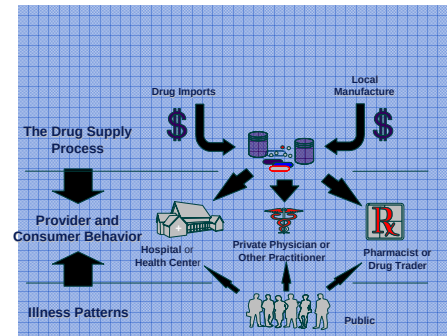
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DOHA Ministerial Declaration on TRIPS and Public Health

- Date 2001
- Set new dates for implementing patent law in poor countries
- Decided that countries unable to manufacture the pharmaceuticals could obtain cheaper copies elsewhere if necessary
- Decided that manufacturing countries may export to countries that lack production capacity, provided certain conditions and procedures are followed

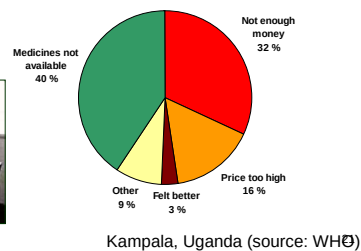
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Components of the Medicine Use System

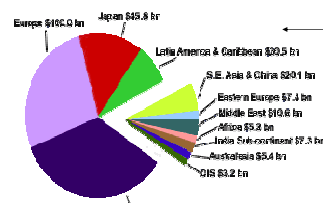


28% of people could not obtain all prescribed medicines - barriers were money, prices, availability

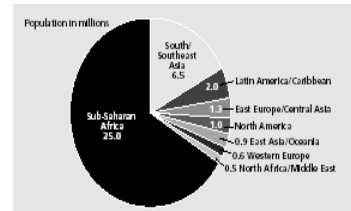
Reasons for not obtaining all prescribed medicines



World drug market and Population distribution



www.ims-global.com



www.prb.org

The skewed pharmaceutical market

- 15% of the world's population consumes 91% of the world's production of pharmaceuticals, by value
- Developing country markets constitute 88% of vaccine sector volumes, but only 18% of global revenues from vaccine sales
- Africa constitutes just 1.1% of the global pharmaceutical market, by value
- Every year more than US\$ 70 billion is spent on health research and development by the public and private sectors. An estimated 10% of this is used for research into 90% of the world's health problems. This is known as "the 10/90 gap"

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Prices and financing



Malaria price of mefloquine (Lariam®) price study East-Africa 1999

- Average retail price in Tanzania for 100 tablets is 549 USD
 - Max retail price in Norway for 100 tablets is 308 USD
- Norway:
- very small market
 - not reimbursed
 - Nordic labelling
 - Nordic package insert but: price control, i.e. max retail price

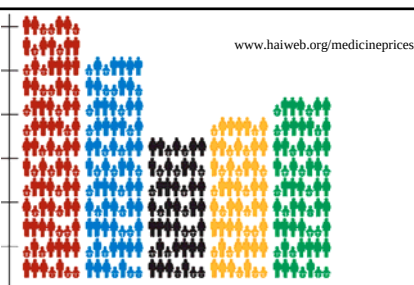


Medicine Prices
a new approach to measurement

Medicine prices - a controversial topic

- Awareness of relatively rapid price rises in many countries
- Publicity over high price of ARV medicines in relation to HIV/AIDS epidemiology
- Controversy over R&D costs (innovation) and price of new (patented) medicines
- Globalisation of high prices - concerns about WTO/TRIPS
- Price differences in different international markets are common
- Concern with medicine price information raised in World Health Assembly from 1999

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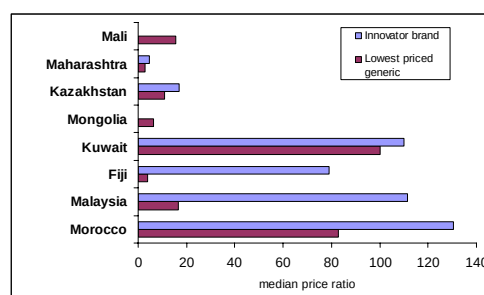
Medicine Prices a new approach to measurement

2003 edition

Working draft for field testing and revision

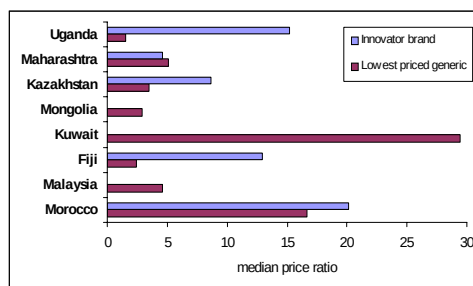
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Brand vs generic prices in relation to international reference price (MSH 2003) for ciprofloxacin 500mg tabs, private pharmacies



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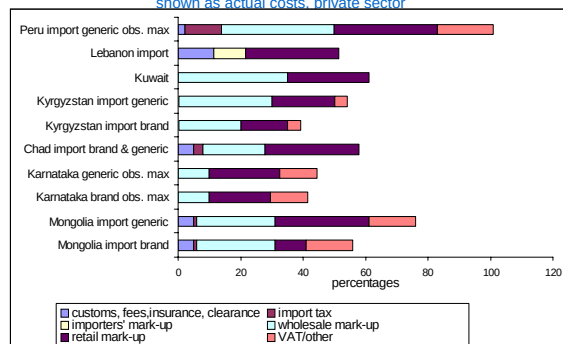
Brand vs generic prices in relation to international reference price for amoxicillin 250mg caps, private pharmacies



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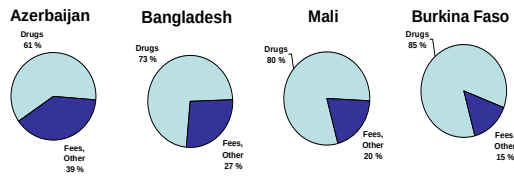
Add-on component costs - governments are also taxing the poor

shown as actual costs, private sector



Medicines are the largest household health expenditure in low-income countries

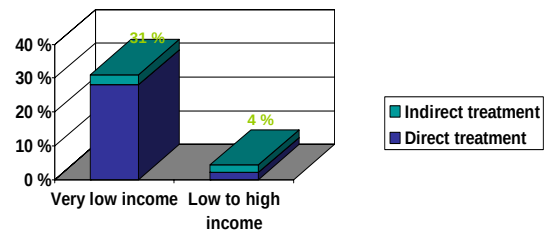
Spending on medicines as a percent of total out-of-pocket health spending



Source: Azerbaijan - UNICEF-Bamako Technical Report No. 35; Bangladesh 1995 - National Accounts 1996/97; Mali (1986) - Diarra K and Coulibaly S. *Financing of recurrent health costs in Mali*. Health Policy and planning; 1990, 5(2):126-33.

For low income households, treatment costs can consume a large share of income

Malaria treatment as % of annual income - Malawi

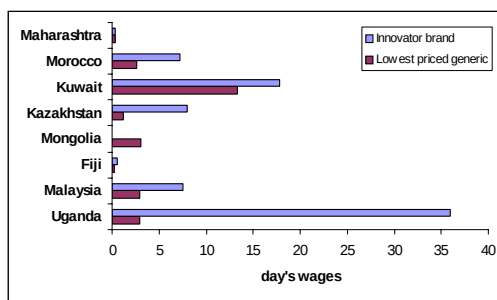


Entling M, McFarland DA, Schultz LJ, Chitsulo L. Economic impact of malaria in Malawian households. *Trop Med Parasitol* 45(1994) 74-79 (ID:17)

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Affordability

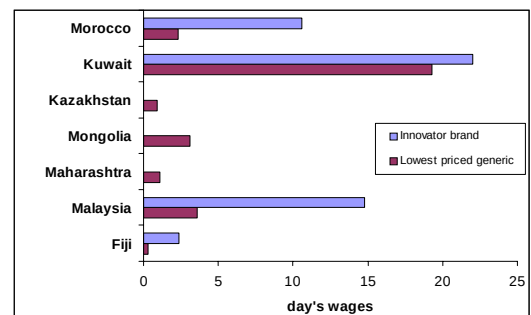
– day's wages, lowest paid unskilled govt. worker, needed to buy 30 days ulcer treatment with ranitidine 150mgx2/d



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Affordability

– day's wages, lowest paid unskilled govt. worker, needed to buy 30 days ulcer treatment with omeprazole 20mg/d



Wider problems of medicine prices

- Medicines have variable and often high prices, and are unaffordable for large sectors of the global population and a major burden on government budgets
- Burden falls directly on most patients in developing countries – but little is known about the prices people pay and how these prices are set, from the manufacturers' selling price to the patient price
- Trade agreements can severely affect the price and availability of medicines
- Many developing countries do not have pricing policies

But, the prices of medicines are well above their production costs so there is great scope for reductions

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Impact of lack of affordable medicines on reproductive health

A lack of affordable medicines and other health commodities has a direct impact on the health of mothers and children. E.g., the UN Population Fund (UNFPA) estimate that each US\$ 1 million shortfall in support for contraceptives means an estimated 360 000 more unwanted pregnancies; 150 000 additional induced abortions; 800 maternal deaths; 11 000 infant deaths; and 14 000 additional deaths of children under 5.

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Impact of lack of affordable medicines on HIV/AIDS in Africa

A lack of affordable medicines and other health commodities has a direct impact on the number of people that receive treatment for HIV/AIDS. In 2004 around 75 000 Africans had access to antiretrovirals (the drugs that keep the virusload low. First line treatment may cost around USD 292 per year if generics are purchased from India, when the patients need second line treatment, the cost may increase to around USD 1594.

In addition, HIV-positives may need treatment for other infections such as tuberculosis, fungal infections.

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Affordable prices

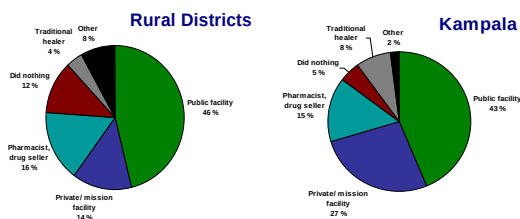
- Use available and impartial information on prices
- Allow price competition in the local market
- Promote bulk procurement
- Implement generics policies
- Negotiate equitable pricing for newer essential medicines for priority diseases
- Undertake price negotiation for newly registered essential medicines
- Reduce mark-ups through more efficient distribution and dispensing systems
- Encourage local production of essential medicines of assured quality when appropriate and feasible
- Include WTO/TRIPS compatible safeguards in national legislation and apply them as appropriate



Medicine Prices
a new approach to measurement

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Sources of care in rural districts and Kampala, Uganda - households rely heavily on public services

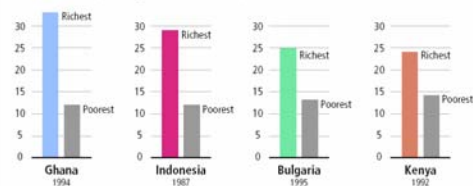


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Public health spending neglects poor people and favours the wealthy...

HDR 2002

Share of public spending on health services (percent)



Health insurance coverage varies considerably

Regions/Countries	Population coverage for countries with health insurance
	Median
Established Market Economies	> 95
Middle Eastern Crescent	50
Latin America and Caribbean	35
Asia and Islands	10
Sub-Saharan Africa	8
India	5
China	30

Source: WHO/DAP, ARA

Sustainable financing

- Increase public funding for health, including for essential medicines
- Reduce out-of-pocket spending, especially by the poor
- Expand health insurance through national, local, and employer schemes
- Target external funding at specific diseases with high public health impact
- Explore other financing mechanisms, such as debt-relief and solidarity funds

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Some actors on the world medicines scene

- World Health Organisation (WHO)
- UNICEF
- UNAIDS
- The World Bank
- EU
- Bilateral donors (e.g. Norad, Japan, USAID)
- MSF (Médecins sans frontières)
- The pharmaceutical industry (IFPMA, generics manufacturers)

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Current trend: Public/Private Partnerships

- Attempt to fill gaps in the health needs of developing countries through
 - - establishment of public-private collaboration
 - - networks
 - - partnerships
- Private sector: for-profit and not-for-profit
- Public sector: international organisations, development and aid agencies, governments, academia

WHO partnerships

- European Partnership on Tobacco Dependence
- Global Alliance for TB Drug Development
- Global Alliance to Eliminate Lymphatic Filariasis
- Global Alliance for Vaccines and Immunization
- Global Elimination of Blinding Trachoma
- Global Polio Eradication Initiative
- Multilateral Initiative on Malaria
- Medicines for Malaria Venture
- Partnership for Parasite Control
- Roll Back Malaria
- Stop TB
- UNAIDS/Industry Drug Access Initiative



Donations –
the rich
peoples 'gifts'
to the poor

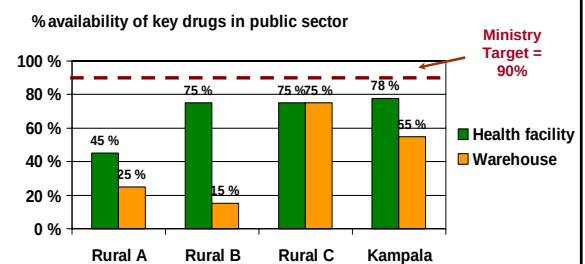


Reliable health and supply systems

- Integrate medicines into health sector development
- Create efficient public-private-NGO mix approaches in service delivery
- Assure quality of medicines through regulatory control
- Explore various purchasing schemes such as procurement co-operatives
- Include traditional medicines in healthcare provision (with associated quality assurance)

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% availability varied 2-fold among health facilities, 5-fold among warehouses



Uganda (source: WHO) 48



Medicine Prices a new approach to measurement

Availability issues

- Many examples where the availability of expensive innovator brands was high while the availability of cheaper generics was low

Malaysia, private pharmacies	Innovator brand		Lowest priced generic	
	% avail	MPR	% avail	MPR
Enalapril 10mg	75%	20.3	34%	10.07
Amoxicillin 500mg + Clavulanic acid 125mg	81%	3.18	44%	1.33
Prazosin 1mg	50%	12.11	25%	6.26
Ibuprofen 200mg	62%	20.77	44%	12.47

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COUNTERFEIT

DRUGS

Quality

Guidelines for the development
of measures to combat
counterfeit drugs

Counterfeit

■ Drugs that are copies or of poor quality continues to kill – in fact is increasing

■ Medicines of poor quality circulates freely in many countries

■ Illegal production and trade with medicines

■ Sale by internet is increasing



"Med en enkel tablettmaskin finns det goda möjligheter att göra sig en förtjänst på att slå tabletter som innehåller billigt bakpulver."

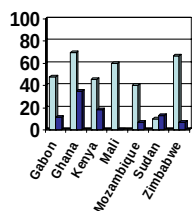
Counterfeit

- Product without active ingredient
- Product with wrong amount of active ingredient
- Product with wrong ingredient(s)
- Products with correct amount of active ingredient, but in false package
- Copy of a patented product
- Product with a high amount of contamination

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Assured quality is vital - even for common antimalarials, quality varies greatly

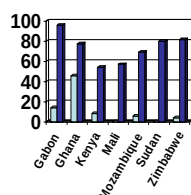
Chloroquine tablets - % failure*



Content Dissolution

* Samples were judged to have "failed" if content was <93% or >107%, and dissolution <80% in 45 minutes.

Sulphadoxine/pyrimethamine - % failure*



Content Dissolution

* Samples were judged to have "failed" if content was <90% or >110%, and dissolution <65% in 30 minutes.

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Key messages

- Properly used, essential medicines save lives, reduce suffering and improve health
- By improving access to essential medicines and vaccines, up to 10.5 million lives could be saved each year worldwide: 4 million in Africa and South-East Asia alone
- Concerted action is needed to ensure fair and sustainable financing, affordable prices, reliable health and supply systems, and the rational use of medicines. Efforts are also needed to develop new vaccines, drugs and other health technologies that meet developing country needs
- This requires partnerships between developing country governments and healthcare providers, donors, international agencies, non-governmental organisations, pharmaceutical and biotechnology companies and the broader private sector, as well as consumers and health researchers

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