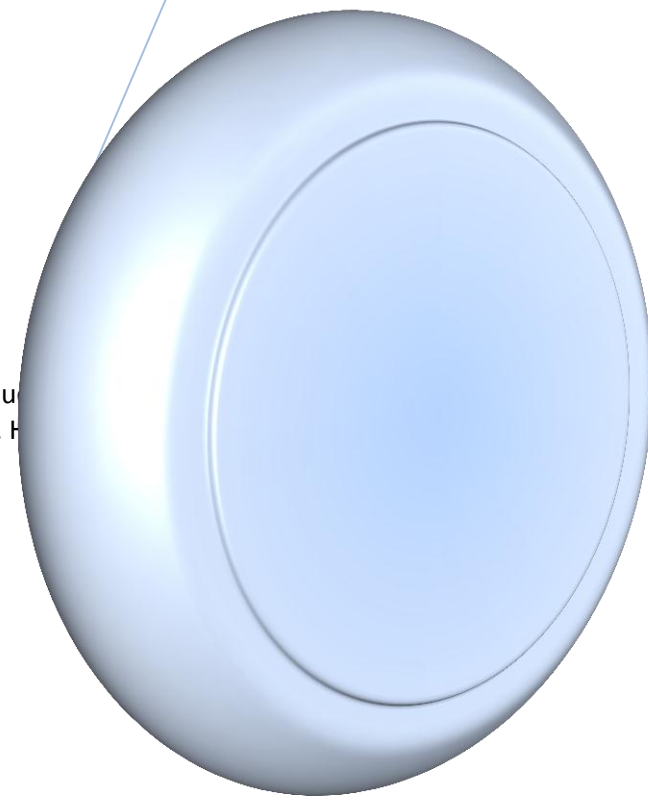
Creating professional + ethical doctors

International Regulation

A PharmAware Guide

These issues stretch right across the world. And it is not just issu
about profits but the research that goes into making the drugs. H
we explore some issues.



PharmAware NC
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Introduction

Globally there is a turnover of around 800 billion dollars in pharmaceuticals. They make up one of the largest group costs in health expenditure, with average percentage of the health care budget spent on pharmaceuticals accounting for 24.9%, ranging from 7.7% to 67.6%.

Low income countries spend the greater proportion of their budgets on pharmaceuticals, due to prices being controlled in high income countries. Many being bought over the counter, directly out of the patients pocket. These estimations also do not take into account the estimate $83 billion business of traditional medicines.

However, as 78% of the total costs for pharmaceuticals is spent by 16% of the population from high income countries the incentive for pharmaceutical companies to produce new medicines comes from them. This is why we have a 'research gap', 'access gap' and 'patent gap (TRIPS!)'.

Research gap

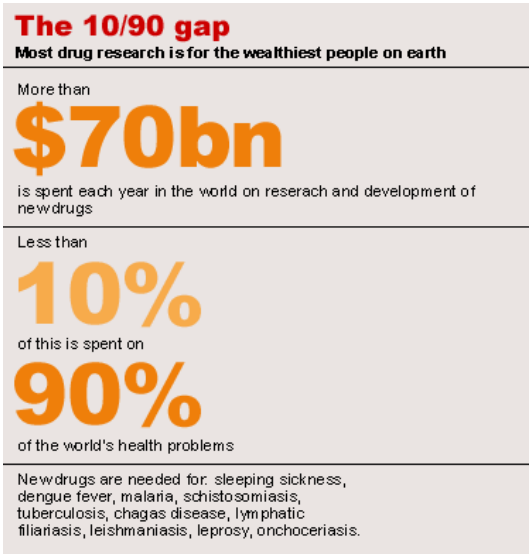
As mentioned earlier pharmaceutical companies make the majority of their profit from developing treatments for high income countries. However as many of these countries fund multiple health programmes and schemes for those disabled by ill health it sometimes seems a little backwards that they put so little pressure on their own pharmaceutical companies to do more to narrow this gap.

- 10/90 gap- was coined in the 1990's to highlight that 90% of the worlds drug research was aimed at 10% of the worlds population
- The 1/99 gap is the new term to indicate that 1% of the worlds research is aimed at neglected tropical diseases that affect up to 99% of the worlds population
- HIV/AIDS, TB and Malaria were attributed to 125 million DALYs (disability adjusted life years) in 2004 yet received 80% of the funding for research into diseases in low/middle income countries.
- Whilst diarrhoea and pneumonia accounted for 165 million DALYs yet received 5.72% of the worlds funding for research

Access gap

- At least one third of the world's population has no regular access to medicines
- Reasons include high prices, lack of infrastructure, limited/poor quality storage conditions, lack of trained staff, poor political will
- Access to essential medicines is one of the five components of the UN's realisation of the right to health

This access gap has often been blamed for the rise in substandard and counterfeit medicines, a market with an estimated $35-44 billion turnover a year and constitutes up to 10% of developing countries pharmaceutical market



Substandard drugs:

‘Substandard medicines are products whose composition and ingredients do not meet the correct scientific specifications and which are consequently ineffective and often dangerous to the patient. Substandard products may occur as a result of negligence, human error, insufficient human and financial resources or counterfeiting’ (WHO 2003).

Counterfeit drugs:

‘Counterfeit medicines are part of the broader phenomenon of substandard pharmaceuticals. The difference is that they are deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients’ (WHO 2003).

Patent gap:

'Intellectual property', the 'WTO', DOHA agreements. One thing that all aspects of the patent system have in common is their complexity, however hopefully you will find the quick facts section below clears some things up for you. Much more information is available in the extra resources section.

Quick Fact Guide to Patents!!

- The WTO provides a forum for negotiating agreements aimed at reducing obstacles to international trade and ensuring a level playing field for all, thus contributing to economic growth and development'.
- Patents provide the patent owner with the legal means to prevent others from making, using, or selling the new invention for a limited period of time, subject to a number of exceptions.
- Trade-related aspects of intellectual property rights TRIPS: were introduced in 1994 to monitor the ways in which new knowledge could be shared. The idea behind TRIPS consists of 3 main components: to ensure inventors and creators knew their would be future benefits from their inventions; to ensure all new inventions are publically available for study (a compulsory part of a patent) in order to allow technology and knowledge transfer and, when the patent has expired, allows competitors to produce the drug; and to allow the drug to be used in times of emergency, whereby the normal patent ideas would be over overruled.
- DOHA agreement: created in 2001 in response to a court case between the South African government and many pharmaceutical companies. The South African government had initiated deals into importing generic HIV/AIDS treatments that were still covered by a patent. This was in response to the high prices of the patented drug and the widespread HIV/AIDS epidemic in South Africa. Whilst the 1994 TRIPS act was meant to allow for this trade to proceed the South African governments actions were deemed (by pharmaceutical companies) to be illegal. The court, however, found in favour of South Africa and in response the DOHA agreement was created to try and clarify these issues.
- Important points: the affected country would be allowed to decide themselves what constitutes a public health emergency, they would be allowed to order compulsory licences for medications. (Whereby they can ask another company to produce the drug without consulting the patent holder first).

Least developed countries are also exempt from the long bureaucratic process of declaring the public health emergency and assessing pharmaceutical patents until 2016 (or the time in which they are more developed, whichever is sooner).