Technology Innovation for Sustainable Development

Essential Technologies - Pharmaceuticals

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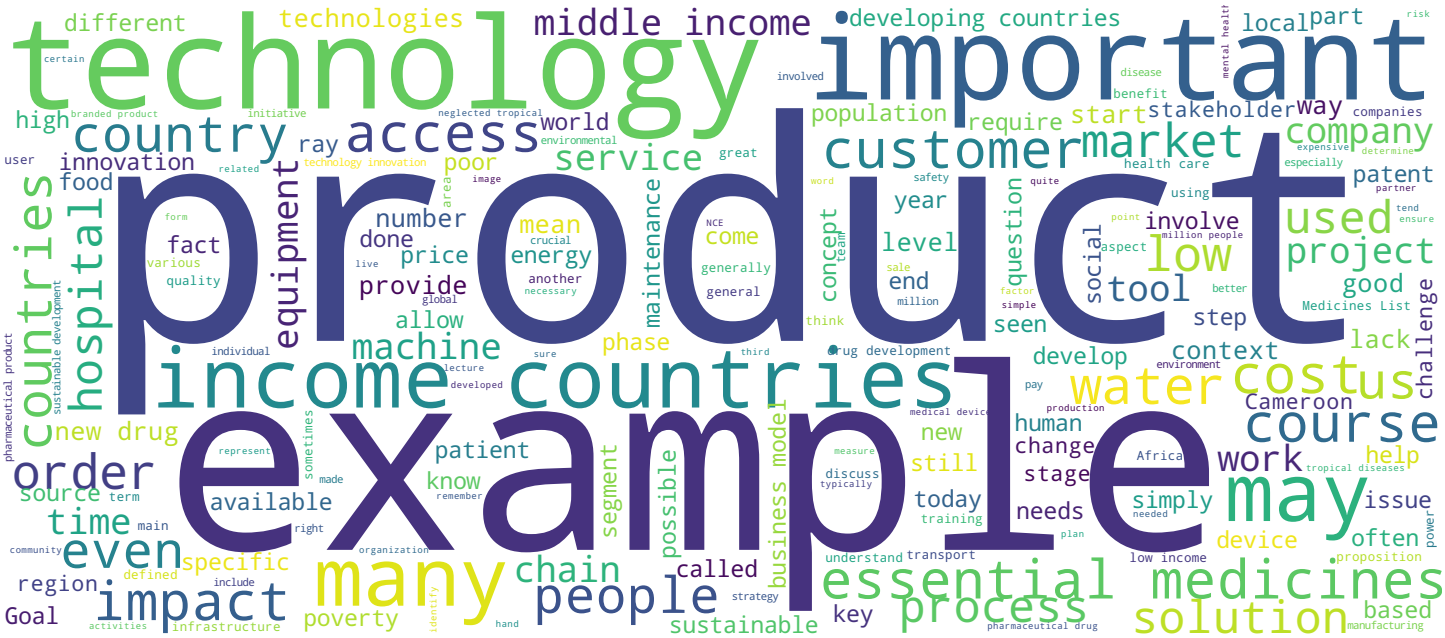

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This session aims to provide an overview of the essential technology domain of pharmaceuticals. Before we begin, let's try and clarify a few terms and expressions that we will be using widely in this session. What is a pharmaceutical drug exactly? For the purposes of this course, a pharmaceutical drug is any substance or compound that is used to cure, treat, or prevent disease. It may also be referred to as a pharmaceutical product, medicine, medication, or simply a drug. We can distinguish between two broad categories of drugs, based on the manner in which they are produced and administered. Small-molecule drugs are low-molecular weight compounds that are chemically synthesized and then formulated into a tablet that is given orally to the patient, whereas biological drugs or biologicals are high-molecular polypeptides, proteins and antibodies that are produced via biotechnological or recombinant means, and are typically administered by injection.

Notes

Summary

0m 13s

Pharmacuetical Development Process

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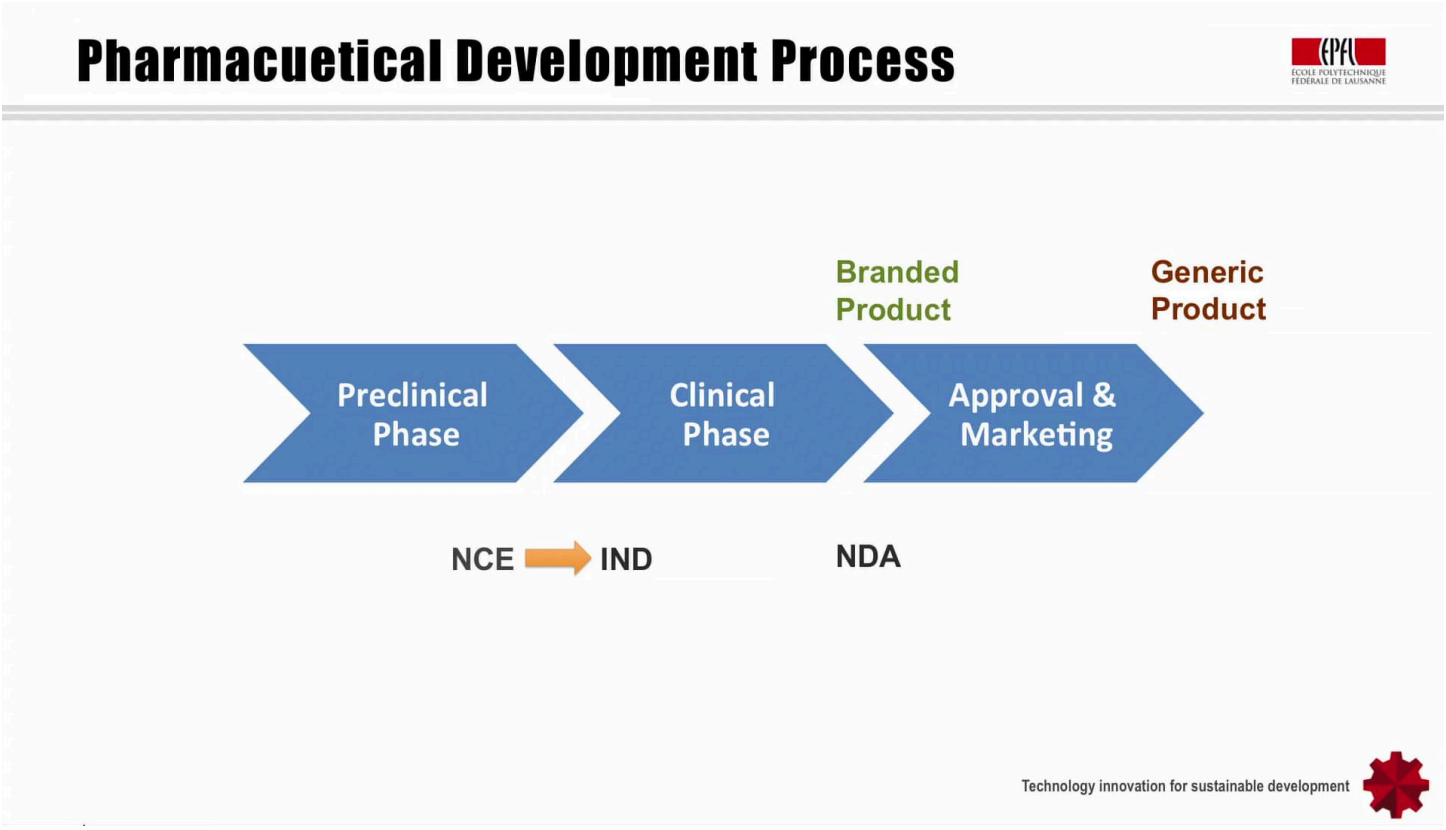
How are pharmaceutical drugs developed? For simplicity, we can consider the drug development process to be divided into 3 broad stages: It starts with Preclinical Development, which essentially occurs entirely in the laboratories, in order to eventually produce what is termed a New Chemical Entity or NCE. This is then followed by the Clinical Development stage, which primarily occurs in hospitals and clinics. It essentially involves testing the NCE from the Preclinical Stage in humans for Safety and Efficacy against the intended disease or diseases. At this stage, the NCE is now referred to as the Investigational New Drug or IND upon approval by a suitably accredited national or regional regulatory body, such as the Food and Drug Administration or FDA in the US and the European Medicines Association or EMA in Europe. If the Clinical Development stage goes well and the clinical trials are successful a New Drug Approval is granted, which leads to the final stage, that is a Branded Product and the post-approval and marketing phase. Now, the time it takes from the commencement of Preclinical Development to the Approval of a new drug is about ten to fifteen years, and costs about 2.6 billion US dollars, based on the last study, in 2014, from the Tufts Center for the Study of Drug Development.

Notes

Summary

1m 22s



So, the development of a new drug is lengthy and very expensive, but also a highly inefficient process with very low success rates. Given the high costs of drug development, prior to the start of the Drug Development Process, a patent that protects the drug is then filed. This patent is valid for twenty years, afterwhich the drug becomes available to any other parties who may wish to produce and market a copy or generic version of the drug, usually at a lower price than the branded product. Consequently, most of the leading pharmaceutical companies from developing countries are primarily involved with the manufacture of generic pharmaceutical products rather than the development of new drugs entirely. Thus, the development of new drugs is almost exclusively confined to companies in the highly industrialized countries, such as the US, Western Europe and Japan. This also inherently implies that most of the available drugs are mostly tailored for those populations and often less adapted to the rest of the world population, especially developing countries.

Notes

Summary

3m 00s

Essential Medicines

- **Essential Medicines List**

- Safety & Efficacy
- Cost-competitive

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Since the creation of the modern Food and Drug Administration in 1938, there is almost 1.500 drugs that have been approved. Therefore, for any country wishing to establish a repertoire of essential medicines that the country must aim to have, in order to ensure adequately meeting national medical needs, choosing which medicines to prioritize can be a significant challenge, especially if lacking the suitable expertise for such a task. In order to confront this challenge, the World Health Organisation or WHO judiciously assembled an Essential Medicines List. And WHO defines Essential Medicines as those medicines or pharmaceutical products that satisfy the priority health care needs of the population. They are selected with due consideration to public health relevance, their safety and efficacy, and cost-competitiveness. In other words, essential medicines are intended to be available within the context of functional 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.

Notes

Summary

4m 11s

Essential Medicines

- **Essential Medicines List**
  - Safety & Efficacy
  - Cost-competitive
- ➢ **Model Medicines List**

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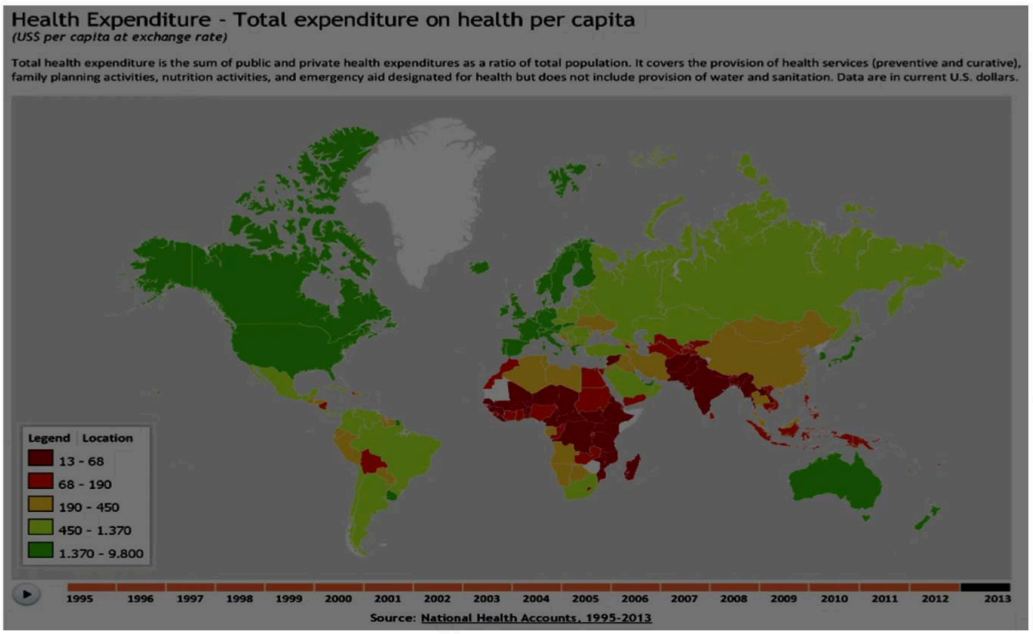
Thus, the Essential Medicines List aims to serve as a Model Medicines List or some sort of template that countries can then adapt and develop their own national Essential Medicines Lists. It can assist national decision-makers in reducing costs by helping them identify priority medicines to meet their country's health needs. And in, in high-income countries, the list helps to provide insurance companies, for example, with a neutral, gold-standard list for reimbursement.

Notes

Summary

5m 28s

Disease & Poverty Link



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We now look at the link between poverty, disease and access to essential medicines. This slide shows that the countries with the lowest per capita health expenditure, indicated in red and dark red, are also some of the poorest countries in the world. Pharmaceuticals account for up to 30% of health expenditures in transitional economies, while this figure rises to as high as 66% in low income countries. Clearly, a lower per capita expenditure on health, implies less availability of essential medicines.

Notes

Summary

6m 03s

Disease & Poverty Trap

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Interestingly, according to the WHO, a previous survey carried out in Uganda showed that for certain nationally listed essential medicines, out-of-pocket prices for patients were over thirteen times higher for branded products than the international pricing reference. And even for generics, the prices were still almost three times higher than the international reference. This is clearly a surprising finding, and reveals a vicious cycle, where the Poor will simply get poorer and sicker.

Notes

Summary

6m 40s

Neglected Tropical Diseases

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Besides the general diseases that tend to affect the whole world, in general, tropical and subtropical regions have additional diseases that are particularly endemic in those regions, collectively known as the Neglected Tropical Diseases or NTDs. The term “neglected” highlights the fact that the diseases affect mainly poor and marginalized populations in low-resource settings. NTDs are a diverse group of communicable diseases that prevail in tropical and subtropical conditions in over 149 countries. They affect more than 1.4 billion people, including more than 500 million children, costing developing economies billions of dollars every year. These diseases are to be contrasted with the big three diseases, HIV/AIDS, tuberculosis and malaria, which, relatively speaking, receive greater treatment and research funding.

Notes

Summary

7m 13s

Neglected Tropical Diseases - WASH

- **Neglected Tropical Diseases**

- A child with Chagas disease: Note swelling of the right eye.

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There are about seventeen neglected tropical diseases, and examples include: chagas, dengue and chikungunya, sleeping sickness, and trachoma. NTDs thrive in areas where there is lack of basic sanitation. Thus, Water, Sanitation and Hygiene services are also critical to care for the people who have many of these diseases, and for accelerating and sustaining progress on neglected tropical diseases overall.

Notes

Summary

8m 12s

Emerging Health Challenges - NCD

- **Non-communicable Diseases: 63% of all global deaths (36M p.a.)**

  - Cardiovascular
  - Mental health

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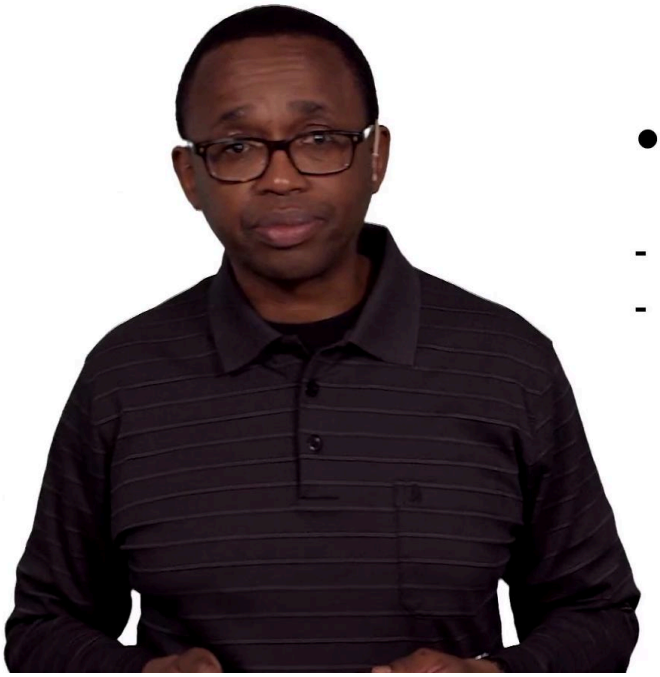
Besides infectious diseases, an emerging and potentially greater health challenge is in the form of Non-communicable diseases or NCDs NCDs account for 63% of all deaths, that is 36 million out of 57 million global deaths. And 80% of NCD deaths occur in low and middle-income countries. So, NCDs are not only a health problem but a development challenge as well. Within the NCDs, cardiovascular and mental health are increasingly posing immense challenges.

Notes

Summary

8m 42s

Type 2 Diabetes



- **Non-communicable Diseases:**
  - Type 2 Diabetes: 422M in 2014
  - Rising fastest in LMICs

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Within cardio-vascular diseases, Type 2 diabetes is increasing at an alarming rate. The number of people with Type 2 diabetes has risen from 108 million in 1980 to 422 million in 2014. In particular, diabetes prevalence has been rising more rapidly in middle and low-income countries. Diabetes is one of the leading causes of death today, in fact, and the majority of these deaths indeed occur in low and middle income countries.

Notes

Summary

9m 17s

Global Mental Health

- **Non-communicable Diseases**

- Epilepsy: 50M and 75% in LMICs.
- Depression: 350M affected

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In Mental Health, Epilepsy and Depression are particularly noteworthy. Epilepsy is a chronic non- communicable disorder of the brain that affects people of all ages. Approximately 50 million people worldwide have epilepsy, making it one of the most common neurological diseases globally. Nearly 80% of the people with epilepsy live in low and middle-income countries. However, about 75% of people with epilepsy in low and middle- income countries, do not get the treatment they need. Another mental health disease of high significance is Depression. According to WHO, depression is the leading cause of disability worldwide, and is a major contributor to the overall global burden of disease. It affects around 350 million people worldwide and this number is projected to increase. Fewer than half of those people affected have access to adequate treatment and health care. The issue of improving access to essential medicines to developing countries is a massive and multi-factorial challenge. And one of the biggest issues remains economic: cost & affordability. But even if the budget for medicines is available sometimes, other factors may undermine the ultimate mission of access Such factors may include fake medicines and lack of suitable infrastructure, for example, such as cold chain for vaccines.

Notes

Summary

9m 47s

www.mpedigree.net

Fake medicines account for almost a third of medicines in Africa. One study, published by the American Journal of Tropical Medicine and Hygiene, found that in just one year, fake and poorly made malaria drugs contributed to the deaths of more than 100,000 children across Africa. The British think-tank, International Policy Network, estimates that, globally, 700,000 deaths a year are caused by fake malaria and tuberculosis drugs. Now, a company from Ghana, mPedigree, has been hard at work to tackle this serious problem. How does it work? Pharmaceutical manufacturers can sign up on to the mPedigree scheme platform, where they can upload the pedigree information of each pack of medicine into the central registry. When consumers buy a product made by a manufacturer participating in the scheme, they are able to query the pedigree information stored in the registry by means of a free SMS message. An automatic response from the registry certifies whether the particular product is truly "from source" or not. Today, mPedigree claims it has labels on more than 500 million drug packets.

Notes

Summary

11m 25s

Emerging Innovations

And Clients also include giant drug companies, such as AstraZeneca, Roche, and Sanofi, and more There are various other technology initiatives that promise to improve, access to much needed essential medicines, which we cannot cover, unfortunately, during this lecture, due to time constraints. However, references for further reading have been provided at the end and they cover other initiatives to fight fake drugs, to provide cold chain to ensure safe access to vaccines and, and more. This now brings us to the end of this lecture. Good-bye.

Notes

Summary

12m 45s