Introductory Remarks:
Innovation and Access in Medicines

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New & Re-Emerging Diseases

- HIV/AIDS
- SARS
- Various Influenzas
  - Dengue
- Lyme Disease
- Hantavirus
- Ebola Virus
- TB, Malaria, Dengue
HIV/AIDS

- 65 million have been infected: 25 million deaths and more than 40 million are currently infected
- HIV/AIDS and the status of other diseases (e.g., malaria, TB) point to disparities in health outcomes between developed and developing countries
- No cures, no vaccines – yet -- though 20 ARV’s have prolonged life and made AIDS a manageable chronic disease – *(for those who can access these ARV’s)*
Industry Innovation

• Over 20 ARV’s have been developed
• 80 HIV/AIDS medicines in clinical trials, including more than a dozen vaccines
• Recent developments: fusion inhibitors (Fuzeon) and integrase inhibitors
• Key partnerships between the public and private sector in drug development
Drug and Vaccines in Clinical Development for Selected Diseases

- Infectious diseases + Respiratory infections: 185
- Cardiovascular diseases: 123
- Solid tumors: 94
- HIV/AIDS: 86
- Brain tumors: 28
- Skin cancer: 45
- Breast cancer: 49
- Colon cancer: 48
- Prostate cancer: 44
- Pain: 44
- Asthma and other respiratory diseases: 44
- Diabetes: 50
- Musculoskeletal diseases: 55
- Lung cancer: 70
- Schizophrenia: 12
- Multiple sclerosis: 12
- Parkinson's disease: 18
- Depression: 25
- Alzheimer's disease: 26
- 

* Excluding HIV/AIDS; including 61 vaccines
** Including 15 vaccines
Key Role of Drug Resistance

• Emerging as important issue in HIV/AIDS as well as being serious problem in fight against TB, malaria and other infectious diseases (e.g., streptococcal pneumonia)

• *Points to the need for continuous innovation even for HIV/AIDS and other diseases having current therapies*
# Process of Pharmaceutical R&D

<table>
<thead>
<tr>
<th>R&amp;D Stage</th>
<th>Research &amp; Discovery</th>
<th>Preclinical Development</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Registration</th>
<th>Phase IV</th>
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<tbody>
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<td><strong>Main Activities</strong></td>
<td>Drawing on basic exploratory research to identify targets, initial research on new compounds is carried out in the laboratory (high throughput screening, lead identification and optimization) to select the</td>
<td>Selected compounds are studied in animals under Good Laboratory Practice for toxicity and safety; in parallel, specific analytical methods are developed for further</td>
<td>Successful compounds are then tested in humans in 3 phases of clinical trials:</td>
<td>If the results of clinical trials are satisfactory in terms of quality, efficacy and safety, a regulatory dossier is presented to the regulatory authorities for</td>
<td>Post-marketing studies involving thousands of patients are initiated after the launch of the medicine, to identify any previously unforeseen side effects.</td>
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<td><strong>Phase I</strong> – safety and tolerability in healthy volunteers</td>
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<td><strong>Phase II</strong> – safety, efficacy and bioequivalence studies in small groups of patients</td>
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<td><strong>Phase III</strong> – large trials with different populations to demonstrate proof of efficacy, safety and value</td>
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<td><strong>Success Rate</strong>*</td>
<td>Less than 1 %</td>
<td>70 %</td>
<td>50 %</td>
<td>50 %</td>
<td>90 %</td>
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<td><strong>Time</strong></td>
<td>4-6 years</td>
<td>1 year</td>
<td>1-1.5 Years</td>
<td>1-2 years</td>
<td>2-3 years</td>
<td>1-2 years</td>
<td>Several years</td>
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Patents and Access

‘We need to combine incentive for research with access to medication for the poor. Intellectual property protection is key to bringing forward new medicines, vaccines and diagnostics urgently needed for the health of the world’s poorest people.’

Kofi Annan, UN/UNAIDS/WHO press release
April 5, 2001
Four Pillars of Innovation

- **Successful Healthcare Systems**
  Enable swift dissemination of innovation and appropriate application of new medicines

- **Efficient Markets**
  Help perceive innovation as investment and lead to efficient allocation of scarce public health resources

- **Effective Intellectual Property Protection**
  Build a solid base for knowledge based economy and provide for an incentive to innovate

- **Adequate and Predictable Regulatory Requirements**
  Create stable but evolving regulatory environment to streamline innovation process
Improving Access to Therapy

- Unequivocal and ongoing political commitment by national governments;
- Strengthened national capacity;
- Engagement of all sectors of national society and the global community;
- Continued investment in research and development by the pharmaceutical industry;
- Efficient, reliable and secure distribution systems; no parallel trade;
- Significant additional funding from new national and international sources.