

*Conference on Intellectual Property
and International Public Health*

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Remarks by
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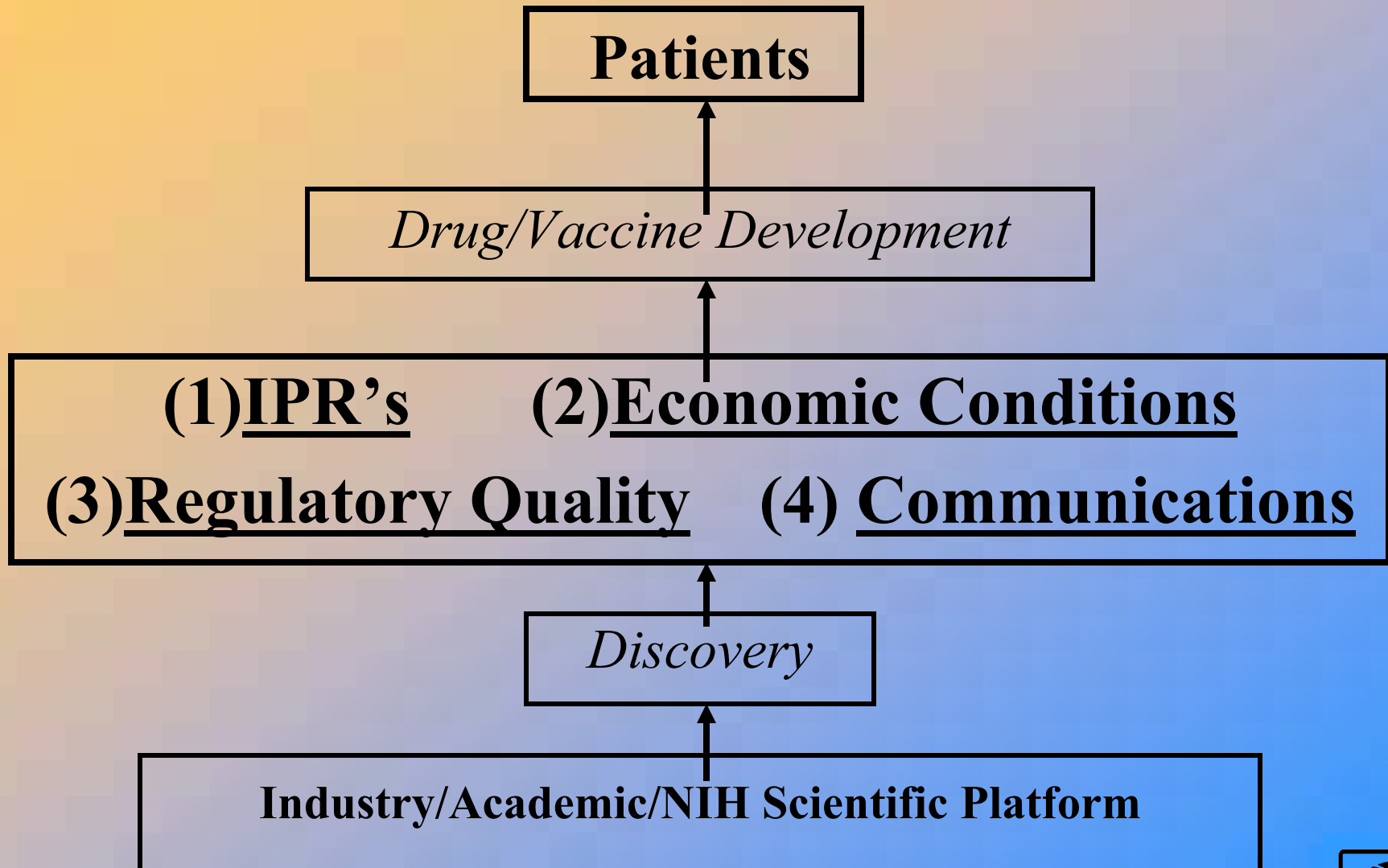


IFPMA Background

- Represents R&D pharmaceutical industry that also produces vaccines, biotech, generic and OTC medicines
- Other activities:
 - Partnered with WHO et al. to form the Medicines for Malaria Venture (MMV) Helped form the Global Alliance for Vaccines and Immunization (GAVI)
Interacted with companies in the AAI-HIV initiative
 - Helped coordinate industry's efforts to reach the “waiver” on the WTO TRIPS/Public Health “Paragraph 6” issue (2003)
 - Serves as secretariat to the International Conference on Harmonization (ICH)



Four “Pillars” of Drug Development



Global Pharmaceutical Markets

| <u>Country/Region</u> | <u>Global Share</u> | <u>Trend</u> |
|------------------------|---------------------|--------------|
| North America | 42% | ++ |
| W. Europe | 25% | -- |
| Japan | 11% | -- |
| Australia/NZ | 1% | ++ |
| Latin America | 7% | + |
| SE Asia/China | 6% | +++ |
| Middle East/South Asia | 4% | + |
| East Europe/CIS | 3% | +++ |
| Sub-Saharan Africa | 1% | + |

(Groupings: North America, W. Europe, Japan, Australia/NZ = 79%; Middle East/South Asia, East Europe/CIS = 20%)

Population Contrast: Developed countries 22%
Developing countries 78%

Source: IMS and World Bank



Developmental Contrasts

| | |
|-----------------------------|--|
| <p>Developed Countries</p> | <ol style="list-style-type: none">1. Adequate funding available;2. Substantial social and private insurance;3. Sound regulatory systems assure quality health services and products;4. Wide array of choice arising from domestic and foreign competition |
| <p>Developing Countries</p> | <ol style="list-style-type: none">1. Low funding of health;2. Little social or organized private insurance;3. Lack of regulatory controls, thus frequent poor quality/counterfeits;4. Little choice of services/goods and protectionist measures |

Pricing Issues and the Distribution of *Patented* Pharmaceuticals

- Patents and access: an over-weighted link
- Governmental factors in improved access – differential prices
- Parallel trade vs. price discrimination favorable to poor countries
- Non-manufacturers' issues
- Recent experience in HIV/AIDS

Access to Essential Drugs

- WHO: A third of world's population lacks regular access to essential drugs; about 1% are AIDS patients
- This issue has very little to do with patents -- For over 300 essential medicines identified by the WHO for AIDS and other major debilitating or deadly diseases, patents cover barely over 1 percent of essential medicines are patented in developing countries
- In fact, we have had until now a systematic global failure to get quality essential off-patent drugs to hundreds of millions of people in developing countries – TB, malaria, polio, diarrheal diseases, yellow fever, etc.
- *As we have not solved the lack of access to “older” drugs, access to “newer” drugs implies trying to overcome similar problems – “Learn from history”*



Disease Burden and Mortality in the World's Poorest Countries (High Mortality Developing Countries)

| | MORTALITY (% of Total) |
|---|---------------------------|
| HIV/AIDS | 9.9 |
| Diarrhoeal diseases | 6.7 |
| Childhood diseases (incl. Measles, pertussis, tetanus) | 4.5 |
| Malaria | 4.0 |
| Tuberculosis | 3.8 |
| Tropical Diseases | 0.5 |
| Respiratory Infections (e.g. Pneumonia) | 9.9 |
| Maternal Conditions | 1.7 |
| Perinatal Conditions | 6.7 |

Source: WHO



Health Spending Per Capita

| | Total | Public | Donors |
|---|---------|---------|--------|
| Least Developed Countries: | \$11 | \$6 | \$2.3 |
| Other Low-income Countries: | \$25 | \$13 | \$0.9 |
| <i>(Minimum necessary level: \$40-\$60)</i> | | | |
| Lower Middle Income: | \$93 | \$90 | \$0.6 |
| Upper Middle Income: | \$241 | \$125 | \$1.1 |
| High Income Countries: | \$1,907 | \$1,356 | 0 |

Source: Global Forum for Health Research; WHO/CMH

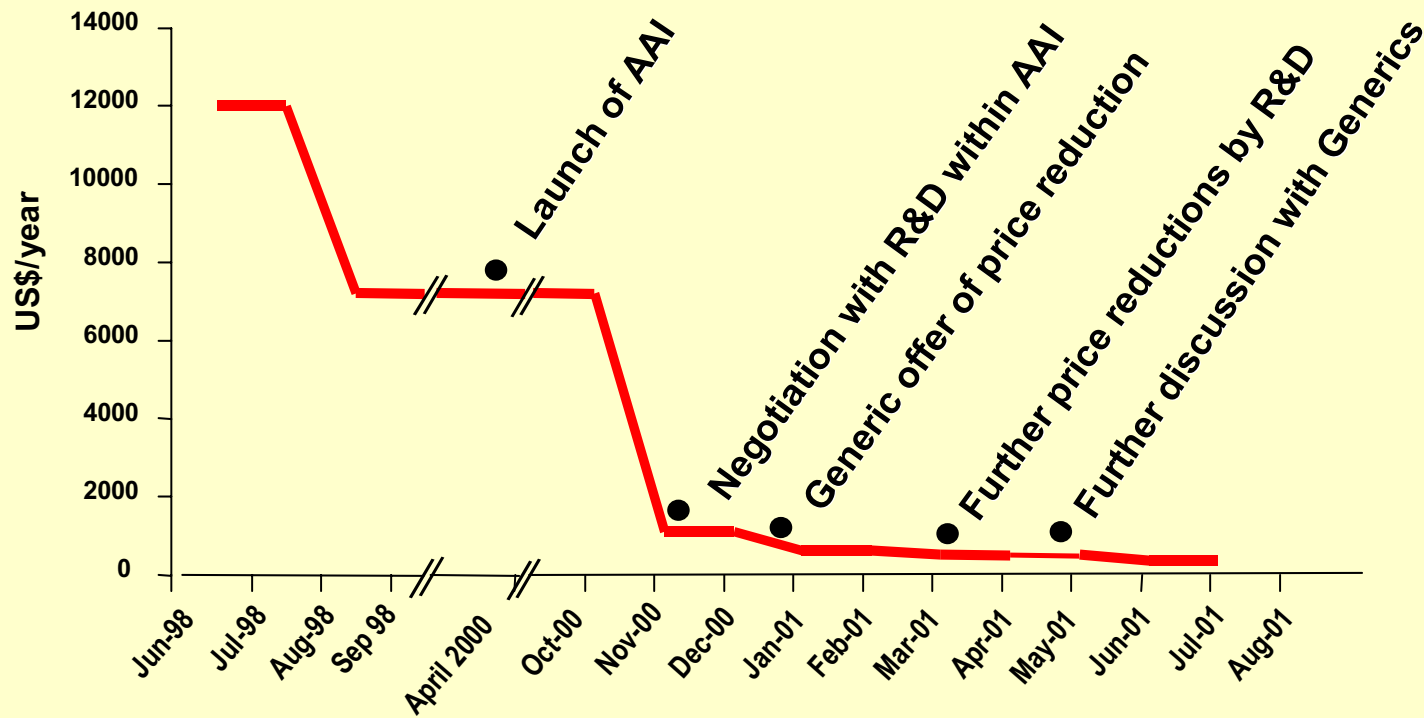


Parallel Trade and Price Discounting

- Doha Declaration on Public Health: flexibility and rights vs. benefits
- Paragraph 6 Motta and Menon Texts
 - Countries are to take all reasonable measures to prevent parallel exports and parallel imports
 - Product labeling should aim to avoid confusion
- Poor countries are at the greatest risk from parallel trade: diverted products *and additional risks of counterfeit trade*



Price reductions of a first line ARV regimen in Uganda



Factors Relating to Treatment Suppliers

- **Price**
- **Accompanying Services (e.g., training)**
- **Quality**
- **Sustainability of Supply**

WHO/MSF/UNICEF AIDS PRICE COMPARISONS

Generics Price Range Patent Holder Price

Protease Inhibitors:

| | | |
|------------|---------------|-------|
| Indinavir | \$387-467 | \$400 |
| Nelfinavir | \$1,500-2,026 | \$880 |
| Ritonavir | \$219-1084 | \$83 |
| Saquinavir | \$1,335 | \$920 |

NNRTI's:

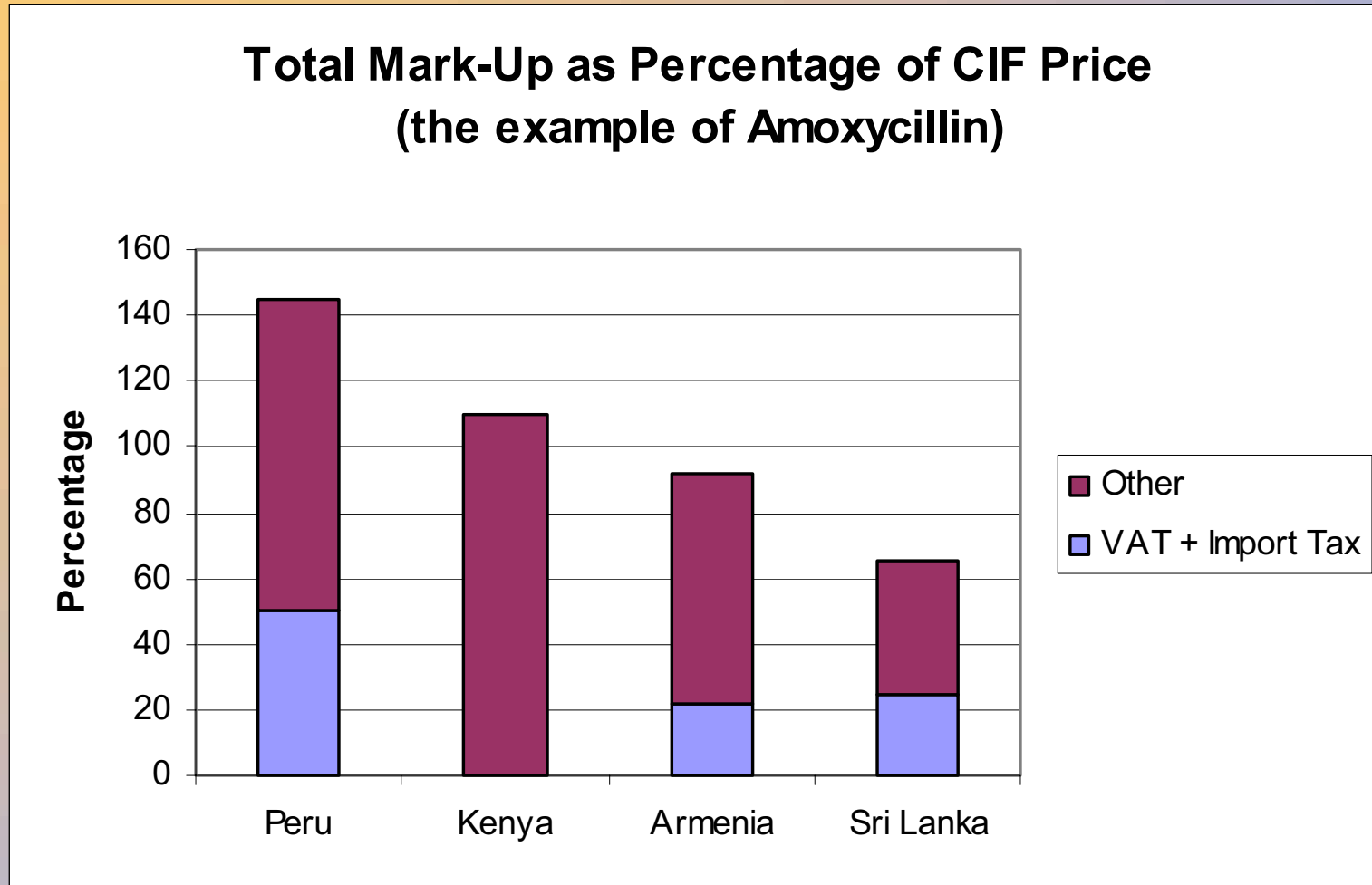
| | | |
|------------|-----------|------------|
| Efavirenz | \$462-578 | \$347 |
| Nevirapine | \$105-244 | \$0, \$438 |

NRTI's:

| | | |
|------------|-------------|-------|
| Abacavir | \$831-1,335 | \$986 |
| Didanosine | \$185-650 | \$310 |
| Lamivudine | \$65-163 | \$128 |
| Stavudine | \$31-73 | \$55 |
| Zidovudine | \$140-292 | \$274 |



Non-Manufacturers' Factors in Prices



Source: Madden J., Medicine Prices: a new approach to measurement. Illustrative examples of results from pilot studies, 2001-2002. WHO, HAI, 2003.



Doha TRIPS/Public Health: Paragraph 6

- Countries with inadequate manufacturing
- Perez-Motta text/Menon “Chair’s statement
- Key Elements:
 - Flexibility for public health problems, not for commercial/industrial policy objectives
 - Prevention of parallel trade by all countries
 - Measures notified and on agenda of TRIPS Council
 - Many countries “opt-out” of potential use – either totally or partially (exc. extreme circumstances)



Basic Government Policy Factors in Improving Access

1. *Unequivocal and ongoing political commitment by national governments*
2. *Strengthened national capacity*
3. *Engagement of all sectors of national society and the global community*
4. *Efficient, reliable and secure distribution systems*
5. *Significant additional funding from new national and international sources*
6. *Continued investment in research and development by the pharmaceutical industry*



Further Policy Factors

- Minimize trade policy and domestic policy distortions: tariffs, VAT's, anti-dumping measures
- Examine flexibility of TRIPS (Paragraph 6, etc.)
- Foster partnerships to improve access to medicines (AAI, GAVI)
- Examine domestic and international conditions that would reverse outflows of skilled medical staff

Issues in Differential Pricing

- No industry collaboration: individual firms acting individually for competitive reasons
- Differential pricing by generic companies
- Distribution security for differential prices
- Political security for differential pricing
- Politics of donations and/or discounts
- Country differential prices vs internal population differentials: public vs private sector

Fundamental Conclusion

1. Pharmaceutical companies look beyond their role today as discoverers and developers of new drugs and vaccines
2. Trade policy (I.e., compulsory licensing, parallel trade) offers very little in way to improve access in developing countries
3. Prices are as much a function of demand – but not just in the classical economic sense: differential pricing is a function of commitment and funding

Thank you.

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