

# **The patent status of medicines on the WHO model list of essential medicines**

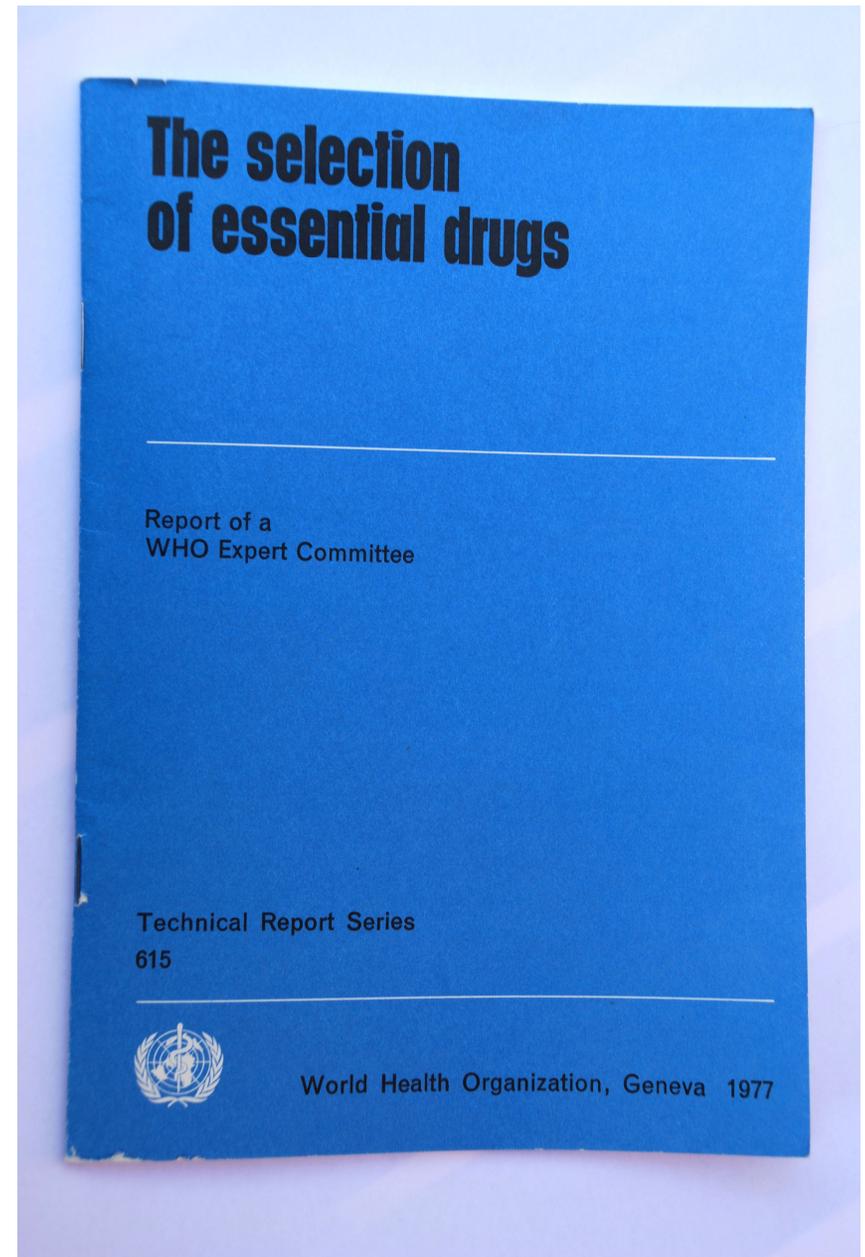
**Comments by Richard Laing**

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# History of the WHO Model List of Essential Drugs (Medicines)

- **1977 First Model list published, ± 200 active substances**
- **List is revised every two years by WHO Expert Committee**
- **2002 Revised procedures approved by WHO**
- **March 2009 list contains 355 active substances**
- **Next revision 2011**
- **Many developed countries call such a list "positive list," or "formulary list" or "reimbursement list"**



# Essential medicines

- **The concept of essential medicines**

A limited range of carefully selected essential medicines leads to better health care, better drug management, and lower costs

- **Definition of essential medicines**

Essential medicines are those that satisfy the priority health care needs of the population

(Report to WHO Executive Board, January 2002)

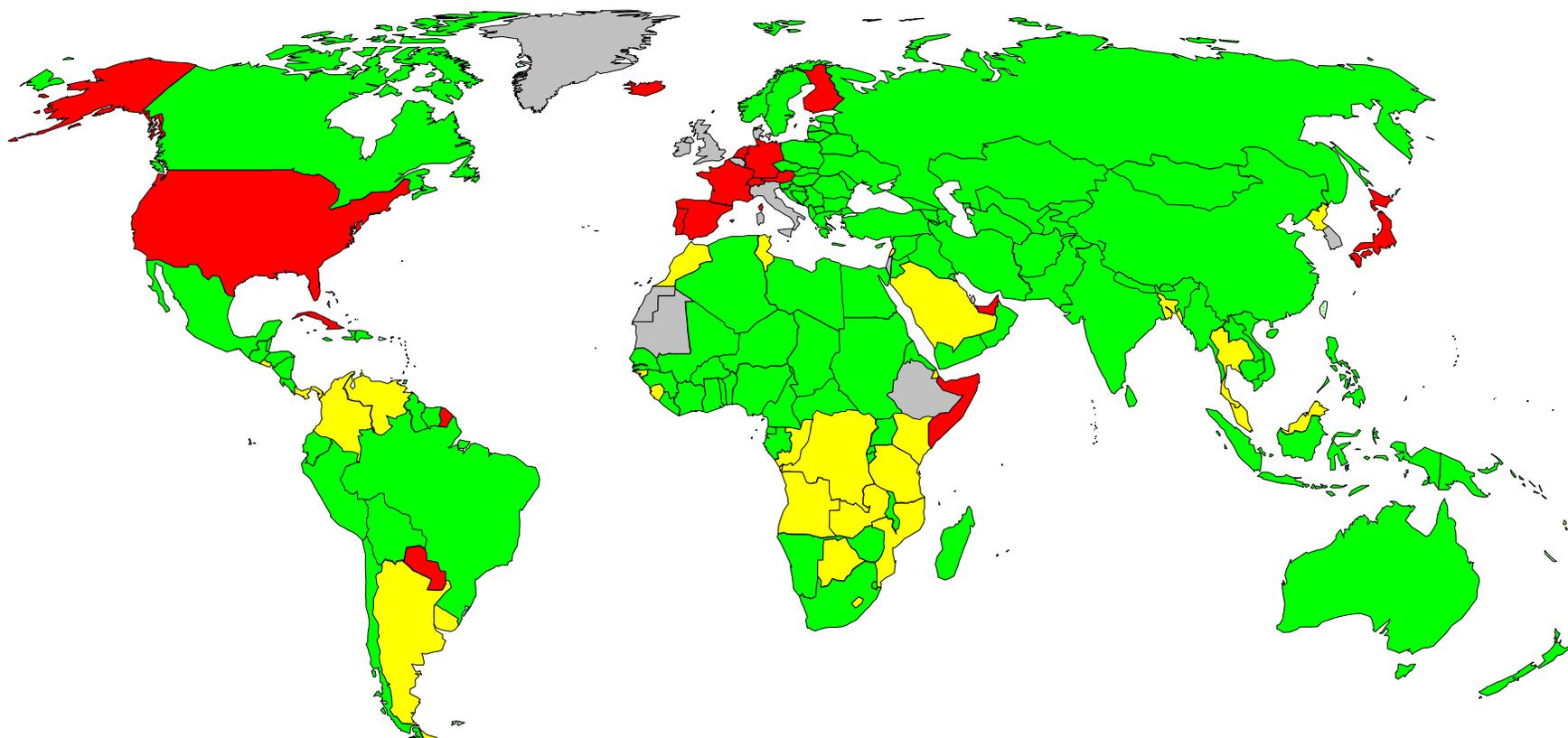
## Full description of Essential Medicines (Expert Committee Report, April 2002)

**Selection criteria:** Essential medicines are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness (**No mention of patent status ever**)

**Purpose:** 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 at a price the individual and the community can afford.

**Implementation:** 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.

# The essential medicines concept is nearly universal



Countries with an official selective list for training, supply, reimbursement or related health objectives.  
Some countries have selective state/provincial lists instead of or in addition to national lists.

## Key Literature: Essential Medicines List and Patents

- **Howard & Laing** Lancet 338 1991 Changes in the World health Organization Essential Drug List (*16 out of 238 as NCEs 6.7%*)
- **Attaran & Gillespie-White** Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa? JAMA. 2001; *studied patent statuses of 15 antiretroviral drugs in 53 African countries. found that these antiretroviral drugs are patented in few African countries (Median 3)*
- **Laing, t'Hoën, Waning, Ford** Twenty Five years of the WHO Essential Medicines List Lancet 361 2003 *No analysis of patent status*
- **Attaran** How do patents and economic policies affect access to essential medicines in developing countries Health Affairs 23 3 (*19 of 319 patented less than 20 years before 2002 5.9%*)

# Latest Study Kowalski, Cavicchi, Doigan, Bryan, Merrell, Clark, Newbold, Gudavalli, Mullet & Stanford 2011

- **Develop methodology to assess the patent status of medicines on the WHO MLEM.**
- **Generate a detailed report for the public on the present (2010) patent status of medicines that were on patent in 2003 and those medicines added to the Model List since 2003 by country and level of development.**
- **Analyze patent status of Essential Medicines by the development status of countries.**

## Key Results

- Many countries especially Least Developed Countries have no evidence of patent activity for medicines added to the EML
- For those countries where patents have been identified these may not be valid, may be expired, may not be relevant

***My Personal Conclusion:***

***At present, patents do not appear to be a major barrier to access to Essential Medicines on the WHO Model List in Low and Middle Income Countries***

***So***

***Why is access not better?***

# **Non patent barriers to Access to Essential Medicines in Low and Middle Income Countries**

- **Poverty and Financing Methods. Out of Pocket payments are inequitable and are often catastrophic**
- **Medicine prices are too high due to duties, taxes, mark ups and sometimes manufacturer costs**
- **Health systems may fail to use limited resources to purchase generic Essential Medicines**
- **Trade agreements including TRIPS+ measures related to data exclusivity and patent linkage creates regulatory and other barriers**

# My Conclusions

- **Congratulations to the Franklin Pearce team which produced the analysis and report**
- **Just a start, but could be expanded to be part of the WIPO clearinghouse function discussed at last symposium.**
- **Thank you**