

(taken from the talk by Dr. Hobbiger of NAPP laboratories, who manufacture Oxycodone which has very recently become available in the UK.)

In 1999, Walker, at the Centre for Medicines Research, proposed the following components for successful drug development:

- Innovative drug discovery target leads
- Efficient drug development
- Rapid global registration
- Unimpeded patient access to medication

The last point, is, of course, a vital one for patients.

Dr. Hobbiger suggested that drug development should be true to the science but meeting the needs of the customers.

The Worldwide Pharmaceutical Research and Development (R&D) budget expenditure has increased 8 fold in 20 years:

In 1982.....US\$ 5.4 billion

In 1998.....US\$>40 billion

Development times are decreasing:

Bristol Myers Squibb (make Kenalog): time from drug candidacy to clinical trials down from 20 months to 6;

Lilly: formal development to globalisation reduced from 12.8 years to 7.

Smith-Kline Beecham: clinical development down to 5.5 years.

The cost of getting a drug to registration is US\$500 million!

Phases of development:

- I. First exposure to man (10s of volunteers)
- II. First exposure to patient (100s of patients)
- III. Efficacy and safety studies (1000s of subjects)

Exploratory development is the first part of development in which tolerability, pharmacokinetics (the way the body affects the drug) and pharmacodynamics (the way the drug affects the body) are defined in man. (Posner, 1998)

Human pain models tend to be used.

In the Lancet in December 1999, the following quote was used:

“Experimentation must be done in human beings, because testing a drug on lions or horses might not prove anything about the effect on man.” Avicenna (980-1037)

Animal studies are limited by ethical concerns, interspecies differences and measuring pain.

Healthy volunteers are used because it is quicker and easier (fewer confounding factors, for instance.)

There are, however, two conflicting camps. Rowbotham (from USA, not the speaker at the conference) suggested last year that ethics committees will require volunteer studies, whereas Urban (also in 1999) asserted that volunteer studies are not necessary.