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ADR: a new global phenomenon, thanks to the ICH

In order to harmonise the rules governing market access for new drugs, the medicines agencies of the wealthiest countries and three pharmaceutical industry trade associations, acting together within the International Conference on Harmonisation (ICH), have imposed their criteria for evaluation of new drugs on the entire world (1). It might have been feared that the ICH "guidelines" favoured the interests of big companies at the expense of patients' interests (1). Recent developments however indicate that such fears are groundless.

Towards a (nearly) worldwide medicines agency. The ICH announced the upcoming creation of a worldwide Agency for Drug Reconciliation (ADR), which will most likely be headquartered in Monaco (2).

The plan aims to reduce the cost of pharmaceutical research, most notably by avoiding the proliferation of multiple clinical trials required for applications for marketing authorisation (MA). Starting in 2015, the ADR will become the one and only avenue for marketing authorisation for new drugs in every country in the world, with the exception of Monaco.

Plan is viewed favourably. The ICH member states support this plan as a way of better managing their human and financial resources in a period of economic crisis. The World Health Organization (WHO) and the World Trade Organization (WTO) have expressed, respectively, their praise for "*an op-*

portunity to move forward on the normative aspects of regulatory science", and for "*the achievement of a worldwide market ruled by free and fair competition of goods and capital*" (2).

Pharmaceutical companies have emphasised the plan's added value from an ethical point of view: at last, just one clinical trial will be sufficient to gain access to the worldwide market, "*minimising the anxiety and suffering of the participants in the clinical trials that are usually required by lily-livered bureaucrats*" (2). And numerous patients' groups and learned societies have praised the plan, in the name of history and of economic realism (2).

Opposition from one rebel group. Only the (de)Medication in Europe Forum has raised its voice in disagreement (3). According to this group, ADR would sound the death knell for national drug regulatory agencies, and would threaten certain fundamental rights of citizens. In the face of this dissenting position, *Prescrire* has announced its intention to "*dodge the question*", in order to avoid disrupting the revolution of historical proportions represented by the creation of the ADR (4).

Prescrire

Selected references from Prescrire's literature search.

1- Prescrire Editorial Staff "ICH: an exclusive club of drug regulatory agencies and drug companies imposing its rules on the rest of the world" *Prescrire Int* 2010; **19** (108): 183-186.

2- ICH "Big is beautiful: the creation of Agency for Drug Reconciliation" Results of 2012 consultation. website accessed 29 February 2013: 404 pages.

3- (de)Medication in Europe Forum "European Agencies first" Press release April 1st: 404 signs and spaces.

4- Prescrire Rédaction "Agence mondiale du médicament : révolution historique!" *Rev Prescrire* 2013; **33** (354): 293.