

## Counter-attack

**T**he carefully maintained symbiosis between pharmaceutical firms and healthcare professionals causes the latter to abandon their critical faculties and forget their true social function: to serve patients' needs (see on pages 6-8). In a fiercely competitive climate, naturally the pharmaceutical companies are seeking to promote their products; they are incapable of producing comparative and balanced information which take into account all the available treatment options with their pros and cons (see news about the threatening introduction of DTCA in the EU on page 10, and a Gardasil<sup>®</sup> advert under scrutiny on page 18).

Raising awareness on more or less sophisticated marketing techniques is a key task. This has been done for years by ISDB bulletins in many ways such as texts on this issue, surveillance of sales reps, adverts under scrutiny, primary research, etc. Other awareness tools are spreading. For instance, PeRx is a new tool including

documentary modules aimed at healthcare professionals (see on page 15).

Raising awareness may not be enough. Counter-attacking through lobbying and proposals is an alternative. To do so, ISDB bulletins have joined forces for more than 20 years and regularly collaborate with other networks (Health Action International (HAI), Medicines in Europe Forum (MIEF), International Network for Safe Medication Practices Centers (INSMP)). Counter-attacking is also the objective of 'Pharmageddon'. In line with the Precautionary Principle, Social Audit and HAI see the need to investigate and explore Pharmageddon: "the prospect of a world in which medicines and medicine produce more ill-health than health, and when medical progress does more harm than good" (see on pages 4-5).

Let's push collectively for patient-centred healthcare policies! ■

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## COMMITTEE MEETING

### Preparing the Managua General Assembly

*Next Committee meeting will take place in Paris the 9 and 10 November 2007.*

Committee members will start drafting the programme for the General Assembly; then it will be circulated to all members for comments and input through the ISDB forum. Also to be discussed: organisation, preparation of committee election, social programme. This meeting will also give European members an opportunity to share information on important European issues such as pharmacovigilance and patient health information.

@ Inputs from members are welcome before the meeting.  
 Contacts: the executive Committee members  
 (maria.font@ulss20.verona.it; jschaaber@bukopharma.de; ckopp@prescrire.org)

## WELCOME!

### 3 New ISDB full members

**Projekt Farmaka.** Projekt Farmaka (Belgium) has become full member following several years as associate member.

@ Contact person: Stijn Dumon (stijn.dumon@farmaka.be)  
 More information: [www.formularium.be](http://www.formularium.be)

**Pharmakon.** Pharmakon (Spain) has joined ISDB as a full member. The Bulletin is funded by the Aragon Health Service  
 Commenced publishing 2002

Distributed free to healthcare professionals

Frequency: monthly

Language: Spanish

Format: paper and electronic

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**INVIMA Boletín de Farmacovigilancia.** INVIMA (Colombia), a pharmacovigilance bulletin, has joined ISDB as full member. The Bulletin is funded National Institute of Drug and Food Surveillance – INVIMA & National University of Colombia  
 Commenced publishing 2004

Frequency: 4 a year

Language: Spanish

Format: electronic only

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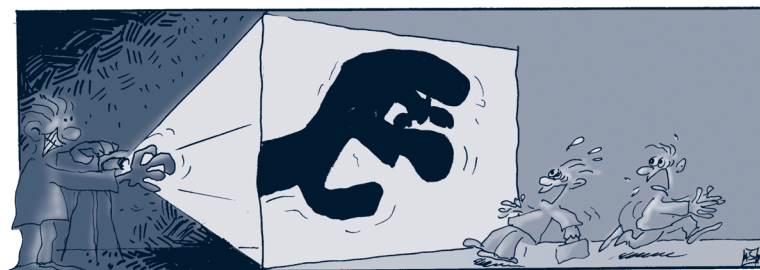
More information: [www.invima.gov.co:8080/Invima/farmacovigilancia/boletines.jsp](http://www.invima.gov.co:8080/Invima/farmacovigilancia/boletines.jsp)

## HAI ANNUAL GENERAL MEETING

### BUKO invited to speak on “disease awareness”

On the weekend of 12, 13, and 14 October Health Action International held the HAI Europe Annual General Meeting in Brussels. The Open Seminar on Friday 12 October, focused on the move to reopen DTCA discussions in Europe, and was entitled: Ensuring Independent Medicine Information in Europe. Jorg Schaaber from BUKO (Germany) was invited to speak on ISDB’s behalf on “disease awareness”.

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 More information: [www.haiweb.org](http://www.haiweb.org)



## GOOD SOURCE

### Cochrane library and free access by ISDB members: how to?

*As ISDB members you are able to have complimentary access to The Cochrane Library: send an email to Jennifer Beal ([jbeal@wiley.co.uk](mailto:jbeal@wiley.co.uk)) who will give you the passwords.*

**More information on Cochrane library:** Created in 1993 and now established in nearly 90 countries, the non-profit Cochrane Collaboration has acquired an international reputation for the Cochrane Database of Systematic Reviews, a collection of regularly updated reviews of the efficacy of a growing number of medical therapies and interventions for disease prevention. The Cochrane review methodology is strict and explicit (1,2). The Cochrane Database of Systematic Reviews is the main documentary resource in the Cochrane Library. It is published four times a year, both on CD-ROM and online. In the last few years the Cochrane Collaboration has acquired the active support of health authorities in a number of countries (in South and Central America, Australia, Spain, Ireland, Iceland, Finland, Norway and the United Kingdom). Health care professionals and the public in these countries have benefited from free (publicly funded) access to the online Cochrane Library.

#### References:

- 1- “What is the Cochrane Collaboration?” Website <http://www.cochrane.org> accessed on 17 March 2005.
- 2- “Cochrane Collaboration newcomers’ guide” Website <http://www.cochrane.org> accessed on 17 March 2005.

## TREASURER'S VOICE

**Don't forget ISDB subscription 2007!**

Dear members who have not pay yet,

Your membership fee for 2007 is due.

45 Euro Developing countries

225 Euro Bulletins with budget of under 20,000 Euro

900 Euro Bulletins with budget of 20,000 Euro and more

Payments should be directed to:  
Int. Society of Drug Bulletins  
Bank: Sparkasse Bielefeld, Germany  
Account No.: 124 156  
IBAN: DE43 4805 0161 0000 1241 56  
SWIFT-BIC: SPBIDE3BXXX

If you didn't get an invoice by mail or e-mail, please let me know so that I can send it again. If you have any questions related to your membership fee or want to apply for an exemption please contact me.

**Jörg Schaaber**  
ISDB treasurer

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## WONCA

**ISDB and World Organization  
for General Medicine in Paris  
on 17-20 October 2007**

WONCA (World Organization for General Medicine) is heavily sponsored by drug companies, so ISDB is the right organisation for introducing independent information. A Prescrire editor (Mariane Samuelson) will represent ISDB and promote ISDB values through a poster, soon available on ISDB website.

## CALL FOR INFORMATION

**Improving ethics of clinical trials in developing  
countries: WEMOS mobilizes**

*A Non Governmental Organization, WEMOS, is lobbying to improve the ethical aspects of clinical trials in developing countries. WEMOS needs ISDB members' help in order to identify unethical practices.*

WEMOS is concerned about the fact that increasingly clinical trials are being carried out in low income and developing countries. Regulations and monitoring to protect the rights of trial subjects are often lacking in these countries. More and more drugs that are being used by European consumers are tested on people in developing countries. As such European authorities (and consumers) have a responsibility towards trials subjects in developing countries.

WEMOS interviewed registration authorities in Europe and it appeared that they hardly checked whether drugs had been tested ethically in developing countries. (Even though European directives mention that drugs can only enter the European market when they are tested according to ethical guidelines). WEMOS organizes a meeting in Brussels in October. During this meeting they want to discuss with members of parliament, the European Commission, experts and registration authorities how it can be possible to avoid unethically tested drugs to enter the European market. They want to focus on the role of the registration authorities.

To explain the problems to the authorities, WEMOS needs to collect further examples of unethical trials in developing countries. If you are aware of such examples, please get in touch with Annelies den Boer.



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Summary of their survey findings and examples of unethical trials in developing countries available on request to those you wish to report on this issue.

**COLOPHON:**

- **Newsletter editors:** Christophe Kopp and Florence Vandevelde.
- **Contributors to this Newsletter:** Teresa Alves; Robyn Clothier; Annelies Den Boer; Maria Font; Andrew Herxheimer; Donald Light; Benoit Marchand; Clotaire Nanga; Charles Medawar; Blanka Pospisilova; Jörg Schaaber.
- **Design and lay out:** Nathalie Froment at Prescrire.

*ISDB members are invited to comment on this Newsletter or provide pieces for the next one.*

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## HEALTH ACTION INTERNATIONAL

### “Pharmageddon?”

*Pharmageddon: “the prospect of a world in which medicines and medicine produce more ill-health than health, and when medical progress does more harm than good”...*

*Health Action International, Social Audit and friends are in the early stages of planning a conference on Pharmageddon? They are looking for submissions with a pithy title and text of less than 350 words.*

*People who submit the best entries will be invited by Health Action International to attend and present at the conference. In addition, Social Audit is offering at least eight prizes of at least 1,000 each, for any submission published on the Social Audit website.*

*The aim is to develop understanding of the threat, and a better model of what it might be. Send contributions to Charles Medawar Charles Medawar and Tim Reed before 31 December 2007*

*Emails: [charles@socialaudit.org.uk](mailto:charles@socialaudit.org.uk) and [tim@haiweb.org](mailto:tim@haiweb.org)*

*We reprint below the introduction to Pharmageddon? project.*

*Www\_ More information at [www.socialaudit.org.uk/60700716.htm#Pharmageddon](http://www.socialaudit.org.uk/60700716.htm#Pharmageddon).*

**P**harmageddon has been defined as, “the prospect of a world in which medicines and medicine produce more ill-health than health, and when medical progress does more harm than good”. We see the need to investigate and explore that risk and to identify the factors and features that describe it.

Pharmageddon embraces the arguments of Ivan Illich (1976) but extends his focus. He warned of the risks of medicalisation, the generally dehumanising and damaging effects of professional interventions: “the medical establishment has become a major threat to health”. Beyond direct drug injury (clinical iatrogenesis), he was concerned about the ill-effects of medicine on culture and community, “the paralysis of healthy responses to suffering, impairment and death” that resulted from “the expropriation of health”.

But since Illich wrote, the whole shape of medicine has changed – both the knowledge base and its applications - and the pharmaceutical industry has come to dominate the medical establishment and the thrust and ethos of drug research, regulation, prescribing, availability and use.

The values of the market increasingly count. Now the leading companies, ‘the Pharmas’, have the driving influence on lifestyle, well-being and health outcomes. Their interests and investments have a major impact on the nature and availability of drug treatments, and on the essence and conduct of medicine, worldwide.

The surge towards globalisation since

the 1990s has placed the pharmaceutical industry where it is today. The Pharmas are now centred in the USA – which represents half the global market – and mainly reflect American health values and ways of doing things. The Pharmas are also major instruments of US foreign policy, and their interests are well defended as such.

Pharmageddon stands for the lament that the state of world health represents a colossal waste of what medicine and medicines could accomplish, by structurally harnessing all the talent, energy and commitment that is there. Increasingly this is not happening, which is neither morally defensible, nor in the best interests of our future. It is damaging to the climate of health, the oxygen of community and the core of personal well-being.

Pharmageddon is marked by the contrast between over-medication and drug deprivation; it also implies a strong causal link between the two. Under-medication in poorer communities, and over-medication in richer ones, are connected as closely as obesity and malnutrition, like two sides of the same coin.

Intensive drug marketing and excessive drug consumption has produced an industry whose capacity to innovate and provide is compromised, and whose viability seems increasingly to depend on systematic exaggeration of drug benefits and suppression of evidence of risks and harm. In place of transparency, the industry has now largely taken into its own hands the role of

providing information to the public and professionals, filling the air with messages about health priorities, expectations and needs. The net result is a drug supply system that starves national health and sustains global health deprivation.

Outside the major drug markets, populations suffer and die because drugs they need are completely unaffordable, because trade rules block access, and/or for lack of relevant innovation. Elsewhere, the obsession with drug treatment, health observance and disease awareness, is producing nothing like the desired effects. The USA exemplifies this trend: it is beset by diseases of affluence, most obviously by obesity, with diabetes and related complications. But in spite, and no doubt also because, of all the treatment options, fewer than one in twenty citizens manages to maintain a normal weight, eat a nutritious diet, take adequate exercise and not smoke.

For all this, the notion of Pharmageddon may still seem almost inconceivable – as did the risk and threat of Climate Change, just a few years ago. It is natural to deny risks when the misery in prospect results from so much good intent and great talent, and from the enjoyment of huge benefits, valued freedoms and countless goods. And because medicines are especially precious goods, the idea of Pharmageddon offends personal and vested interests alike.

Parallels seem to exist between health and environmental catastrophe. The issues compare to the relationship between a car journey and Climate Change: they are inextricably linked, but not remotely connected in scale or relevance in the average driver’s mind. Just as Climate Change seems inconceivable as a journey outcome, so most personal experience of medicines flatly contradicts the notion of Pharmageddon.

As clinical practitioners, or individual consumers with access to medicines, most people have seen, felt, witnessed and/or imagined their sometimes miraculous effects and results. But, to pursue the analogy, the risk of Pharmageddon is to do with the way in which all drug travel changes the climate of health, even when so many

individual drug journeys seem vital or worthwhile.

Both because and in spite of all the benefits of good medicine, it seems crucial to consider whether, collectively, we are rapidly losing sight and sense of health. Increasingly it seems we are. At least we need to challenge the dominant fallacy that drugs more and more resemble magic bullets and offer ever better solutions for the main trials of life.

At the same time, we need to accept that Pharmageddon is not simply the product of malevolence, but the natural outcome of something like a 'conspiracy of goodwill' – a universe driven by self interest, but dominated by a complex of corporate bodies all competing to survive. If Pharmageddon seems to beckon, it is in spite of what everyone wants, not because of it.

That also applies to the Pharmas. All might be well if their products matched promise and met genuine health needs. In fact, the Pharmas are panicked by this huge shortfall and become more predatory, gluttonous, devious and oppressive, to try to compensate for it. Health outcomes drift further and further away from mainstream thinking: excessive promotion, data suppression and falsification, secrecy, bribery, fraud and deep conflicts of interest are increasingly revealed.

The consequences go far beyond the drug disasters that make the headline news. Pharmageddon implies that we have now arrived at a tipping point where leading companies devote their main energies to marketing lifestyle products, rather than on finding ways of meeting real medical needs. The brave new world in prospect is one in which commercial imperatives trump health priorities, when Pharmas and followers systematically change our understanding and experience of what it means to be human, flattening the distinctions between cultures, degrading the clinical arsenal, and developing vast numbers of drugs, most not needed and all purporting to be best. The net result is not only therapeutic disappointment, but also crushing pressures that no public health system could ever survive.

Many people have concerns about many different flaws in the present system of pharmaceutical medicine, but what do they all add up to? Our starting point is simply that the word, Pharmageddon, may mean something important and deserves to exist,

if only as a description of forest rather than trees.

The etymology seems to fit. Pharmageddon conveys the idea of a battle between health and ill-health, right and wrong and for better or worse. It also challenges the tendency to take for granted that progress in pharmaceutical medicine leads naturally to better health. Armageddon was "the great symbolic battlefield of the Apocalypse, scene of the final

struggle between good and evil". Apocalypse ( – APOKALYPSIS) literally means the lifting of the veil, "a term applied to the disclosure to certain privileged persons of something hidden from the mass of humankind..." (Wikipedia, 2007).

The time has come to lift the veil: the broader significance of the risks must be explored and revealed. If Pharmageddon is part of any future reality, we all need to know

## PAKISTAN

### Change at TheNetwork for Consumer Protection

Dr Talib Lashari has been appointed new executive coordinator for TheNetwork for Consumer Protection.

Email: [main@thenetwork.org.pk](mailto:main@thenetwork.org.pk)

Website: [www.thenetwork.org.pk](http://www.thenetwork.org.pk)

## BIRTH NOTICE

### The new Cochrane Adverse Effects Methods Group

*Andrew Herxheimer invites all ISDB members to join the Cochrane Adverse Effects Methods Group (AEMG).*

The Group will help all those who want to review adverse effects of interventions systematically - and of course that includes all editors of drug bulletins.

You will be able to share your Adverse Effects problems and get help to solve them. Just send an e-mail to Andrew <[a.herxheimer@ntlworld.com](mailto:a.herxheimer@ntlworld.com)> if you would like to join. It costs nothing, and there are no duties!

More at

[www.adverseeffectsmethods.cochrane.org](http://www.adverseeffectsmethods.cochrane.org); see Cochrane News issue 40 (August 2007) for more details.

## AFRICA COORDINATION

### A letter to African drug authorities promoting independent information

Healthcare professionals in Africa have often difficulties accessing reliable sources of information on diagnostic and therapeutic strategies. The information "vacuum" is filled by drug companies and their promotional material, so there is an urgent need for comparative, evidence-based, and user-friendly medical information in Africa.

The ISDB Africa regional coordinator, Clotaire Nanga, together with ISDB Committee, has written a letter to African drug authorities in order to present the ISDB and promote independent information as a tool to improve healthcare quality. This letter aims also at checking if there is any organization dedicated to rational use of medicines that publishes a drug bulletin in African countries. This letter was already sent to 15 English-speaking countries drug authorities. More in a coming issue.

FRANCE

## Pharmaceutical industry: the bugbear of healthcare professionals' training and patient information

*Gilles Bardelay, co-founder of la revue Prescrire, wrote this piece for the French media. He explicitly drew on ISDB publications of the last 20 years, so we reprint it as an honour to Gilles's inspiring vision and leadership.*

“**P**he successful transplant is one which the organism accepts as part of itself and incorporates into its living whole. By this definition, today's pharmaceutical industry is like a successful transplant within the body of the medical profession.

The pharma industry can do everything, and everything is expected of it. It is a constant presence, watchful and attentive, good-natured and thoughtful, pre-empting every slightest wish: plying junior hospital doctors with food and drink, improving food in the hospital staff room, providing or upgrading the department's computer or photocopier, sponsoring the boss and the deputy's trips to the USA, staging mock oral exams to help trainees prepare for their competitive exams, laying on drinks for graduation ceremonies or for the hospital bridge tournament, the continuing education session lunch, providing therapeutic information, computer network logistics and training healthcare sector managers, etc., etc.

Clinical research, bibliographies, publications, conference proceedings, continuing education, equipment, leisure facilities, gadgets... we are deeply indebted to the pharma industry.

The carefully maintained symbiosis between pharmaceutical firms and healthcare professionals causes the latter to abandon their critical faculties and forget their true social function.

It distracts them from their real market and human value: patient service rather than the volume of drugs prescribed. (...)” (1).

The above quote is from an editorial in la revue Prescrire, published in 1998. Over the last 30 years, numerous voices from around the world have expressed alarm at the serious dangers of allowing pharmaceutical firms to be involved in the training of healthcare professionals. The distinctions between commercial and

industrial objectives on the one hand, and health and economic concerns in serving patients' best interests on the other are becoming increasingly blurred.

These warnings and recommendations based on the extensive experience of independent professionals can be summarised quite simply: being profit-driven, in the face of tough competition the pharma firms inevitably always seek to promote their own products. They are incapable of producing composed, objective, comparative, balanced conclusions which take into account all the available treatment options with their pros and cons.

And this holds true in every area: therapeutic innovation, drugs' adverse effects, patient information, definition of diseases, screening.

### No claim of a therapeutic advance without a comparative analysis

“(...) Innovation is a central issue for those concerned with drug therapy: the public, health professionals and their information providers, health policy makers and regulatory authorities, organisations paying for medicines, and the pharmaceutical industry. Of these, health professionals have a key role to play in ascertaining the value of a new drug therapy and making a decision about prescribing or dispensing it. Their individual skills must however be supported by independent information. Patients and the public rely on the professionals to ensure that their best interests are upheld. The pharmaceutical industry increasingly creates the impression that there is an imperative for a faster development and approval of innovative interventions\* that patients should rapidly have access to. Yet professionals working in independent drug bulletins have shown that this impression is misleading (...).

Overall, no more than a few percent of newly approved drug interventions in one year offer a worthwhile advantage to patients over previously available options. The ISDB Declaration puts the needs of patients and professionals first, and aims to define 'therapeutic advance' in terms of 'comparative advantage'. Patients' needs include both individual and collective needs of the population. The term 'innovation' covers three concepts:

- The commercial concept: any newly marketed me-too product, new substances, new indications, new formulations, and new treatment methods.

- The technology concept: any industrial innovation, such as use of biotechnology, or the introduction of a new substance delivery system (patch, spray, etc.), selection of an isomer or a metabolite.

- The concept of therapeutic advance: a new treatment that benefits the patient when compared to previously existing options.

It is in the pharmaceutical industry's interest to blur the distinction between the three concepts. And in the name of claimed innovation the pharmaceutical industry imposes its agenda on regulators, and targets professionals and the public through advertising. (...)

When judging whether a new intervention is a therapeutic advance, it is crucial to consider efficacy, safety, and convenience (helping patients to use it well). Efficacy, safety and convenience are inter-related: they must be assessed concurrently and regularly re-assessed as new evidence emerges. (...)”(2).

The above extract from the ISDB Declaration on therapeutic advance in the use of medicines, published in 2001, underscores how unfeasible it is for a pharmaceutical firm to produce or promote the necessary comprehensive and comparative information that will enable patients and healthcare professionals to make informed medical decisions.

## Adverse effects cannot be prevented without independent information

Drugs' adverse effects have a tangible impact on patients' quality of life, resulting in more hospitalisations and prolonged hospital stays, and increasing mortality. Furthermore they place a huge financial burden on healthcare systems. Hence the crucial importance of training healthcare professionals in these areas. But, as the ISDB stressed in 2003, in the ISDB Declaration on Pharmacovigilance, numerous obstacles concur to minimise the perception of adverse effects (3). And in particular:

**Conflicts of interest among drug regulatory agencies.** "(...) Conflicts of interest may arise because drug regulatory authorities are, to a growing degree dependent on fees from the pharmaceutical industry. On the other hand the fees keep the drug regulatory agencies more independent of shrinking public budgets. But, in many countries, those who advise regulatory authorities often have substantial links with, and sometimes direct funding from, pharmaceutical companies. (...)

In the pre-approval stage, regulators and their scientific advisers tend to weigh the balance of scientific doubts about drug safety in favour of the drug's promoters in order to facilitate early licensing. In the postmarketing phase, they also take this approach to the interpretation of spontaneous ADRs and other safety data.

It may be a hindrance for appropriate action, if the same authority which is responsible for clearing products for approval also has the task of monitoring their safety and, under given conditions, has to remove them from the market. That creates an inherent conflict of interest. Measures may be delayed because they could signal poor quality of approval decisions and the authority may have to explain why it allowed the drug to reach the market. The unwillingness to disclose the information is intensified by the fear that disclosure may threaten a product, affect company profits and share prices, and be followed by litigation. (...)"(3).

Already in 1996, among the reasons for the regulatory agencies' increased abuse of secrecy, the "Statement of the

international working group on transparency and accountability in drug regulation" criticised this danger: "(...) Industrial influence: many companies clearly prefer that entire regulatory files be regarded as secret.

Over-caution: there may be an exaggerated fear of upsetting commercial susceptibilities. (...)" (4).

**Misinformation by the pharmaceutical firms.** "Pharmaceutical companies are primarily interested in sales and turnover, while patients are interested in health and wellbeing. To capture market share pharmaceutical companies emphasise the drug's efficacy in their "information" and minimize the significance of ADRs, e.g. classifying them as unproven events (AE). Anything to do with harms tends to remain buried, because of the commercially sensitive connotations. (...)

Playing down problems may be considered 'natural', given that pharmacovigilance activities may unearth problems that otherwise do not come to light. Drug representatives may hesitate to forward ADR reports because they could harm the company, or because their own income depends on sales figures. Financial liabilities can be so important that when ADRs lead to a drug crisis the company may primarily inform the stock market rather than health professionals and the public (...)"(3).

**Insufficient training of doctors as a result.** "Physicians are reluctant partners in ADR reporting. Physicians fail to report an estimated 95% to 98% of all adverse events for varying reasons<sup>51-54</sup> they don't think about it because they have not been educated to do so they think the features of ADRs are already well known, especially when the suspected drug is old they interpret ADRs as minor or irrelevant they lack the interest to listen to the patient they have doubts about the causal role of the drug(s) involved and wrongly assume that causality has to be established they suspect that the ADR has never been previously discussed and fear that their suspicion might therefore be wrong they suspect that the ADR has already been reported by a colleague they lack the time they fear a lot of extra work, because of time-consuming requests for addition-

al information they are concerned that the ADR might subject the reporter or others to disciplinary action or a lawsuit they fear they could be sued by the company for 'false' statement and compensation reporting is thought to be ineffective they are ignorant of the requirements for reporting they plan to collect and publish a personal series of cases they lack understanding of what types of ADR should be reported the ADRs simulate a common spontaneously occurring disease or simulate the symptoms of the treated disease relevant information is missing such as drugs prescribed by other physicians or medicines taken without prescription (patients rarely tell physicians about their use of alternative medicines) they lack financial compensation for the time and effort of reporting they lack feedback from authorities or medical professionals in the system reporting forms are not to hand.

Besides the lack of education in reporting ADRs, many physicians have lagged behind other professionals in learning how to effectively communicate risk. In other industries, such as aviation and nuclear industries, where risks have to be conveyed to the public this is usually done only by a few specially trained people working on behalf of their organisations. In health care, where the risks are usually far higher and more uncertain and complex, almost every doctor who interacts with patients has to communicate information on risk, yet few have any training (...)" (3).

## No relevant patient information unless there is transparency concerning the sources

Healthcare professionals must not only be familiar with the first-line treatments, prevent and manage adverse effects, they must also help patients by giving them relevant information. But, as is emphasised in the "Joint Declaration on Relevant Information for Empowered Citizens" published in 2006 by a large number of European patient groups and healthcare professionals, there must be an end to the blurring of roles between the pharmaceutical firms and the other healthcare actors, a confusion that is constantly maintained by the European Commission (5).

"Health information is a fundamental

and necessary part of healthcare. However, the development of direct-to-consumer advertising, of disease awareness (or “disease-mongering”) campaigns, “compliance programs”, and direct and indirect pharmaceutical industry support of patient’s organizations have blurred the boundaries between drug promotion and health information.

If patients are to be able to make informed choices about their health, there needs to be a clear distinction between information and advertising that is disguised as “information”. Relevant health information should be:

- reliable: evidence-based (listing data sources), unbiased, and up-to-date, with full transparency on authorship and financing (enabling rejection of information influenced by conflicts of interests);

- comparative: presenting benefits and harms of the full range of available treatment options (including, where appropriate, the option not to treat), together with an explanation of the natural history of the disease, or condition; and

- adapted to users: understandable, accessible, and culturally sensitive. (...)

Recommendations on treatment choice must be independent both of individual companies that have a product for sale, and the industry as a whole. The statement by industry lobbyists that “Consumers and patients are effectively excluded from receiving information about their medicine and its comparative effects [because of the] ban [for] drug developers from informing patients [...] even on the developers own web sites”, makes no sense. Pharmaceutical companies, and all “partners” financed by pharmaceutical companies, cannot provide unbiased comparative information on available drug and non-drug treatment alternatives. Pharmaceutical companies do have a specific role to play: by law, they must provide well labelled drugs, including patient information leaflets. Directive 2004/27/CE requires package leaflet evaluation by patients. This is an important and much-needed step. Informative packaging and patient information leaflets are likely to contribute to better medication use and prevention of errors.(...)”(5).

“(...) The independence of physicians,

pharmacists and more generally all healthcare professionals is a prerequisite for quality care and patients’ lasting trust.

This requirement begins with university and within healthcare training organisations, where students must learn the bases of professional ethics.

This need for rigour and independence will be reinforced throughout their career. Professionals must preserve their only true capital: their freedom of thought and action in healthcare, training and research.”(1).

This need for independence is all the more crucial today as healthcare is increasingly treated as a commodity as a result of international competition in the marketplace. If we want to prevent modern treatments from doing more harm than good, we need a huge collective wake-up call.

**Gilles Bardelay**

**Co-founder of la revue Prescrire**

1- Prescrire Rédaction “Indépendance” Rev Prescrire 1998; **18** (182): 16.

2- ISDB - Extracts from the “Declaration on Therapeutic Advance in the Use of Medicines” November 2001, [http://www.isdbweb.org/pag/therapeutic\\_dec.php](http://www.isdbweb.org/pag/therapeutic_dec.php) (English version: 12 pages).

3- ISDB - Extracts from the “Berlin Declaration on Pharmacovigilance” November 2003, <http://66.71.191.169/isdbweb/pag/publications.php> (English version: 28 pages).

4- HAI, Dag Hammarskjöld Foundation “Statement of The International Working group on Transparency and Accountability in Drug Regulation” September 1996.

5- Extracts from the “Joint Declaration of HAI Europe, ISDB, AIM, BEUC, Medicines in Europe Forum: Relevant Health Information For Empowered Citizens” October 2006, <http://66.71.191.169/isdbweb/pag/documents.php> (English version: 8 pages).

CHINA

**ISDB WANTED**

*There is no ISDB member in China, and this deserves to be noticed and lamented. China is becoming an attractive place for drug companies to conduct clinical research, as reported in this extract from a Financial Times paper (reprinted below). To the best of our knowledge there are no independent sources of drug information produced in China, and government strictly controls the media and Internet sources of information. The Australian ISDB member Therapeutic Guidelines has an agreement with the Chinese company Chemical Industry Press that is translating TGs titles in Chinese.*

REPRINT

**China overtakes India in drug testing**

China has overtaken India as one of the fastest-growing locations for drug trials, in a fresh sign of the importance of the world’s most populous country to the pharmaceutical industry.

An analysis by the Financial Times of data on [www.clinicaltrials.gov](http://www.clinicaltrials.gov), one of the most comprehensive websites where researchers register their studies, shows that China has 274 clinical trials under way, compared with 260 in India.(...)

The trend reflects intensifying interest by the healthcare sector in China, which is growing rapidly as a result of rising income and expanding health coverage and is already forecast to be the world’s fifth-largest pharmaceuticals market by 2010. (...)

India and China have both received increased attention by pharmaceutical companies in recent years, reflecting a strong medical infrastructure, substantially lower costs and the relative ease of recruiting patients with diseases under investigation - which allows trials to be launched more rapidly.

The government in China - like that in India - still raises concerns about the extent of intellectual property protection, quality, slow regulatory approval and difficulties in exporting blood and tissue samples from patients for analysis in laboratories abroad.

However, pharmaceutical groups including AstraZeneca, Novartis and Roche have committed substantial sums in recent years to open research and development centres in China. (...)

**Article extracts by Andrew Jack in London and Amy Yee in New Delhi; August 28 2007**

Full texte available on:

<http://www.ft.com/cms/s/0/b44cfc94-54fe-11dc-890c-0000779fd2ac.html>

## BULLETIN ROUND-UP

We welcome suggestions and contribution to this section where we reprint articles of interest from ISDB Bulletins. Thanks a lot!  
 @\_ Contacts: ckopp@prescrire.org; fvandeveld@prescrire.org.

### DIC NEWSLETTER (INDIA)

## Redefining the role of Pharmacists!

*The future of community pharmacy looks grim. In Europe, the European Commission has challenged the key role and responsibilities of pharmacists in dispensing medicines. This article reprinted from the April-June 2007 issue from DIC Newsletter (India) is a reminder of the pharmacist's role, in India and elsewhere. Clinical pharmacy is actually the core of the profession, which put patients' health and interests first.*

The role of the pharmacists is undergoing rapid transition and like medical profession this branching in specialties. A new specialty is Clinical Pharmacy is developing in India, on similar lines of the developed nations. The word clinical is derived from a Greek word: klinikos which means bed. Therefore a clinical pharmacist should spend substantial amount of the time at the bed side of the patients – listening and counseling them, taking part in the therapeutic selection in consensus with the other

healthcare team members and talking to the family members of the patients. The clinical pharmacists have got few core clinical activities—Drug information, Adverse Drug Event management, taking admission drug histories, participation in medical ward rounds, and managing drug protocols—with a cumulative result of best health. Pharmacists should come out, from hibernation and spend quality time with the patients, who need his advice. Whenever a role of pharmacists is explained, the pharmacists are said to be one standing behind the counter with a spatula in one hand, without giving importance to the patients. There are multiple descriptors attached to pharmacist like compounder, physician assistant, community, specialist, distribution etc. which confuses the patients and a clear role of the pharmacists has to be explained to the patients and healthcare professionals with the goal of achieving optimal health outcomes. For this situation probably pharmacists themselves are responsible as he is unable to explain what he actually could offer to the healthcare settings. However, with the support of Pharmacy Council of India, PharmD is soon to be started in our country. Hence,

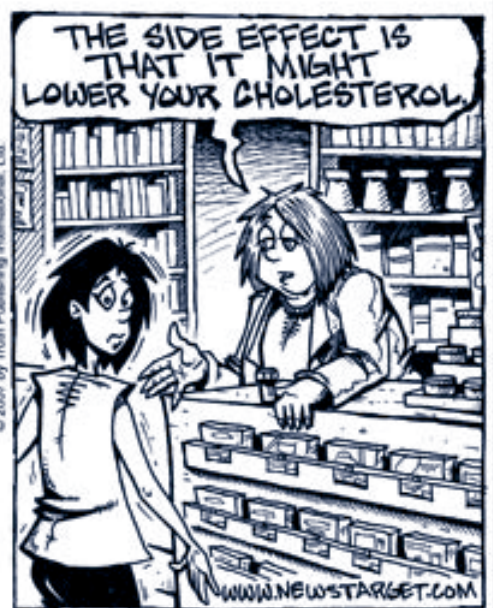
we can foresee that pharmacist's new role will be clearly defined and there will be significant contribution to health care and optimizing on the more positive outcomes from our much needed services. Above all, pharmacist must communicate, listen and talk to the patients/consumers of health-care and to regulatory agencies, educating them about the clinical role that pharmacists to fulfill in preventing and reducing the burden of acute and chronic illness by helping patients make the best use of medicines. At the same time the syllabus of our courses has to be upgraded such that pharmacist could execute our exact role.

Contact: Dr. P.K. Lakshmi  
 (kspcdic@blr.vsnl.net.in; sureshlakshmi6@yahoo.com)  
 Website: www.kspcdic.com

**Read also:** Farmacéuticos June 2007  
 "Parafarmacia: calidad, credibilidad y profesionalidad"

Pictures creator: Mike Adams  
 Source: [www.NewsTarget.com](http://www.NewsTarget.com)  
 Want to use this cartoon? Specific, limited permission is granted to reprint in any book, movie, website, magazine, newspaper, animation or other media under "professional courtesy" conditions available on [www.newstarget.com](http://www.newstarget.com).

### COUNTER THINK



# Ongoing campaigns

## ISDB bulletins are still mobilized against DTCA in Europe

*Direct-to-consumer advertising is likely to pop up again in the EU, this time masquerading as patient information on health and diseases. [see ISDB press release called "Patient-'information' by Big Pharma: a threat to public health" and campaign material on [www.ISDBweb.org](http://www.ISDBweb.org)].*

The European Commission is going to announce the results of its public consultation on health information to patients: legislative modifications are expected that would allow pharmaceutical companies to 'communicate' with the public. The objective is to boost competitiveness of EU pharmaceutical industry and attractiveness of Europe for investors, against the USA and increasingly, Asian countries.

Repeatedly reporting on this story in ISDB bulletins is crucial, with links to ISDB website; it will help to convince policy and opinion makers.

In July 2007 Newsletter, we started to quote the articles published on this topic in ISDB bulletins. A rapid screening of the bulletins received since July 2007 at ISDB library gives the following. ➡

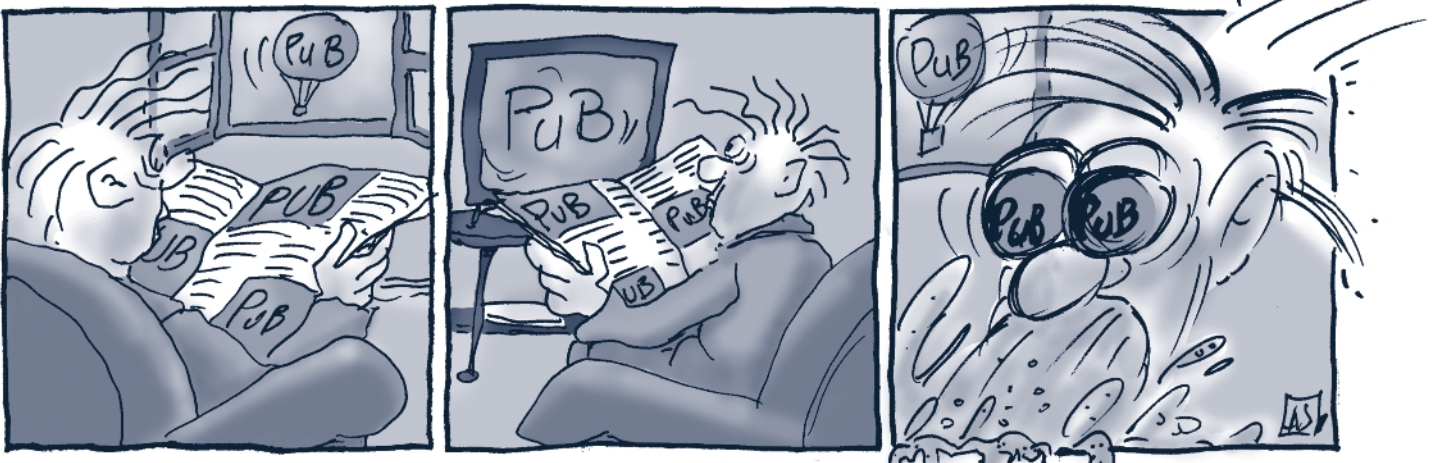
Thank you very much!

- "Pharmawerbung in Patientenköpfe" *Pharma-Brief* 2007 ; (5) : 1-3.
- "Pazienti 'Informati' dalle aziende Farmaceutiche: una minaccia per la salute pubblica" *Dialogo sui Farmaci* 2007 ; (3) : 118.
- "Ci risiamo!" *FOCUS Bolettino di Farmacovigilanza* 2007 ; (49) : 1.
- "Pazienti « informati » alle aziende farmaceutiche" *R&P* 2007 ; (23) : 128.
- "Werbung für rezeptpflichtige Arzneimittel bei Patienten" *Der Arzneimittelbrief* 2007 ; 41 (7) : 49-50.
- "Direct to consumer advertising of drugs in Europe: evidence on its benefits and harmes is available but is being ignored" by Nicole Magnini and Maria Font *BMJ* 2007 ; 335 : 526.

### More information on DTCA

- Campaign material on [www.ISDBweb.org](http://www.ISDBweb.org)
- "Industry-supported health information for patients back on the agenda in the EU" *ISDB Newsletter* July 2007; Vol. 21, N°2: pages 13-15.
- "A Decade of Direct-to-Consumer Advertising of Prescription Drugs" *New England Journal of Medicine* on content.nejm.org/cgi/content/full/357/7/673
- "EC report on drug advertising found to be "biased"" by Ray Moynihan *BMJ* 2007; 23 June 2007 (following ISDB, MIEF and HAI joint open letter to EU Commissioner in June 2007)
- "Say no to drug ads: advertising prescription medicines does nothing for people's health" *NewsScientist* ; 30 June 2007 : 5.

Pub=Ad



# Ongoing campaigns



## Future of pharmaceuticals in the European Union

*A strategic consultation paper released by the EU Commission end of July 2007 is a source for concern.*

On the agenda for the coming years:

- flexibility of regulation concerning “variations” of existing **marketing authorisations** (see the joint ISDB/Medicines in Europe Forum position pages 13-14)
- flexibility of legislation concerning **clinical trials**, while the clinical trial Directive was transposed into national law some years ago (read also the presentation of the study on clinical trial registries in the US by Public citizen page 16)
- so called “rationalisation” of **pharmacovigilance**
- increased **obstacle to generic marketing** disguised as a fight against counterfeit medicines
- nanomedicine** regulation that will blur the boundaries between medicines and medical devices and clear the ground for pharmaceutical companies
- plus the 3 topics discussed by the EU Pharmaceutical Forum : **Direct To Consumer Advertising** (read page 10), **drug price and refunding, added therapeutic value**. For more information, read the joint Medicines in Europe Forum, ISDB and HAI joint position on these issues in ISDB Newsletter July 2007 page 18: “EU pharmaceutical Forum: Public health is not its overriding priority”.

More information on this consultation:

[http://ec.europa.eu/enterprise/phabiocom/comp\\_new.htm](http://ec.europa.eu/enterprise/phabiocom/comp_new.htm)

### Tips for campaigners

Those of you who want to monitor EU regulatory affairs should visit regularly the following websites:

- DG Pharmacos of the EU Commission [ec.europa.eu/enterprise/pharmaceuticals/pharmacos/new.htm](http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/new.htm) and [ec.europa.eu/enterprise/phabiocom/comp\\_new.htm](http://ec.europa.eu/enterprise/phabiocom/comp_new.htm)
- EMEA news [www.emea.europa.eu/whatsnewp.htm](http://www.emea.europa.eu/whatsnewp.htm)
- EMEA Implementation of the New EU Pharmaceutical Legislation [www.emea.europa.eu/htms/general/direct/legislation/legislation-human.htm](http://www.emea.europa.eu/htms/general/direct/legislation/legislation-human.htm)
- Medicines for children [www.emea.europa.eu/htms/human/paediatrics/introduction.htm](http://www.emea.europa.eu/htms/human/paediatrics/introduction.htm)
- Heads of Medicines Agencies [www.hma.eu/mri.htm](http://www.hma.eu/mri.htm)

# Ongoing campaigns

## European lay media overlook medicines affairs

*Donald Light has visited Europe and notice that European media appears to be less interested in news on medicines than the US media. Regarding France, he's right and Prescrire invited him to write a piece on this topic for journalists (reprinted below). A French version will be sent to key French journalists working on medicines.*

*What about other EU and non-EU countries? Please tell us what you think and send Newsletter editors the good media sources from your country (contacts: ckopp@prescrire.org; fvandeveld@prescrire.org).*

### Kept in the Dark about Dangerous Medicines

As a visiting researcher in Europe on medicines, I wonder why does the European press report so little about the dangers of medicines that patients take? Is it that European readers do not want to be informed about risks of medicines they take? Or that editors of newspapers and television news think such news is not important? There a new story every month, and it's ready to write up.

Take for example a major story about the drug, aprotinin, widely used to reduce bleeding in cardiac surgery. It made front-page news in the U.S. when the Food and Drug Administration (FDA) issued a Warning that it significantly increases heart failure and stroke. What put it on the front page, however, was that Bayer had commissioned a study that showed the drug caused high rates of death and renal damage but then did not report the results. European television and printed news made little of it; yet companies are being put in charge of monitoring risks after drugs are approved.

Would Europeans not want to know about this direct conflict of interest? A Bayer executive read current incentives right when he noted that the less evidence of bad news you gather, the less evidence you have that there is bad news. Shouldn't European viewers and readers be informed and concerned?

In December a major story broke in the US on secret company documents showing that Eli Lilly managers had covered up evidence that one of the world's leading drugs for schizophrenia, Zyprexa, carried high risk of obesity and diabetes. According company emails and documents given to the *New York Times*, Lilly knew about the high risks before the drug was approved and worked to minimize evidence of it so that doctors would not be informed of the risks to their patients. This story went on for days. European press coverage was minimal. Why?

On March 14<sup>th</sup>, the FDA decided to issue a serious warning on 14 sleeping medicines taken widely in the US and Europe. These pills cause some people to choke or their faces to swell. They cause others to get up and make phone calls, prepare food, and even drive their cars in their sleep, without knowing it. This warning received wide press in the United States but not by most European newspapers or TV news shows.

Why not? Some people tell me that Europeans trust their doctors and trust their government regulators. They assume all is well. If so, they are naïve, and under-reporting keeps them in the dark. It appears that Europeans cannot trust their regulators to be vigorous protectors of their public health, though French vigilance is better than most.

On April 12<sup>th</sup>, the FDA (the U.S. regulator) rejected by a vote of 20-1 a new painkiller from Merck called Arcoxia, because it had almost no benefits and substantial risks of cardiovascular trauma. The news is that most European countries have approved this dangerous and useless drug. Merck is marketing here, and doctors are prescribing it to patients. Yet because of little press coverage, they do not know that the FDA thinks it is useless and dangerous. Shouldn't pointed questions be asked about why this drug was approved here in the first place and whether it should stay on the market?

On May 9<sup>th</sup>, front-page news broke on large "rebates" to American doctors treating cancer patients for prescribing anemia medication. Six cancer doctors in one practice alone received US\$2.7 million for prescribing medication worth \$9.0 million to the company. One result is doctors overprescribing and raising red blood-cell counts to a dangerous level. The story makes one want to find out what kinds of rebate or kickback schemes are legal in different European countries and how they are affecting the quality of patient care.

The press is the key to informing the public and to making information about the medicines that Europeans take transparent. Why do papers and TV news programs report so little, when the stories are ready to be written from key web sites, news sources, and official reports? A well-informed citizenry by an independent press is the best defense against the risks of medicines.

**Professor Donald W. Light, Ph.D.**  
Fellow, Netherland Institute for Advanced Study  
Contact: [dlight@Princeton.EDU](mailto:dlight@Princeton.EDU)

## EMA is defining paediatric needs in psychiatry deadline for comments 31 January 2008

After a new Regulation on paediatric medicines EMA is busy defining what they call “paediatric needs”. The work is done by the Paediatric Committee belonging to the European Medicines Agency (EMA), who is compiling an ‘inventory’. The ‘inventory’ will be based on data collected in Member States on “existing uses of medicinal products in the paediatric population”. But not all common practices are evidence based.

The same Committee will also examine marketing applications. So the same body will be required to make a list of public health needs while providing service to pharmaceutical firms. Indeed, how EMA could resist industry pressures while fees from marketing applications cover around 70% of its budget.

**Action.** Have a look at and comment on the draft “Assessment of the Paediatric Needs – Psychiatry” that has been released for consultation till 31 January 2008.

It includes amazing “needs” such as SSRIs in children...The more we respond to the consultation, criticizing the way needs are assessed, the better for child health.

Draft available at:  
[www.ema.europa.eu/htms/human/paediatrics/inventory.htm](http://www.ema.europa.eu/htms/human/paediatrics/inventory.htm)

## ISDB and Medicines in Europe Forum call for centralised drug approval for all medicines in the EU

*In response to a EU Commission consultation on “variations” of drug authorisations, Medicines in Europe Forum and ISDB called on European policy makers to suppress the messy and secretive “mutual recognition procedure”. They also advocated the same “centralised procedure” for all medicines in the European Union. We reprint below the Medicines in Europe Forum (MiEF) and the ISDB joint contribution to the public consultation organised by EU Commission Enterprise Directorate (September 2007) (1), following a preliminary proposal (October 2006) (2).*



## Towards centralised and transparent marketing authorisations for all medicines

- *We welcome the European Commission’s initiative aimed at clarifying the legislative framework for marketing authorisation variations within the European Union. But further harmonization of marketing authorisation procedures is needed, and these procedures must also be made more transparent in order to ensure that they guarantee both patients’ best interests and fairness for competing drug companies.*

Marketing authorisation procedures in the European Union are so heterogeneous that it is difficult, and sometimes impossible, for European citizens (particularly health-care professionals and patient organizations) to understand what is going on.

**Too many types of easier and faster authorisations.** Drugs that circulate within the EU can be authorised through the centralised procedure, or a national procedure, or the mutual recognition (decentralised) procedure following national authorisation. Easier and faster authorisations have accumulated over the years, making this general framework even more complex. They include accelerated procedures, marketing authorisation granted in exceptional circumstances, conditional, simplified authorisation, paediatric authorisation, and orphan drug status. National characteristics such as authorisation for temporary use and approval for “temporary therapeutic protocols” in some Member States, are also largely exploited by drug companies seeking faster market access for their products.

The heterogeneity of national marketing authorisation conditions (despite harmonized rules), especially for marketing authorisations variations — the subject of this consultation — generates conflicts that have to be resolved through referral procedures.

And even when an agreement is reached the decisions are slow to be enacted.

The situation is therefore highly confusing, to the point where it can even be difficult to identify the different indications in which a particular drug is approved depending on the European countries.

**Still too opaque.** Secrecy still pervades marketing authorisation at all levels of the system. Decisions taken by drug regulatory agencies are not systematically upheld by readily accessible assessment reports. EMEA does post European Public Assessment Reports (EPAR) online, but their quality has always been highly variable (even though it is improving), and EPARs for extensions of indications are sometimes released several months after the fact (3,4). National agencies do not publish all their assessment reports (NPAR), and when they do they rarely translate them, even into English.

European citizens often have no reliable way of knowing whether a company fulfils the undertakings it make in exchange for a non-standard marketing authorisation procedure (5). Instead they have to keep an eye on medical journals for the results of post-market studies, cohort follow-up studies, etc.

And when it comes to adverse effects, secrecy is still the rule in 2007, as we pointed out, once again, during the consultation on the European pharmacovigilance system (6).

**Towards a transparent and centralised procedure for all.** Harmonization of administrative requirements and criteria for extensions of national marketing authorisations would be a step in the right direction. This would avoid unnecessary complications for applicants, healthcare professionals and patients, and might also reduce the need for referral. However, further reform is needed to create a system that is fair and understandable for all stakeholders, that promotes appropriate drug use, and that bolsters the credibility of the European regulatory system.

Throughout the adoption procedure for Directive 2004/27/EC (modifying Directive 2001/83/EC), the Medicines in Europe Forum pleaded for true harmonization, most notably through a broadening of the centralised procedure's field of application; gradual but nonetheless rapid suppression of the national procedure and of the mutual recognition procedure; optimization of expertise and resources, with Member State expertise being reallocated to the centralised procedure; and strict assessment (and 5-year reassessment) of marketing applications based on common and clinically relevant criteria (7). Post-market follow-up data collected in each Member State, and especially pharmacovigilance data, should be gathered, analysed and serve as the basis for valid decisions applicable throughout the European Union.

This plea in favour of the centralised procedure was heard by the European Parliament: as of 20 May 2008, the centralised procedure will be obligatory for 7 categories of drugs, namely those indicated in AIDS, cancer, neurodegenerative disorders, diabetes, rare diseases, autoimmune diseases, and viral infections (8). But there was also strong lobbying in favour of the mutual recognition procedure, which is judged more "flexi-

ble" by drug companies and more directly lucrative for those regulatory agencies that are most often chosen as the "reference Member State" (9). As a result, the mutual recognition procedure and the decentralised procedure are still widely used, and it is a source of confusion and sterile competition between national agencies. And, while there are some steps towards greater transparency, it still remains highly secretive in 2007.

**Whatever legislative and regulatory measures are taken in order to harmonize variations of national marketing authorisations, the Medicines in Europe Forum and the ISDB call for real efforts to ensure full harmonization of the European system for approving new drugs and indications, and for existing transparency requirements be respected in practice.**

The quality and safety of medicinal products requires a certain incompressible level of administrative constraints to be imposed on manufacturers; any attempt to go beyond this limit in the EU would jeopardize citizens' health. The use of the mutual recognition or decentralised procedure, currently predominant, is prejudicial to the global efficiency of the EU medicines market and undermines the safety of European citizens. A harmonized system, which creates a level playing field for competing companies and offers EU citizens concrete guarantees of safety, is the only option for a world-class system.

*The Medicines in Europe Forum  
The International Society of Drug Bulletins*

#### References

- 1- European Commission - Enterprise and Industry Directorate General "Better regulation of pharmaceuticals: towards a simpler, clearer and more flexible framework on variations" Public Consultation ; 10 July 2007. Site internet [http://ec.europa.eu/enterprise/pharmaceuticals/varreg/variations\\_issue\\_paper\\_20061020.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/varreg/variations_issue_paper_20061020.pdf): 12 pages.
- 2- European Commission - Enterprise and Industry Directorate General "Better regulation of pharmaceuticals: towards a simpler, clearer and more flexible framework on variations" Issue paper ; 20 October 2006. Site internet [http://ec.europa.eu/enterprise/pharmaceuticals/varreg/variations\\_issue\\_paper\\_20061020.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/varreg/variations_issue_paper_20061020.pdf): 16 pages.
- 3- Abbasi K and Herxheimer A "The European Medicines Evaluation Agency : open to criticism" *BMJ* 1998 ; 317 : 898.
- 4- ISDB European Group "European Medicines Evaluation Agency" *ISDB Newsletter* 2001; 15 (1): 11-13.
- 5- Prescrire Editorial Staff "Post-market studies: broken promises" *Prescrire Int* 2007; 16 (89): 123.
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- 7- Prescrire Rédaction "Pour une réglementation qui réponde aux besoins élémentaires de santé publique" *Rev Prescrire* 2002 ; 22 (230) : 544.
- 8- " Regulation (EC) N° 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency " *Official Journal of the European Union* 30 April 2004: L 136/1 - L 136/33.
- 9- Prescrire Rédaction "Les dangers de la procédure d'AMM par reconnaissance mutuelle" *Rev Prescrire* 2002; 22 (230): 542.

## REVIEWS ON ADVERSE EFFECTS

### BioMed Central Medical Research Methodology

See the paper mentioned by Andrew Herxheimer "Systematic reviews of adverse effects: framework for a structured approach" available from: [www.biomedcentral.com/1471-2288/7/32](http://www.biomedcentral.com/1471-2288/7/32)

Thanks a lot, Andrew

Contact: [a.herxheimer@ntlworld.com](mailto:a.herxheimer@ntlworld.com)

## PERX

### Prescribing Evidence-Based Therapies

<http://perxinfo.org/perx.html>

The perRx Project is a US educational program funded by the Attorney General Consumer and Prescriber Education Grant Program. The program was developed to improve awareness of drug development and pharmaceutical marketing practices and to positively impact prescribing behaviors, specifically among advanced practice nurses. An innovative, multi-media, interactive web-based pharmaceutical curriculum has been developed that targets advance practice nurse students and other clinician audiences.

Four documentary modules have been created that detail the extent and effect that pharmaceutical marketing may have on prescribing behaviors. The content includes information on the FDA and the drug approval process, promotions and marketing activities by pharmaceutical companies, and the ethical dimensions of prescribing. Experts from the fields of nursing, medicine, bioethics, health care policy and journalism are interviewed in the documentary. Dramatic vignettes are also presented with a humorous interplay in order to create a format that is educational, thought provoking and entertaining.

## BIRTH NOTICE

### PLoS Neglected Tropical Diseases

PLoS Neglected Tropical Diseases is the first open-access journal devoted to the neglected tropical diseases (NTDs). The journal will publish high-quality, peer-reviewed research on all scientific, medical, and public-health aspects of these forgotten diseases affecting the world's forgotten people.

Www\_More info on: <http://www.plosntds.org>

## Best blogs to bookmark

*Time has come to recommend talented bloggers who cover medicines in society. Feel free to forward good blogs from your country, irrespective of language.*

### Gooznews (USA) [www.gooznews.com](http://www.gooznews.com)

Merrill Goozner run an excellent blog on a number of issues such as drugs, social security, conflicts of interest, regulation and especially the US FDA. He is also director of the Integrity in Science Project that raises awareness on the adverse effects of commercialisation of science. ([www.cspinet.org/integrity/watch/index.html](http://www.cspinet.org/integrity/watch/index.html))

### Other blogs of interest include:

- Pharnalot at <http://pharnalot.com>
- Eye on the FDA at [www.eyeonfda.com](http://www.eyeonfda.com)
- Health Care Renewal <http://hcrenewal.blogspot.com>
- Health Affair [www.healthaffairs.org/blog](http://www.healthaffairs.org/blog)
- Hooked: Ethics, Medicine, and Pharma at <http://brodyhooked.blogspot.com>

## CLINICAL TRIAL REGISTRY

## A Public Citizen study on the quality of clinical trial registries

*Public Citizen Health Research Group published 'A Policy Study of Clinical Trial Registries and Results Databases (HRG Publication #1819)' by Aneel Damle, Peter Lurie and Sidney M. Wolfe, July 17, 2007. The study has appeared on Public Citizen website*

*[www.citizen.org/publications/release.cfm?ID=7534#Results](http://www.citizen.org/publications/release.cfm?ID=7534#Results).*

*Rather than add comments, let's cite some key points:*

As evidence that pharmaceutical companies have suppressed unfavorable study results has grown, the need for publicly available clinical trial registries and results databases has gained increasing public currency.

In one example of selective publication, industry-funded academic scientists withheld from publication certain studies of the Selective Serotonin Reuptake Inhibitor antidepressants that failed to demonstrate drug efficacy. Had these studies been published, the known risk-benefit profile of the drugs would have been altered. In another revealing example, the Journal of the American Medical Association published a report in 2001 claiming that, after six months of therapy, the COX-2 inhibitor celecoxib (Celebrex) was associated with a reduced incidence of gastrointestinal ulcers compared to two older pain medications. However, the authors of the study failed to disclose that at the time of publication they had already received data covering a twelve-month period – the planned duration of the study. The twelve-month data showed no advan-

tage with respect to gastrointestinal toxicity for Celebrex over the other drugs. These two cases underscore the dangers of pharmaceutical companies withholding data from physicians and patients. Online databases have been put forth as a potential solution to these sorts of selective publication (...).

All of the currently available clinical trial registries and results databases are inadequate. Although the public registries are acceptable to the International Committee of Medical Journal Editors (ICMJE), none includes results. Most private Web sites include results databases, but these are voluntary, of variable quality and inconsistent design. Moreover, they are not consolidated in a single Web site, forcing potential users to search multiple Web sites to find information. Cross-listing of trials in several databases generates further confusion. Although search portals can ameliorate some of these problems, they cannot improve Web sites that are themselves poor. Finally, as with any non-public venture, there are significant questions as to transparency, enforceability and quality assurance. The only way to force the development of a combined registry/results database is for the federal government to enact legislation and to assess significant penalties for non-compliance (...).

A combined registry/results database is necessary. This study makes clear that without federal legislation no ICMJE-compliant combined database is likely to exist. The importance of this deficiency is reinforced if one considers the Web sites from the perspective of the study participants, who have laid their bodies on the line to greater or lesser extents in these studies. It is the altruism of human study subjects that allows clinical trials to proceed, an altruism grounded in the belief that they are contributing to scientific research to make the world better for others. Yet studies that fail to be published cannot advance medical science (although their non-publication, if the study results are adverse, can advance the financial interests of pharmaceutical companies).

## Wikipedia: be careful

*Several drug companies have now been caught deleting important information from Wikipedia, the virtual encyclopedia, in order to downplay the risk of their drugs. A good reason why to be careful with such documentation... We reprint below extracts from a blog that tackled the issue.*

REPRINT

"(...) The tool (...) reveals changes to the online encyclopaedia by linking edits back to the computers from which they were done, using each computer's unique IP address. The scanner has wreaked havoc in news media, politics and among corporations caught red-handed "improving" articles.

"Patients not Patents" found that in July of 2007, a computer at Abbott Laboratories' Chicago office was used to delete a reference to a Mayo Clinic study that revealed that patients taking the arthritis drug Humira faced triple the risk of developing certain kinds of cancers and twice the risk of developing serious infections. The

study was published in the Journal of the American Medical Association in 2006.

The same computer was used to remove articles describing public interest groups' attempt to have Abbott's weight-loss drug Meridia banned after the drug was found to increase the risk of heart attack and stroke in some patients. The site's editors restored the deleted information, but Patients not Patents claim that Abbott's activities illustrate drug companies' eagerness to suppress safety concerns.

Jeffrey Light, Executive Director of the Washington D.C.-based advocacy group said, "The argument that drug companies can be trusted to provide adequate safety information on their own products has been used by the pharmaceutical industry to fight against government regulation of consumer advertising. Clearly such trust is misplaced. As Abbott's actions have demonstrated, drug companies will attempt to hide unfavorable safety information when they think nobody is watching".

**More information:**

<http://www.brandweeknr.com/2007/08/abbott-caught-a.html>.

## BODHI (India) invites readers to assess drug prescriptions

In BODHI May June 2007 on page 47-48 readers are invited to give their opinion on 2 prescriptions including more than 10 products. Clinical details are given. Readers' opinion will be published in a coming BODHI issue.

The 2 pages "No time and space for food" from BODHI May June 2007 issue are reprinted below.

Contact: Pijus K Sarkar  
(fha@cal.vsnl.net.in)

**No time and space for food**

Dear Reader,  
Please look at this prescription. We invite your opinion and intend to publish them in the next issue together with our views.

**ADVICE ON DISCHARGE**  
Rest and salt and fat restricted diet  
1. Tab. LIZOLID (600) - OD x 111 14/3/07 10  
2. Tab. MONOTRATE (20) - BD x cont (8-3)  
3. Tab. CARDACE (5) - AD x cont (10-10)  
4. Tab. NIKORAN (10) - BD x cont (9-9)  
5. Tab. CARDIVAS (3.125) - OD x cont (6-6)  
6. Tab. APRESOL (25) - TD x cont (9-3-9)  
7. Tab. E COSPIN (25) - OD x cont (1 PM)  
8. Tab. CLIPILIT (50) - OD x cont (1 PM)  
9. Tab. RESUVAS (10) - OD x cont (8 PM)  
10. Tab. RACID (20) - OD x cont (6 PM)  
11. Tab. ALPRAM (0.5) - H x cont (10 PM)  
12. Nebulized inhaler - 2 puffs x cont (8-12)  
13. Syr Duphalac - 6 tabs after x cont  
14. Tab. ZYTANIX (40) - OD x cont (1 PM)  
15. Tab. LASIX (40) - OD x cont (1 PM)  
16. Tab. LANTIN (10) - OD x cont (1 PM)  
17. Tab. URONAL (10) - OD x cont (1 PM)  
18. Tab. ALPRAM (0.5) - H x cont (10 PM)  
19. Tab. ALPRAM (0.5) - H x cont (10 PM)  
20. Tab. ALPRAM (0.5) - H x cont (10 PM)

The prescription above has been typed below for clarity along with the INN (generic name) to enable the reader to quickly ascertain its nature and purpose.

Brand name	INN(Generic name)	Frequency and (time of administration)
1. LIZOLID (600)	Linezolid	One tablet twice daily (10 AM - 10 PM)
2. MONOTRATE (20)	Isosorbide mononitrate	One tablet twice daily (8 AM - 3 PM)
3. CARDACE (5)	Ramipril	One tablet twice daily (10 AM - 10 PM)
4. NIKORAN (10)	Nicornadil	One tablet twice daily (9 AM - 9 PM)
5. CARDIVAS (3.125)	Carvedilol	One tablet twice daily (6 AM - 6 PM)
6. APRESOL (25)	Dihydralazine	One tablet thrice daily (9 AM - 3 PM- 9PM)

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## Adverts under scrutiny

Several ISDB bulletins regularly assess and criticize drug adverts: AIS-COIME, Prescrire, Informacion Farmacoterapeutica Vasca, Gute Pillen Schlechte Pillen, etc. An educational tool which is successful.

An example of such "Advert under scrutiny" is presented page 18. The Gardasil® beach towel may reach Europe if we don't oppose pending deregulation of 'direct communication' of drug companies with the public... (read page 10)

**ISDB action:** why not offer this Gardasil® towel advert to EU deputies in your country and to policy makers, and explain the consequences of such adverts on public health and health expenditure?

7. ECOSPRIN (75)	Aspirin	One tablet daily (1 PM)
8. CLOPILET (75)	Clopidogrel	One tablet daily (1 PM)
9. RESUVAS (10)	Resuvastatin	One tablet daily (8 PM)
10. RACID (20)	Rabeprazole	One tablet daily (6 AM)
11. ALPRAM (0.5)	Alprazolam	One tablet at bed time (10 PM)
12. DUOLIN INHALER	Salbutamol + iprapropium	2 puffs 4 times daily (6AM-12NOON-6PM-10 PM)
13. SYR DUPHALAC.	Lactulose	6 teaspoonsful at bed time
14. LASIX (40)	Furosemide	One tablet daily (6 AM)
15. ZYTANIX	?	One tablet daily (1 PM)

**The history**

A 71 year old male patient was admitted in a hospital for two weeks (from 25.02.2007 to 10.03.2007) for shortness of breath, decreased urine output, swelling of legs and cough without expectoration. He was discharged with suitable advice. Within weeks he consulted a different doctor with the sole request to reduce the number of his medicines.

It is no surprising that he felt that he had neither space nor time for all the medicines in the prescription on discharge.

The timing at which he was to take medicines were 6 AM, 8 AM, 9 AM, 10 AM, 12 noon, 1 PM, 3 PM, 6 PM, 8 PM, 10 PM. The volume of water he would need to swallow these medications cannot be calculated but can be imagined.

The second prescription is similarly typed out without any further comments.

Brand name	INN(Generic name)	Frequency and (time of administration)
1. Tab. TIDE 10	Torseamide	1 tablet twice daily (8 AM - 3 PM)
2. Tab. MONOTRATE 20	Isosorbide dinitrate	1 tablet twice daily (8 AM - 3 PM)
3. Cap. CARDACE 5	Ramipril	1 capsule twice daily
4. Tab. NIKORAN 10	Nicornadil	1 tablet twice daily
5. Tab. AVAS 10	Atorvastatin	1 tablet after dinner
6. Tab. GLYNASE 5mg	Glipizide	1/2 tablet before breakfast
7. Tab. LANOXIN	Digoxin	1/2 tablet on alternate days
8. Tab. STALCOPAM PLUS	Escitalopram	1 tablet daily at bed time
9. Cap. OMEZ ASR	Omeprazole	1 capsule before breakfast
10. MUCABNE GEL	Oxazethine + Al-Mg hydroxide	3 teaspoonsful thrice daily before meal

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**This ad (a beach towel) is legal in the USA and New Zealand, where direct-to-consumer advertising for prescription drugs is approved (a).**



**THE AIM OF DTCA AND HEALTH INFORMATION FROM PHARMA COMPANIES IS TO BOOST PROFITS**

**The truth about Gardasil<sup>o</sup>:**

- **uncertainties on prevention of mortality and morbidity related to cervical cancer**
- **key preventive measures risk being overlooked**
- **high price**

**NO WAY TO DIRECT-TO-CONSUMER COMMUNICATION FROM PHARMA COMPANIES!**

*a- PHARMALOT, an excellent US blog has the following comment: What better way to advertise to other beachgoers that you're free of a sexually transmitted disease than to wrap yourself in this nicely designed terry velour towel, which measures 30 inches by 60 inches. Catch a wave and then use the towel to make clear to that attractive person nearby that genital warts or HPV won't be a problem. Truly, this is a new way to advertise the advantages the vaccine has to offer. Frisky teenagers will love them!*

*(Source : : [www.pharmalot.com/2007/08/for-summer-fun-the-gardasil-beach-towel/](http://www.pharmalot.com/2007/08/for-summer-fun-the-gardasil-beach-towel/))*