



Newsletter

September 2010

Editorial

Lively ISDB

If you regularly visit the ISDB website, you can see that many activities happen. Progress is achieved by motivated ISDB working groups (read pages 6-19 and 20-25). And, looking at bulletins' content, one can discover plenty of good ideas, smart editorial methods and interesting actions. Unfortunately, due to too much work with their bulletins and/or lobbying activities, the Newsletter editors failed to produce the Newsletters regularly in 2009-2010 and to relay the news. And there is a risk that the situation will not significantly improve in the coming months...

Active communication and exchange among ISDB members are vital. They allow for timely support when a bulletin faces political or financial trouble; for sharing best practices ("benchmarking"), which helps to improve ISDB bulletin's methods; for collective actions, with a greater impact, to be undertaken.

These are good reasons for each ISDB member to make a proactive communication effort to all ISDB colleagues (a). Indeed **we encourage you to use the ISDB website forum more frequently and to respond to others' questions or proposals.** The new online forum on ISDB's website now allows you to start individual threads for different topics so that they are easier to follow.

Please do not be shy or too modest! Take a few minutes to regularly report on your actions, feel free to invite others to take part in a collective action under your coordination, raise awareness on a problem you face, share the results of a reader survey you conducted in your bulletin, etc.

Apart from the satisfaction contributing can bring to the collective ISDB project, by sharing your experiences you will probably get interesting feedback and advice from ISDB colleagues. **Think ISDB: it is fun to build long-term friendships and collaboration!**

The Committee

a- You can use the new ISDB web forum (read on page 4) or send an e-mail to Nuria Homedes (nhomedes@utep.edu), Ciprian Jauca (jauca@ti.ubc.ca), or Florence Vandeveldde (fvandeveldde@prescrire.org) for a publication in the Newsletter.

Content

ISDB News

Dates for your diary	2
Welcome to new members: <i>Maharashtra State Pharmacy Council's Drug Information Bulletin, A.I.S. Bolivia Bulletin, Boletim Brasileiro de Avaliação das Tecnologias em Saúde (BRATS)</i>	3
Good bye to <i>Information från Läkemedelsverket</i>	3
A new ISDBweb	4
How to use the new ISDB forum? Easier than it seems!	4
An ISDB editorial workshop on pharmacovigilance	5
EVITA: an interesting method	6
Prices of HPV vaccine: results of an ISDB survey	7
Online SPCs worldwide: results of an ISDB survey	8

Members' News

<i>Australian Prescriber</i> and adverse reactions: back to the future	9
<i>Therapeutic Guidelines</i> awarded	9
<i>La Lettre du GRAS</i> : 25 years of publivigilance!	9
<i>Minerva</i> : 10 years, and developing online CME	9
Darko Božidar Vrhovac passed away	10
ISDB editorial workshop in Bogota	10
<i>Cuban BIT's</i> reader survey	10
HAI <i>Europe</i> full member of the EMA's patients' and consumers' working party	11
<i>Prescrire</i> : a new website	11
<i>Gute Pillen Schlechte Pillen</i> : producing independent patient information	12
<i>Atd Arzneimitteldatenbank</i> online	13
BUKO Pharma-Kampagne: a new website for young people	13
<i>No grazie pago io!</i> Continuing Medical Education (CME) without sponsors is possible	13
<i>Medwatcher Japan</i> : a website in English	13
<i>Kusuri-no-check</i> very active on oseltamivir	13
<i>Genesmiddelenbulletin</i> end of the troubles and a new website	13
An "Evidence Alley" as an antidote to commercial sponsorship ..	14
<i>Fundation Institut Català de Farmacologia</i> : 25 years	14
<i>DTB Navarra</i> : Drug Assessment Reports (DAR) available in English	14
Peter Lurie (<i>Public citizens</i>) moved to the FDA	14
Bulletins round-up	15

Ongoing campaigns

EUROPE Towards direct-to-consumer advertising of prescription drugs in Europe? A critical moment	16
EUROPE Pharmacovigilance: end of September 2010, vote on the improved European Commission's proposals	16
EUROPE 'Pharmaceutical package': list of recent lobbying actions undertaken	17
TRANSPARENCY European Medicines Agency (EMA) under scrutiny	18
TRANSPARENCY "Handling of the influenza A/H1N1 "pandemic": European citizens want to know more"	19
INTERNATIONAL ICH: an exclusive club	19

Perspectives

Pharma needs to work with non-traditional partners to survive ..	19
Google makes no-cost online medical records service available to public	19

Restricted to members

Minutes of ISDB Committee conferences:

- 23 June 2009 (phone conference)
- 15 December 2009 (Committee meeting in Bielefeld, Germany)
- 9 March 2010 (phone conference)
- 29 June 2010 (phone conference)

Dates for your diary



ISDB members are very welcome to attend the following meetings and conferences:

5 & 6 October 2010 (Paris, France): ISDB Committee meeting in Paris; main point on the Agenda: preparation of next General Assembly (end of 2011)

Detailed Agenda:

- Tuesday 5 October 2010:

Morning (start at 9 am):

- ISDB business; Follow up on ISDB means of communication
- Update on Working Groups (WG) achievements
- Choice of the location for the next GA
- Determining the dates and number of days

Afternoon

- Brainstorming on priorities for the next General Assembly (GA)
- Preparing a first draft programme together (preparing the plenary sessions, choosing several workshop topics)

- Wednesday 6 October 2010

Morning

- Preparing a first draft programme together (preparing the workshops)

Afternoon

- Results of the "bulletin assessment survey" (assessment to be done before) and organising the following steps
- End of the meeting at 4 pm

Contribute to the preparation of the 2011 ISDB General Assembly

To contribute to the preparation of the next ISDB General Assembly, you can:

- Send written proposals about topics and organisation, via ISDB webforum or by e-mail to Committee members;
- Join the next ISDB Committee meeting on 5 & 6 October 2010 (Paris, France).

Contact:

Florence Vandevelde,
ISDB General Secretary
(fvandevelde@prescrire.org)

Read the minutes!

For an update on the working groups (WG) achievements, read the minutes of ISDB Committees on pages 20-24 in this Newsletter (restricted to members).

7 & 8 October 2010 (Amsterdam, the Netherlands): Healthy Skepticism symposium "Selling Sickness - Influence on influence"

The conference will focus on describing problems with pharmaceutical promotion, understanding the causes, developing solutions and enabling collaboration.

Detailed program, call for posters, registration at:

<http://www.gezondescepsis.nl/conference-2010.html>

Contact: Peter Mansfield (peter.mansfield@adelaide.edu.au) or Sandra van Nuland, Project manager Gezonde scepsis (conference@medicijngebruik.nl)

12 October 2010 (Brussels, Belgium): International multidisciplinary symposium "Science, clinical practice and psychotropic drugs: How do they interact?"

The symposium will attempt to analyse the social phenomenon of the overprescription of psychiatric drugs along two different lines: the scientific basis for the prescription of these drugs (how was it constructed and is there any scope for questioning its validity?); the question of disease categorisation, the distinction between mental pathology and the ups and downs of daily life, and the impact of disease-mongering on how we perceive ourselves.

Speakers: David Healy, Kalman Applbaum, Alain Giami, Trudy Dehue, Walter Vandereycken, Benoit Majerus

Detailed program and registration form available at:

www.freeclinic.be/IMG/pdf/colloque_psychotropes_UK-2204_1_.pdf

Contact: Monique Debauche (La Lettre du GRAS, Belgium) colloque@freeclinic.be



WELCOME

Maharashtra State Pharmacy Council's Drug Information Bulletin

Maharashtra State Pharmacy Council, which publishes the *Maharashtra State Pharmacy Council's Drug Information Bulletin*, was granted **associate membership** in June 2009. Welcome within ISDB family!

Distributed: freely to pharmacists who are registered with Maharashtra State Pharmacy Council (annual payment of fees)

Frequency: 4 issues a year

Language: English and Marathi

Contact person: Sampada Patvardhan (info@mspcindia.org)

Address: Maharashtra State Pharmacy Council

ESIS Hospital Compound

LBS Marg, Mulund (W)

Mumbai – 400 080

India

Website: www.mspcindia.org

WELCOME

A.I.S. Bolivia Bulletin

Published by Acción Internacional para la Salud Bolivia (Health Action International Bolivia), *A.I.S. Bolivia Bulletin* was granted **associate membership** in April 2010.

AIS Bolivia Bulletin provides information about current issues that concern the medical society and the general public: health matters like alerts about counterfeit medicines, unethical practices, commercial products that endanger public health, drug policy enforcement and diffusion, generic drugs, rational use of medicines, patients and consumers rights as well as environment protection. Welcome within ISDB family!

Distributed: freely; 9,000 copies are distributed to Bolivian society

Frequency: 6 issues a year

Language: Spanish

Contact person: Oscar Lanza Van Den Berghe (aisbol@entelnet.bo)

Address: Acción Internacional para la Salud Bolivia

N° 1178, Av. Abel Iturralde

Miraflores

La Paz,

Bolivia

Tel: + 591 2 22 22 987

Website: http://saludpublica.bvsp.org.bo/ais/aisfin.htm

WELCOME

Boletim Brasileiro de Avaliação des Tecnologias em Saúde (BRATS)

Published by the National Health Surveillance Agency (ANVISA), the National Supplementary Health Agency (ANS) and the Science and Technology and Strategic supplies secretariat of the Ministry of Health, *Boletim Brasileiro de Avaliação des Tecnologias em Saúde* (in English Brazilian Bulletin of Health Technology Assessment) (BRATS) was granted **full membership** in April 2010. BRATS disseminates reliable information about technologies to all stakeholders involved in Healthcare in Brazil.

Welcome within ISDB family!

Distributed: freely online

Frequency: 4 issues a year

Language: Portuguese

Contact person: Alexandre Lemgruber Portugal d'Oliveira (brats@anvisa.gov.br)

Address: ANVISA

SIA, Trecho 5, Área Especial 57, Brasília - DF

ZIP CODE: 71.205-050

3° ANDAR, BLOCO E – NUREM

Tel: 55 61 3462-4001

Fax: 55 61 3264-4097

Website: www.anvisa.gov.br/divulga/newsletter/brats/index.asp

GOOD BYE

Information från Läkemedelsverket

In March 2010, at its request, *Information från Läkemedelsverket*, Swedish Medical Products Agency's bulletin, left ISDB. Working for a Drug Regulatory Agency, our colleagues felt "difficult to stand behind" ISDB's strong position on the need for the Drug Regulatory Agencies, particularly the European Medicines Agency, to become much more transparent. The Swedish Medical Products Agency is one of the least secretive drug regulatory agencies in Europe. Good luck!

Contact person: jane.ahlqvist-rastad@mpa.se; Björn.Beermann@mpa.se.

Masthead

ISDB Newsletter, April 2009 • **Published by:** *International Society of Drug Bulletins* • **Coordination:** Florence Vandeveld • **Editors:** Helen Barnett, Dulce Maria Calvo Barbado, Juan Erviti, Maria Font, Nuria Homedes, Ciprian Jauca, Luisella Grandori, Rokuro Hama, Christophe Kopp, Joan-Ramon Laporte, Jörg Schaaber, Walter Thimme, Claudia Vacca, Florence Vandeveld; Special thanks to the members who responded to the ISDB surveys • **Reviewers:** ISDB Committee members (Helen Barnett, Christophe Kopp, Jörg Schaaber, Isidro Sia) • **Layout:** Véronique Beauzel, Catherine Marriette, Sandrine Praud (*Prescrire*)

ISDB, the *International Society of Drug Bulletins* (ISDB), founded in 1986, is a worldwide network of bulletins and journals on drugs and therapeutics that are financially and intellectually independent of the pharmaceutical industry. The ISDB brings together some 81 bulletins independent of the pharmaceutical industry. Member publications, serving healthcare professionals and/or the general public, are present in more than 40 countries worldwide.

More information: www.isdbweb.org

Reminder

Send each issue of your Bulletin to the ISDB library!

You can send each issue of your Bulletin to the ISDB library either by post or by email if you make an electronic edition.

The library is located at the ISDB Secretariat:

Post address:

Prescrire

Documentation Center

83 boulevard Voltaire

75558 PARIS CEDEX 11

France

Email address:

documentation@prescrire.org

Thanks in advance!

A new ISDBweb

Since May 2010, ISDB has had a new website, with increased possibilities, and an easier to update format for the web-master.

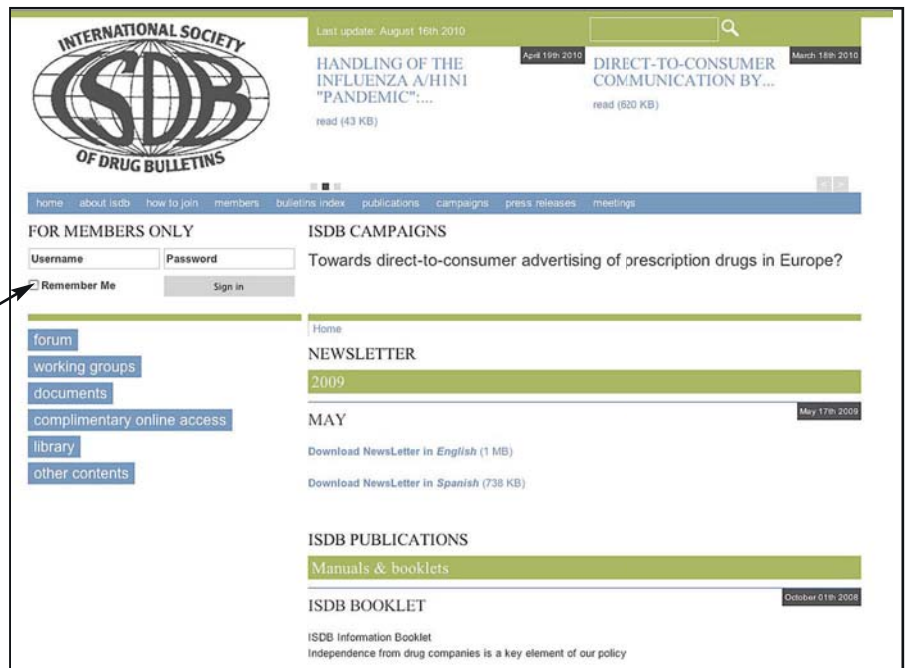
The new home page contains 2 press releases on the latest ISDB actions, the latest Newsletter and one text from the "Campaigning" section. Contents restricted for members only are available on the left-hand side.

This new website also offers new tools: an online forum that is independent from the Yahoo groups and its advertising (read below), the possibility to organise petitions, etc.

The cost for this new website was 3 800 euro.

More: Discover ISDB new website at: www.isdbweb.org.

Contact for further information/suggestions: Maria Font, webmaster (maria.font@ulss20.verona.it)



How to use the new ISDB forum? Easier than it seems

We were used to the yahoo ISDB webforum: to post a new message, we just had to write an e-mail at the address of the forum. It was easy to use, but there were advertisings, and no possibility to organise the messages in different threads.

As part of the new ISDB website, the webmaster managed to free ISDB members from the yahoo group and its advertising and proposes us to use a new online forum. To use this new Forum, one has to connect to ISDBwebsite. When you will have done it once, you will notice that it is easy.

How to post a new message?

The 6 steps to follow:

- 1- connect to the ISDB website: www.isdbweb.org;
- 2- on the home page, identify yourself in the «For members only section» (if you forgot them, ask for your username and password to Maria Font at maria.font@ulss20.verona.it);
- 3- click on the «Forum» bottom;
- 4- click on «[new message]»;
- 5- write your message (you can even attach documents);
- 6- click on post.

How to answer a message?

- 1- Click on the title of the message posted: you will open a space where you can write your answer;
- 2- Write your answer;
- 3- Post your message.

Contact for any question/suggestion:

Maria Font, webmaster (maria.font@ulss20.verona.it)





An ISDB editorial workshop on pharmacovigilance

On 14 December 2009, an ISDB editorial workshop was organised on pharmacovigilance using the opportunity of the Committee members meeting in Bielefeld (Germany). Wolfgang Becker-Brüser (*arzneitelegram, Germany*) and Elisabeth Veyriac (*Prescrire, France*) shared their expertise and experience with the workshop participants (more details on the Agenda in the box below).

21 participants attended. ISDB members were invited with (message sent through the Forum).

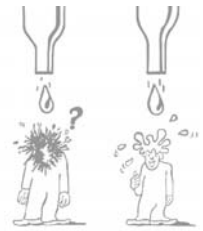
21 participants attended the workshop: the ISDB Committee members, Dick Bjl (*Geneesmiddelenbulletin, the Netherlands*), Anita Conforti (*Focus, Italy*), Amitava Guha (*Rational Drug Bulletin, India*), Clotaire Nanga (*La Lettre du Cedim, Burkina-Faso*), Carole Piriou (*Health Action International*), Victoria Rollason (*Pharma-Flash, Switzerland*), Luis Carlos Saiz Fernández (*Notas Farmacoterapeuticas, Spain*), Victoria Rollason (*Pharma-Flash, Switzerland*), Thomas Stammshulte (*Arzneiverordnung in der Praxis, Germany*), Walter Thimme (*Der Arzneimittelbrief, Germany*).

Discover the speakers' presentations. Presentations and background texts are available on ISDB website at <http://www.isdbweb.org/news/past> (section meeting > past meetings). Extracts from the presentations are also presented in short boxes along the pages of this Newsletter.

Outcomes of the workshop. The 2 crucial issues that were identified for actions were :

- lobbying for more transparency of Drug Regulatory Agencies (DRA);
- lobbying for increased access to pharmacovigilance data, which is often not easily available (read in this Newsletter the "Ongoing campaign" section on page 16 and the "Minutes of the ISDB Committee on 15 December 2009" on page 21).

On the Agenda of the ISDB pharmacovigilance workshop



What?

Adverse drug reactions (ADR) are the dark side of drugs and an often neglected theme that needs more attention. The concept of harm/benefit balance is often ignored. Companies, but also prescribers, tend to focus on benefits. Consumers are often misled by exaggerated and simplified messages on benefits and the absence of any mention of harm.

Aims of the workshop:

- increase ISDB members' editorial expertise in the pharmacovigilance field, notably by giving practical advice to adequately report about drug harms
- raise ISDB members awareness about the political context of pharmacovigilance in Europe and worldwide, and organise lobbying to improve the situation

9:05 – 10:30: Presentation of participants, activities in the pharmacovigilance field, wishes / expectations

11:00 – 12:30: Why and how to write on pharmacovigilance issues?

- 5 reasons to report on ADRs (WBB)
- Risk evaluation and level of evidence (EV): the balance of benefit and harm; what is different when judging benefit and harm? (what is not enough for providing benefit is important in relation to detecting for harm, plausibility, signals); Reliability of ADR data; Levels of evidence (from randomised trial to case reports)
- How to detect (new) risks? Different tools and approaches (WBB); What's wrong with data mining? (WBB); Building an own ADR network (WBB)

12:30 – 13:00: Discussion

14:00 – 14:30: How to communicate ADRs?

- Communication on the balance of benefit and harm: always place pharmacovigilance information in the context of care and of therapeutic alternatives. The communication of doubt (EV)
- Sensitise doctors to see ADRs, Warnings without consequences, the need to repeat warnings (WBB)
- Tools for dissemination (blitz-at) (WBB)

14:30 – 15:30: Case studies with 2 complementary approaches

- From a particular case to generalities: Case studies (Levofloxacin and tendon ruptures: Showing pitfalls in the data representation) (WBB)
- From general points to specific issues: Listing some problems in the management of pharmacovigilance data and giving some examples (i.e. 1st reports hidden or not taken into account, waiting for epidemiological studies results, biased or methodologically deficient clinical trials) (EV)

16:00 – 17:00: Changing structures in pharmacovigilance : Evolution of Pharmacovigilance in Europe and worldwide (Florence Vandeveld, ISDB DTCA working group coordinator)

16:30 - 17:00: Discussion: How to prevent the dismantling of pharmacovigilance in Europe: developing a lobby strategy for the coming months

Background documents of interest:

ISDB Declaration on pharmacovigilance (Berlin, 2002) available at: http://www.isdbweb.org/documents/uploads/Declaration/Berlin_Declaration_Berlin%20Engl.pdf

Herxheimer A (2005) "Communicating with Patients about Harms and Risks" *PLoS Med* 2(2): e42. Available at: <http://www.plosmedicine.org/article/info:doi%2F10.1371%2Fjournal.pmed.0020042>

2 "Methods" texts from Prescrire Editorial staff:

- "Evaluation of treatment benefits: clinical endpoints relevant to patients" *Prescrire International* 2008; 98 : 260.
- "Evaluation of treatment risks taking clinical data, pharmacology and patient characteristics into account" *Prescrire International* 2010 ; 105 : 44.

Evaluation of pharmaceutical Innovations with regard to Therapeutic Advantage (EVITA): an interesting method

During last ISDB Committee, the 15th of December 2009 in Germany, Walter Thimme presented the EVAluation of pharmaceutical Innovations with regard to Therapeutic Advantage (EVITA) method. ISDB Committee members agreed on the need for ISDB members to share information and reflection on drug assessment methods. We therefore briefly present below the EVITA method so that each ISDB member benefits from this reflection basis.

The outcome of an HTA project

EVITA is a project of the Health Technology Assessment (HTA) center at the University of Bremen that is being conducted in cooperation with the NEPI-Foundation of the Lund University Malmö, Sweden, and is sponsored by the National Association of Statutory Health Insurance Funds, Germany.

EVITA aims at formalising the evaluation of the therapeutic advance of new drugs using rating points, in order to help to make decisions such as adding or not a new medicine in drug formularies lists of well selected medicines (for health professionals), in deciding if a new medicine should be reimbursed or not and at what price (for Health Technology Assessment bodies).

EVITA does not evaluate a new compound per se: it evaluates its usefulness for an approved indication.

A simple methodology

EVITA'S methodology is presented on www.evita-report.de. We reprint below interesting extracts:

"The EVITA evaluation attributes positive or negative rating points to the drug in question and its comparator in clinical trials, taking both therapeutic benefit and risk profile into consideration. The compound scores positive points for superiority in efficiency or if there are less adverse effects as demonstrated in randomized controlled trials (RCTs), whilst negative points are awarded for a lack of benefit or an unfavorable risk profile. The evaluation follows an algorithm which considers the clinical relevance of the outcomes, the strength of the therapeutic effect and the number of RCTs. Treatment aim (therapy versus prevention) and disease severity (expressed as treatment category) are mentioned, but these do not influence the score. Using a placebo as a comparator is accepted only in the absence of an established therapy. The results are presented online together with all RCTs considered as well as the reasons for excluding a given RCT from the evaluation. This allows for revision in response to justified criticism and simplifies the inclusion of new data. The EVITA results are presented as a color-coded bar graph; a traffic yield sign with a question mark indicates that the data was unsuitable for evaluation."

uation follows an algorithm which considers the clinical relevance of the outcomes, the strength of the therapeutic effect and the number of RCTs. Treatment aim (therapy versus prevention) and disease severity (expressed as treatment category) are mentioned, but these do not influence the score. Using a placebo as a comparator is accepted only in the absence of an established therapy. The results are presented online together with all RCTs considered as well as the reasons for excluding a given RCT from the evaluation. This allows for revision in response to justified criticism and simplifies the inclusion of new data. The EVITA results are presented as a color-coded bar graph; a traffic yield sign with a question mark indicates that the data was unsuitable for evaluation."

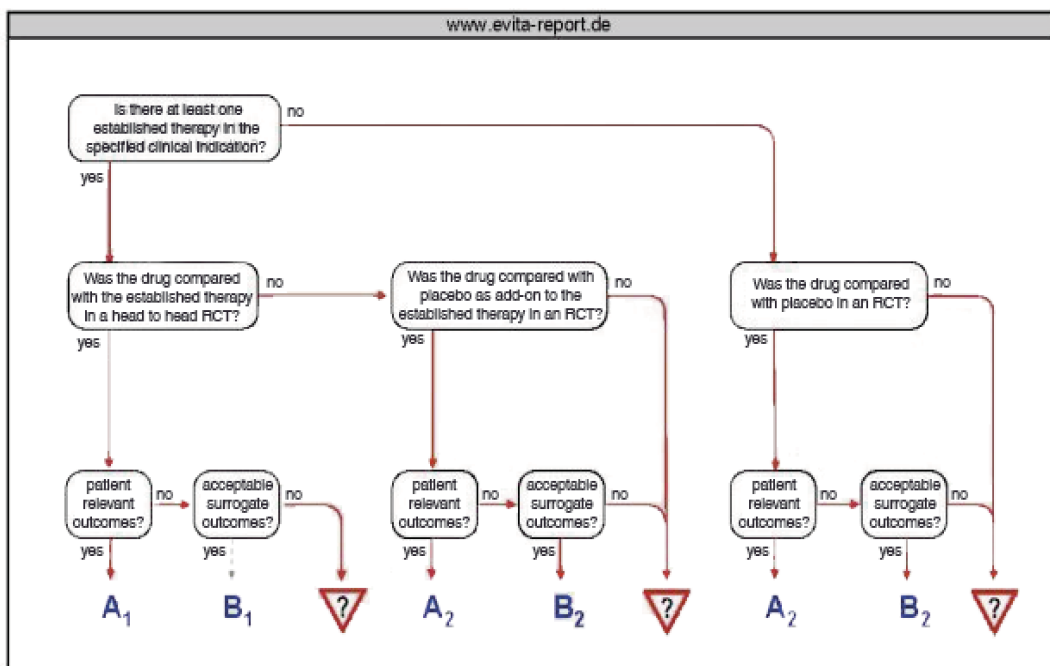
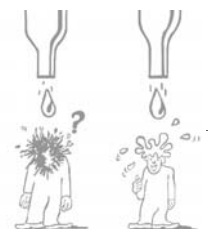


Figure 1. Flowchart of the decision tree leading to the EVITA trial settings

More info (available in English): www.evita-report.de



Five reasons to report on ADRs*

- Drug companies often hide ADRs because they interfere with marketing
- Reporting of ADRs in studies is often insufficient and misleading because they are censored, restricted and distorted
- Most new drugs are introduced without reliable ADR information, but differences in ADR profiles can be important for treatment choice (and are often misused for marketing)
- Health professionals' limited ability to recognise unknown and unexpected AE has to be strengthened - Physicians are stimulated to report what they observe when they read ADR reports
- ADR reporting is essential to conduct benefit-harm evaluations

*Reprint from the presentations made during ISDB workshop on pharmacovigilance (14 December 2009, Bielefeld, Germany). Read in this Newsletter on page 5. More on ISDBweb: in the "past meetings" section

Prices of HPV vaccine: results of an ISDB survey

Methods. In 2009, Philip Sax, ISDB “Pricing” working group moderator, asked ISDB members what is the price of the 3-course HPV vaccines in their country (retail price including taxes), and whether the vaccines were publicly funded (reimbursable). The aim was to compare the situation in many different countries, using a mediated example.

Results. The Table below summarises the data collected, including further data from the literature in the case of Australia, Canada and USA.

PRICES¹ (US\$)² AND REIMBURSEMENT STATUS OF HPV VACCINES, BY COUNTRY³

	<i>Gardasil</i>	<i>Cervarix</i>	<i>Reimbursable</i>
Argentina	755	362	No
Australia	354		Yes
Belgium	489	489	Yes
Burkina Faso	225		Yes
Canada	310		Yes
Columbia	284	295	No
France	529	529	Yes
Germany	620	620	Yes
Israel	592	575	NO⁴
Italy	371	406	Yes
Nicaragua	600	600	No
Philippines	318		No
Spain	604	584	Yes
Sweden	394	336	Yes
UK		(350)	Yes
USA	360		? (depends on health plan)

¹ Retail price including taxes, apart from UK (cost price to NHS).

² Conversion rates used: US\$ = €0.77, C\$1.29, A\$1.31, £0.69.

³ Source of data: ISDB members, apart from Australia (NPS Radar), Canada (CADTH), and USA (The Medical Letter).

⁴ Public funding recommended, but not before 2011.

The prices vary considerably: between US\$200-755 in the case of quadrivalent Gardasil and \$295-620 in the case of bivalent Cervarix. The average price is \$400 for Cervarix and \$435 for Gardasil, indicating a better cost-benefit ratio for the quadrivalent product.

In most countries where both products are available, the price difference between the two is small or non-existent; Argentina is a notable exception here. In countries where only one product was available (usually Gardasil), the price was usually lower (between \$225-360; Gardasil).

The average price in six European countries was \$494 for Cervarix and \$501 for Gardasil. Italy is the cheapest country and Germany the most expensive, irrespective of the product.

The prices in less wealthy countries are among the lowest.

HPV vaccine is reimbursable in most of the countries surveyed, but not in the three Latin America countries and not yet in Israel.

Discussion. Tiered pricing means that prices are different so that the cost to the purchaser reflects or is proportionate to its ability to pay. In accordance to this principle, prices should be lower in poorer countries. There appears to be some evidence here of the partial application of a tiered pricing strategy by HPV vaccine manufacturers.

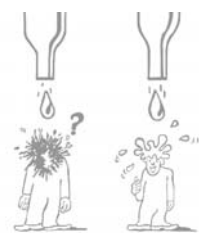
Tiered pricing is an issue that is currently relevant as governments of countries scramble to ensure a sufficient supply of vaccines for the current pandemic swine influenza H1N1(A). A likely scenario is that countries that can pay the most will be first in line.

In the absence of public funding (reimbursement), the woman’s or girl’s family usually has to pay the full purchase price. This means that HPV vaccines are only affordable to the wealthier groups of the population, even if the price in lower income countries is lower than elsewhere.

These prices do not include labour costs (administration) and vaccine wastage costs. Including these costs in the case of Israel would raise costs by approximately an additional 15%.

Contact: Philip Sax (saxp@netvision.net.il)

- More on the way (exceptionally quick) the HPV vaccine was brought on the market and reimbursed:
Haas M. et al “Drugs, sex, money and power: An HPV vaccine case study” *Health Policy* 2009 ; (92): 288-295
- Further reading:
Gerhardus A et Razum O “A long story made too short: surrogate variables and the communication of HPV vaccine trial results” *J Epidemiol Community Health* 2010 ; 64 : 377e378. doi:10.1136/jech.2009.090183



Managing doubts by appraising several sources of data*

Adverse drug reactions are less studied than benefits. There is a lot of uncertainty and one has to cope with the absence of data on adverse effects of drugs, particularly for the most recent ones.

But in terms of adverse effects, converging arguments, even if they are separately weak, are often sufficient to be taken into account, in order to prevent harm.

*Reprint from the presentations made during ISDB workshop on pharmacovigilance (14 December 2009, Bielefeld, Germany). Read in this Newsletter on page 5. More on ISDBweb: in the “past meetings” section



Online Summary of Product Characteristics (SCP) worldwide: results of an ISDB survey

Summary of Product Characteristics (SPCs) and patient leaflets are very important information tools for health professionals and patients.

The results of an ISDB Survey conducted by Maria Font (*Dialogo sui Farmaci*) through the ISDB Forum reveal that several countries provide online access to Summary of Product Characteristics on the Health authorities website (see tables below).

Countries with database containing SPC and patients leaflet available online:

Country	Institution	Website address
Australia	Pharmaceutical Benefits Scheme (PBS)	www.pbs.gov.au
Austria*	Austrian Agency for Health and Food Safety	http://pharmaweb.ages.at
Canada	Health Canada	www.hc-sc.gc.ca
Colombia	Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA)	http://web.invima.gov.co
Denmark*	Danish Medicines Agency	www.dkma.dk
Finland*	National Agency for Medicines	www.nam.fi
France*	Agence française de sécurité sanitaire des produits de santé	www.afssaps.fr
Ireland*	Irish Medicines Board	www.imb.ie
Island	Icelandic Medicines Control Agency	www.imca.is
Latvia*	State Agency of Medicines of Latvia	www.zva.gov.lv
Lithuania*	State Medicines Control Agency	www.vvkt.lt
Malta*	Malta Medicines Authority	www.medicinesauthority.gov.mt
Netherlands*	College ter Beoordeling van Geneesmiddelen Medicines Evaluation Board	www.cbg-meb.nl/cbg/en
Portugal*	Instituto Nacional da Farmácia e do Medicamento	www.infarmed.pt
U.K.*	Medicines and Healthcare products Regulatory Agency	www.mhra.gov.uk
Czech Republic*	State Institut für Drug Control	http://www.sukl.cz
Spain	Agencia Española de Medicamentos y Productos Sanitarios	www.agemed.es
Sweden*	Medical Products Agency-Sweden	www.lakemedelsverket.se www.fass.se
Switzerland	Arzneimittel-Kompendium der Schweiz	www.kompendium.ch
Hungary	National Institut of Pharmacy	www.ogyi.hu

Note: Few European countries fail to offer such database, among them Italy and Germany.

Countries with database containing monographs of drugs available online:

Country	Institution	Website address
Japan	Pharmaceuticals and Medical Devices Agency (PMDA)	www.info.pmda.go.jp
	Japan Pharmacists Education Center (JPEC)	www.jpec.or.jp
Israel	Ministry of Health; The Israel Drug Registry	www.health.gov.il
New Zealand	New Zealand medicines and medical device safety authority(MEDSAFE)	www.medsafe.govt.nz
USA	U.S. Food and Drug Administration (FDA)	www.fda.gov



Case reports: a few worrying reports are enough*

Very often, case reports of Adverse Drug Reactions (ADRs) are the only evidence available.

Published detailed case reports and reports by health professionals and patients to health authorities are a very important source for the discovery of ADRs. They represent clinical cases where the reporter suspected a causal relationship between adverse events and pharmaceuticals. A few worrying reports are enough to alert.

The clinical analysis of these reports includes:

- the timing of symptoms and treatment,
- the description of symptoms,
- other possible causes of the symptoms,
- and known effects of the suspected drug (such as pharmacological effects, and plausible mechanism of adverse effect).

After approval of a new medicine, the great majority of adverse effects are identified on the basis of spontaneous reporting.

*Reprint from the presentations made during ISDB workshop on pharmacovigilance (14 December 2009, Bielefeld, Germany). Read in this Newsletter on page 5. More on ISDBweb: in the "past meetings" section

In this section, we report on news we discover by reading ISDB bulletins or on information that circulates on ISDB webforum (preferably in English).

The aim of this section is to help members to better know each other and increase their level of interactions.

Do not hesitate to get in touch with the resource persons who sign these short texts to have more information or to ask for advice if you plan to organise the same kind of activity.

@_ Please provide us with regular updates on your work and achievements, so that we can share the information with other ISDB members. Thank you in advance!

AUSTRALIA

Australian Prescriber and adverse reactions: back to the future

From 2010, information about adverse reactions is once again included in a special section of *Australian Prescriber*. This section entitled "Medicines Safety Update" is prepared by the production team of the former *Australian Adverse Drug Reactions Bulletin* (ADRAC) under the guidance of the new Office of Medicines Safety Monitoring (OMSM). As the electronic version of *Australian Prescriber* has many overseas readers, the new arrangements will deliver important information about adverse reactions to a wider audience.

More at: www.australianprescriber.com/upload/pdf/articles/1072.pdf

AUSTRALIA

Therapeutic Guidelines awarded

In September 2009, *Therapeutic Guidelines* was granted international award for "Best eBook Publisher" for *eTG complete*. Granting this award, the Association of Learned and Professional Society Publishers (ALPSP) recognized *TG's* innovation in scholarly publishing. Congratulations!

More in Therapeutics Guidelines' Newsletter 2009 (December); (4): 1.

BELGIUM

La Lettre du GRAS: 25 years of publivigilance!

In 2010, *La Lettre du GRAS* celebrated 20 years of Publivigilance® (more than 120 actions aimed at counter adverse effects of advertising on the quality of care, and the insidious contamination by a particular virus: the NEAV "Non Ethic Advertising Virus"). The main action for 2010 is a campaign entitled "No more continuing education, no objective information without experts' independence and transparency at each level". According to the *GRAS*, transparency has an "anti-Dracula effect". And just as doctors learnt that they should wash their hands to avoid bacteriological infections in 1840, it is urgent to "wash our brains" from negative influences on the quality of care.

More details on the history of *La Lettre du GRAS* in its March 2010 issue and at: www.groupechercheactionsante.com.

BELGIUM

Minerva: 10 years, and developing online CME



In December 2009, *Minerva* celebrated 10 years of existence. The team includes 11 persons and develops 4 products in French and in Dutch: the bulletins, a website, a glossary online and

online continuing medical education (read below). There are 10 000 readers: general practitioners, pharmacists and specialists.

In June 2010, *Minerva* developed a new service: the "online analysis", short analysis of recent publications.

Minerva also developed online continuing medical education which are recognised by health authorities ("accreditation" points). 2 trainings (called "modules" in French) are available each year. They consist in online reader tests (on 2 different issues or on 1 issue when it deals with critical reading). A right answer give access to the next question, in case of a false answer, the reader can correct the answer thanks to the justifications given. If the participants answer correctly, the reader tests give them credit.

More info: Explanation of the method of analysis of a publication developed by *Minerva*:

- in French at: www.minerva-ebm.be/articles/nl/2010/5-2010/Module%204_achtergrond_FR_26052010.pdf

- in Dutch at: www.minerva-ebm.be/articles/nl/2010/5-2010/Module%204_achtergrond_NL_26052010.pdf

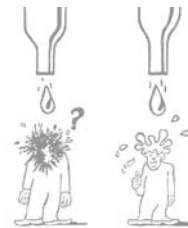
Taking pharmacology and physiology into account*

Pharmacology and physiology must be taken into account in order to evaluate the risks of a drug, particularly a new drug.

- It is useful to consider the known adverse effects of other drugs in the same pharmacotherapeutic class or other drugs that are chemically related. For example, tianeptine dependence and addiction could have been predicted because of the similarity to amineptine, which is known to expose patients to these adverse effects.
- It is useful to consider the known pharmacodynamic effects of a drug. It makes it possible to deduce a series of adverse effects that share the same mechanism: for example atropine-like or amphetamine-like effects or serotonergic effects. Adverse effects of cox-2 inhibitors were predictable knowing the adverse effects of NSAIDs and cyclooxygenases.
- It is useful to consider data from animal studies.
- It is useful to consider how the drug is metabolised: especially whether it is excreted by the kidneys, whether it is metabolised by enzyme systems, whether the gastrointestinal absorption is subject to interferences, etc.

These data are predictive of drug accumulation in some patients, or drug interactions, for example.

*Reprint from the presentations made during ISDB workshop on pharmacovigilance (14 December 2009, Bielefeld, Germany). Read in this Newsletter on page 5. More on ISDBweb: in the "past meetings" section





COLOMBIA

ISDB editorial workshop in Bogota

In November 2010, using the opportunity that several editors of Latin America ISDB bulletins were going to participate in a meeting on pharmacovigilance at the National University of Colombia in Bogota, an ISDB editorial workshop was organised in Bogota by Claudia Vacca (*CIMUN Boletín de Farmacovigilancia*, Colombia) and Benoit Marchand (*AIS-Coime*, Nicaragua), and moderated by Maria Font (*Dialogo sui Farmaci*, Italy).

The main objective of this workshop was to improve Latin American drugs bulletins by strengthening evidence search skills, critical appraisal of drug information and production of independent information.

This was achieved exploring a concrete therapeutic issue (HPV-vaccine).

26 participants came from 9 Latin America ISDB bulletins. Participants were asked to prepare the workshop a few weeks before the meeting using a 5 steps approach inspired by the editorial methodology presented Chapter 7 of the ISDB Manual.

- 1- Identify the objective of the information to produce;
- 2- Develop a search strategy, document selection criteria and organisation of selected evidence;
- 3- Analyse and interpret of the information in every country's context;
- 4- Discussion how to identify and present messages;
- 5- Imagine actions post workshop (i.e. an international publication about cur-



Participants to the Bogota workshop

rent problems associated with coverage and/or HPV's vaccine usage in Latin America using the workshop's outcome).

→ **Outcome of workshop:** The group decided to submit a letter dealing with prices, prevention strategies and the comparison of the Latin American situation with the European situation to an International journal. To be prepared by: María Font, Claudia Vacca, Martín Cañas. To be reviewed by: Francisco Gutiérrez and Juan Furones + reviewers from Latin America bulletins (list to be established by Benoit). And to be finally reviewed by ISDB Committee.

Contact: detailed report of the workshop available on request to Claudia: cpvacag@bt.unal.edu.co.

CUBA

BIT's reader survey

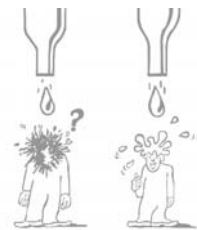
Boletín de información terapéutica (BIT) para atención primaria de salud conducted a reader survey in October and November 2009. Its editor in chief, Dulce Maria, shares with ISDB colleagues the main outcomes.

“**Context.** The Pharmacoepidemiology Development Center began to publish a drug bulletin in 1996 in order to promote rational use of drugs in primary care. It was supported by the Health Ministry and the Panamerican Health Organization. The bulletin started with 20 000 printed copies; nowadays the number of printed copies are only 5000 for the whole country. Its content evolved: from

pharmacoepidemiology issues to consensus guidelines and now it publishes current evidence base guidelines. In 2007, BIT an became associate member of the ISDB, and since then the editorial team has worked to strengthen and improve the quality of the bulletin.

Methods. Our pharmacoepidemiology staff in 9 provinces applied a questionnaire to a total of 605 family physicians.

Results. 96 % of responders considered that the content is interesting or very interesting. About 98 % considered the BIT as useful (56 % archive it to be able to refer to it when needed, 26 % leave it on the library for other



Doubt should benefit the patients*

An adverse event has to be considered as adverse effect when a causal relationship cannot be excluded. It has to be considered as adverse effect when further investigation into the event's circumstances and physiopathology make it plausible that the reaction was indeed a response to the drug. A reasonable suspicion of an adverse effect, or suspicion of a significant increase in the frequency of a known adverse effect, must be reported. It requires all concerned to act promptly to protect patients even before causality or accurate frequencies have been determined, especially if the benefit expected from the drug may be obtained in another way. Information must be promptly available to patients, health professionals and carers.

Half-measures are unacceptable if they result in continued patient exposure to adverse effects, when the risks/benefits balance becomes unfavourable, or when benefits have not been adequately established.

*Reprint from the presentations made during ISDB workshop on pharmacovigilance (14 December 2009, Bielefeld, Germany). Read in this Newsletter on page ????. More on ISDBweb: in the "past meetings" section



readers). 75 % of responders read the bulletin in less than one hour and find it easy to read and understand. 70 % of responders liked the BIT's design and about 80 % considered its size and length convenient. Responders made several suggestions for improvements:

- increase the periodicity and make available more printed copies;
- improve the design with illustrations and graphics;
- include drugs on the Cuban Essential List on the therapeutic recommendations that the bulletin makes;
- write more texts on childhood diseases, food poisoning, drug interactions and update previous texts.

What we plan to do. For the contents, the suggestions of this survey will be considered. We are working to have stable financial support and to increase the frequency of bulletin by strengthening the editorial team. The bulletin does not have any full-time staff which makes it difficult to maintain to publish on schedule. To improve the quality of BIT, the editor was trained by Therapeutic Guideline (Australian ISDB member) (read below). We are planning the creation of an advisory board and will try to get frequent feedback from our readers."

Contact: Dulce Maria Calvo Barbado (dulce@mcds.sld.cu)
Website: www.cdf.sld.cu

Report on Dulce Calvo's training (BIT, Cuba) at TG (Australia)

Thanks to ISDB's support, during one month (end of October until end of November 2009), Dulce Calvo, chief editor of *Bulletin of Therapeutic Information for Primary Health Care*, Cuba, visited the *Therapeutic Guidelines*, Melbourne. The training was exclusive, elaborate & practice oriented. It included the following main areas:

- managing a not-for-profit publishing organisation;
- recruiting and sustaining senior clinician involvement and support; managing the expert writing group process;
- marketing, selling and distributing therapeutic information;
- developing an in-house style guide;
- literature searching and assessing therapeutic information;
- preparing material for electronic publication;
- design and layout for print and electronic publications;
- obtaining feedback on TGL publications, with visits to member of the TGL Evaluation Network;
- obtaining copyright and permissions;
- implementing quality control procedures.

Dulce used the opportunity to visit the *Australian Prescriber* and the National Prescribing Service.

Dulce found this "in house training" very useful: "The capacity to adjust to my interest on searching information, and other areas was great. I learned a lot about the importance for a publication to have all the process well established and designed. (...) The hospitality of the TG was wonderful (...). Thanks to TG and to ISDB for give to young editor this great possibility!"

Contact for more info: Dulce Maria Calvo (dulce@mcds.sld.cu)

CROATIA

Darko Božidar Vrhovac passed away



On 4 December 2009, our colleague and friend Darko Božidar Vrhovac, chief editor of *Pharmaca* from 1981 to 2007, passed away.

Darko worked hard in the pharmacology field and to promote independent information. He invested much energy and worked hard in the ISDB project. For example, he organised with a great commitment several ISDB meetings in his country: in 1987, ISDB Committee meeting in Dubrovnik; beginning of the 1990s Committee in Zagreb, in 2002 General Assembly in Dubrovnik.

More about Darko's commitment to improve rational use of drug in "Tribute to Darko" Uppsala Report 48 January 2010 : 20. www.who-umc.org/graphics/22435.pdf

EUROPE

HAI Europe full member of the EMA's Patients' and Consumers' Working Party



Health Action International (HAI) Europe is an ISDB Associate member. In March 2010, the European Medicines Agency (EMA) has granted HAI Europe full membership of the Patients' and Consumers' Working Party (PCWP). This should enable HAI Europe to deliver its messages more directly and with greater impact. Since many years, often together with ISDB and the Medicines in Europe Forum, HAI Europe contributes to consultations and champions the interests of European citizens and public health in medicines policy.

Contact: Teresa Alves teresa@haiweb.org

FRANCE

Prescrire: a new website

End of June 2010, la revue *Prescrire* launched its new website in French: www.prescrire.org.



Reminder: *Prescrire International* website, the English edition of *Prescrire*, is freely available for all ISDB members at: <http://english.prescrire.org>.

To access the texts for subscribers only, ask for your codes to documentation@prescrire.org telling that you are an ISDB member.

Scoop: by the end of 2010, *Prescrire International* will be published monthly (24 pages).



GERMANY

Gute Pillen Schlechte Pillen: producing independent patient information

Gute Pillen Schlechte Pillen (in English "Good pills - Bad pills") is a bulletin in German for lay people that exists since 2006.

The German project *Gute Pillen - Schlechte Pillen* is an example of collaboration among ISDB members to produce independent patient information. Its editorial team brings together editors from 4 German ISDB bulletins.

ISDB meetings as "development catalyzer" of the project. First thoughts to develop a cooperative patient-information-project were exchanged from person to person during the General assembly in Dubrovnik (2002), deepened in Berlin (2003) and finally presented as a project-plan in Melbourne (2005). The ISDB meetings were actually catalyzing the development of the project. During 2004 and 2005 editors and co-workers of *Arzneimittelbrief*, *arznei-telegramm*, *Pharma-Brief* and sometimes the publishing house (Westkreuz-Verlag) met eight times. The fourth German ISDB-member *Arzneiverordnung in der Praxis* joined in 2007. More details and pictures of our colleagues available at: <http://gutepillen-schlechtepillen.de/pages/die-macher.php>.

A bulletin that evolved. The first issue (12 pages) was sent out in October 2005. The yearly subscription, 6 issues, costs 15 euros. The layout was changed in 2009 (see picture below). Since then, *Gute Pillen - Schlechte Pillen* has 16 pages, a large colour picture on the front page and more pictures as well as a cartoon inside.

The headings and columns are:

- Editorial;
- Drug Therapy (including pricing and regular analyses of advertisings, cartoon and sneering comments);
- Drug Politics, national and international;
- Disease or health oriented Reviews (sometimes protocols of interviews with specialists);
- Letters to the Editor;
- Website with links (i.e. German ISDB members' bulletins) and archive of the past issues (for subscribers only).

A small but effective editorial team. The editorial team (seven persons) meets six times a year either in Berlin or Bielefeld. It selects topics, gives the responsibility of the text production mostly to members of the team, does peer reviews of texts and sends them to the organising editor. The organising editor (Bielefeld) collects the texts from the

authors, makes technical revisions, sends them to all members of the editorial team and then, considering their suggestions, to the publishing house.

A non-profit limited liability company that networks. The legal structure of the project is a non-profit limited liability company. The start capital was provided by the participating journals. More than 100,000 copies of the pilot edition were sent to households in Berlin, and all over Germany, to consumer advice centres, health- and social insurances, adult colleagues, readers of the participating journals, etc.

The best resonance was from direct press-, radio-, or TV-contacts. Also, cooperation with two health insurance companies is positive. They buy selected texts and deliver them to their customers. The income of our company increased 50% from 2006 to 2009. Half of it goes to the publishing house for printing, delivering the issues to the reader, administration of the subscription and the website. The other half of the income goes to the editors for text production, reviewing and editing. Also pictures have to be designed or chosen, the layout has to be prepared, meetings, travel and press contacts take their time. Currently, the income is not paying for all those activities.

A stimulating project. Editors are still "volunteers" for part of their time. But they are quite satisfied with this unique project. The fact that they all cooperate is a sign of growing significance of independent drug information. In addition they feel that they learn from each other. It is good to meet and work together. Over the years the public perception (letters to the editors, press inquiries), the number of readers and the income is growing.

In May 2010, *Gute Pillen Schlechte Pillen* launched a new website:

<http://gutepillen-schlechtepillen.de>.

Contact: Walter Thimme

(wthimme@zedat.fu-berlin.de), who kindly wrote this piece for the Newsletter (subtitles were added by the ISDB Newsletter editorial committee).



The progress in developing attractive materials is clearly visible by comparing the front page of the first issue (2006) and the new front page (since 2009).



GERMANY

Atd Arzneimittelndatenbank online

Since 2000, Arznei-Telegramm publishes online and updates monthly its Atd Arzneimittelndatenbank (drug database), Arznei-Telegramm's independent assessment of more than 17 000 medicines and the details of the medicines' properties (from doses to adverse drug reactions; from comparison of costs to pharmacokinetic properties). Atd Arzneimittelndatenbank costs 46 euros a year. Arznei-Telegramm also continues to publish each 6 months an updated CD version of the Atd Arzneimittelndatenbank.

In July 2010, Arznei-Telegramm released the 2010/11 edition of its Arzneimittelkursbuch: 17 000 medicines usefulness and costs systematically compared (2560 pages).

Reminder: ISDB members can ask for free access to Arznei-Telegramm and to atd drug database (both German only).

Contact: Wolfgang Becker-Brüser (redaktion@arznei-telegramm.de)

GERMANY

BUKO Pharma-Kampagne: a new website for young people

In November 2009, BUKO Pharma-Kampagne, the organisation publishing the bulletin *Pharma-Brief*, launched a new website for young people: www.pillenchecker.de. The aim of www.pillenchecker.de is to counter pharmaceutical companies' advertising (and disguised advertising under the guise of 'information' on contraception, body mass index calculation tools, etc.) toward young people. The website www.pillenchecker.de also provides critical appraisal tools to analyse advertisements.

More info (in German) at: www.pillenchecker.de



ITALY

No grazie pago io! Continuing Medical Education (CME) without sponsors is possible



No grazie pago io!, the Italian No Free Lunch movement, continues to be very active. In a paper in the *BMJ*, "Rethinking continuing medical education", our colleagues from No grazie pago io! (in English "No thank you, I pay myself") argued that Continuing Medical Education (CME) without sponsors is possible (*BMJ* 2008;337:a973). They explain that many health professionals already make it without industry funding. Industry funding not needed if CME is sober, in little groups, with better educational methodology and evidence based.

They also prepared a communication for the Italian conference about new rules for CME request the CME coordinators to encourage CME courses without pharmaceutical sponsor.

More at: www.nograziepagoio.it/ECM%20proposta%20Nograzie%202009_ultima.pdf (in Italian) www.bmj.com/cgi/content/extract/337/aug14_1/a973 (in English)

Contact: Luisella Grandori (luisegra@tin.it)

JAPAN

Medwatcher Japan: a website in English



Medwatcher Japan launched a new website www.yakugai.gr.jp/en ... in English! Medwatcher Japan is an NGO that was launched in 1997 to monitor and prevent drug-induced disasters. Its official Japanese name is "Yakugai Ombudsperson"; "yakugai" means drug-induced disaster. Medwatcher Japan works closely together with our Japanese ISDB colleagues, *Kusuri-no-check* and the *Informed Prescriber*. Medwatcher Japan started an English website to better share information notably with ISDB members.

More at: www.yakugai.gr.jp/en
Contact: Masumi Minaguchi, attorney (minaguchi@san-tama.com)

JAPAN

Kusuri-no-check very active on oseltamivir

In December 2009, our colleague Rokuro Hama from *Kusuri-no-check* sent several rapid responses to the *British Medical Journal*, one in reaction to the publication of the Cochrane review on oseltamivir (Tamiflu®), another one on a case report of adverse drug reaction due to the early use of oseltamivir.

Thanks a lot for sharing the information on ISDB webforum!

More at: www.bmj.com

NETHERLANDS

Geneesmiddelenbulletin: end of troubles and a new website

The Dutch ISDB drug bulletin *Geneesmiddelenbulletin* has moved from the Health Insurance Board to the Domus Medica in Utrecht. It turned out that the cooperation with the Health Insurance Board did not yield the advantages both partners had expected from it. Especially, the editorial independence of the *Geneesmiddelenbulletin* was difficult to combine with the control the Health Insurance Board wanted to have on expressions that were made under its responsibility. This led to the conclusion that the cooperation would end.

The editorial office was moved from Amsterdam to Utrecht, to the Domus Medica, were almost all Dutch medical and paramedical organisations are housed. This gives interesting opportunities for more and closer interaction with these organisations. The *Geneesmiddelenbulletin* started a technical cooperation with 'Medisch Contact', an independent medical journal containing news items, opinions, interviews and reflections.

Meanwhile, the Foundation *Geneesmiddelenbulletin* was set up and an independent board of management was created. This board is involved with the continuity of the *Geneesmiddelenbulletin* and has no involvement with the content of the bulletin. It consists of experienced professionals specialised in law, finance and administration and also medical specialists and pharmacists. They also watch over the independence of the editorial office, editorial committee and advisory board.

The editorial office is now manned with a text-corrector, an editorial-assistant (a pharmacist), an editor (a pharmacist) and a chief editor (medical doctor-epidemiologist). Furthermore,



there are three free lance co-operators who write part of the smaller articles. Since January 2010 the bulletin comes out every month with a 12-page issue containing a major article and 3-8 smaller articles.

Since June 2010 the *Geneesmiddelenbulletin* is printed in full colour and in September 2010 a new website was opened. The bulletin is working on the possibility to put important contributions of readers in some way on the website, starting from January 2011.

Geneesmiddelenbulletin's new address:

Domus Medica
(Editorial office)
Geneesmiddelenbulletin
Mercatorlaan 1200
3528 BL Utrecht
The Netherlands
Tel nr. 0031-(0)30-2823360 or
06538 06548

New e-mail address: gebu@fed.knmg.nl
or d.bijl@fed.knmg.nl

Website:
www.geneesmiddelenbulletin.nl

NZ An "Evidence Alley" as an antidote to commercial sponsorship



In October 2009, taking the issue straight to the battlefield of a national psychiatrists' conference with its unfortunate history of commercial sponsorship, our colleague David Menkes, from *Healthy Skepticism*, engaged in an original initiative. He devised an antidote called "Evidence Alley" to highlight the availability of evidence-based materials and tools to support clinical decision making. It was deliberately designed to counterbalance the commercial exhibits present at the meeting.

Contact: David Menkes Hamilton
(David.Menkes@waikatodhb.health.nz)

SPAIN Fundación Institut Català de Farmacologia: 25 years



In 2010, the Fundación Institut Català de Farmacologia (Catalan Institute of Pharmacology) (FICF), which publishes the ISDB bulletin *Butlletí Groc*, celebrates 25 years of existence.

Summary of the main achievements of the *Fundación Institut Català de Farmacologia* by its Director, Joan-Ramon Laporte:

"Since its foundation, ICF, which became Fundación ICF in 1998, has significantly contributed to research and training in clinical pharmacology and to independent information on medicines and therapeutics.

- We have published more than 1,000 scientific articles, we have trained 65 specialists in Clinical Pharmacology (...). Almost 140 researchers from 17 countries have also been trained through our Master in Pharmacoepidemiology.

- Butlletí Groc became a reference of independent medicines information. We have also promoted the publication of problem-oriented prescribing guides, of which the first was Índex Farmacològic. Our web offers several medicines information systems; it receives half a million visits per year and more than one million pages are downloaded from it.

- We have contributed to the inception and the development of the Spanish System of Pharmacovigilance, the Spanish Society of Clinical Pharmacology, the European Association for Clinical Pharmacology & Therapeutics and the European and the Latin American Drug Utilization Research Groups (DURG). (...)

FICF's development has been possible thanks to the efforts of dozens of professionals and to the support of various institutions (...)."

Contact: Joan-Ramon Laporte
(jrl@icf.uab.es)

SPAIN DTB Navarra: Drug Assessment Reports (DAR) available in English

Since January 2007, the *Drugs and Therapeutics Bulletin* from the region of Navarra is available in English. Since January 2010, the *DTB Navarra's* Drug Assessment Reports (DAR) are also available in English. Both publications are free.

Reminder: You can subscribe and receive an email alert including direct links to the latest bulletin and/or DAR issues published at: www.dtb.navarra.es

For Spanish-speaking countries there is another web site with more information at www.bit.navarra.es.

Please note that the service of sending alerts to your cell phone is only available for employees of the Navarra Regional Health Service in Spain.

Contact: Juan Erviti (juan.erviti.lopez@cfn Navarra.es)

DTB Navarra's editor training at Therapeutics Initiative

In June 2010, Juan Erviti had the opportunity to visit the Therapeutics Initiative team in Vancouver (Canada), and to learn from their expertise. He was able to attend the regular meetings of the Therapeutics Letter, Drug Assessment, Education and Pharmacoepidemiology Working Groups. He had unrestricted access to any information or meeting that he founded to be of interest and of value to his training program.

This visit and experience has resulted in a collaboration between the *Therapeutics Letter* and the *Drug and Therapeutics Bulletin of Navarra* (Spain), beginning with the co-publication of a Navarra article as a *Therapeutics Letter*. They are also exploring the possibility of working together on a pharmacoepidemiology research study and setting up a satellite Cochrane group of Vancouver's Cochrane Hypertension Group in Spain.

Drafting this news for the ISDB Newsletter, Juan wishes to express its deep and sincere gratitude to all the Therapeutics Initiative members for their hospitality. Juan also wishes to encourage all ISDB members to share their expertise in order to improve the quality of our bulletins.

Contact: Juan Erviti
(juan.erviti.lopez@cfn Navarra.es)

USA Peter Lurie (Public citizens) moved to the FDA

In December 2009, Peter Lurie, from Public citizens, the organisation publishing the ISDB bulletin *worst pills best pills*, was hired as senior staff member at the US Food and Drug Administration (FDA). Peter joined the office of policy to develop strategies facilitating medical product availability. Good luck Peter!

New details:
Mail: peter.lurie@fda.hhs.gov (work)

Phone: 301-796-7527 (work)

Work address:

Food and Drug Administration
Office of the Commissioner
10903 New Hampshire Ave.
Building 1, Room 2320
Silver Spring, MD 20993



We welcome suggestions and contributions to this section where we reprint references of articles of interest from ISDB Bulletins.

Do not hesitate either to proactively signal the articles of interest for other members you publish in your bulletins via the ISDB webforum: <http://www.isdbweb.org/users/login>. Thanks a lot!



@_Contacts: Nuria Homedes (nhomedes@utep.edu), Ciprian Jauca (jauca@ti.ubc.ca), Florence Vandeveld (fvandeveld@prescrire.org).

Web 2.0

• **"Pharmaceutical marketing and the internet"** *Australian Prescriber* 2009 ; 32 (1): 2-4.

Pharmaceutical companies are capitalising on the advent of the internet and the development of new media forms to promote their products. Electronic detailing, interactive websites, email prompts and viral marketing campaigns using social networking sites such as YouTube, MySpace and Facebook are among the tools being used. Such campaigns are targeting both health professionals and the general public. The internet is helping to globalise and to change the nature of pharmaceutical marketing, and thus raises some new challenges for regulators.

Full text (with a glossary to explain words such as "blog", "consumer opinion leaders", etc.) freely available at: www.australianprescriber.com/magazine/32/1/2/4/

• **"Il web 2.0: dalla partecipazione alla in-formazione"** *Ricerca & Pratica* 2007; 23 : 266-269.

Full text freely available at: www.ricercaepatica.it/allegati/00307_2007_06/fulltext/4webwatch.pdf

• US FDA guidelines on social media are expected for 2011. To be followed on.

Influenza "pandemic"

• **"▼ Tamiflu – the wrong message?"** *DTB* 2009 ; 47 (9) : 97.

Full text available online (for subscribers) at: <http://dtb.bmj.com/content/47/9/97.extract>

Contact: Helen Barnett (helen@helen-barnett.co.uk; HBarnett@bmjgroup.com)

• **"Primo bilancio sulla pandemia A(H1N1): un resoconto provvisorio di quanto è successo in Italia"** *Dialogo sui Farmaci* 2009 (6): 258

A provisional evaluation confirms that the "pandemic" flu virulence proved to be similar to that of the seasonal flu. A very limited use of the vaccine was made in Italy. Many factors contributed to the fact that the population appeared to not trust the new vaccine.

The real benefits of antiviral drugs are still controversial. A critical assessment of data, information and decisional pathways is needed in order to improve our knowledge and its communication to citizens.

Full text freely available at: www.dialogosuifarmaci.it/documents/258-259%20Politica%20sanitaria_indd%281%29.pdf

• **"In the face of swine flu, common sense and science"** *Healthy Skepticism International News* 2009 (October).

Full Newsletter freely available at: www.healthyskepticism.org/global/news/int/hsin2009-10

• Collignon P **"H1N1 immunisation: too much too soon?"** *Australian Prescriber* 2010; 33 (2) : 30-31.

Full text freely available at: www.australianprescriber.com/magazine/33/2/30/1/

• **"Media in a pandemic"** *BODHI* 2009 (July-August): 49.

• **«Die gesponserte Pandemie»** *arzneitelegramm* 2010; 41 (6) : 59-60.

Generics & biosimilars

• Bogaert M, Chevalier P **"Équivalence clinique des génériques: personne à convaincre"** *Minerva* 2009 ; 8 (5) : 53.

• **"Facts and Myths about Generic Drugs"** *Wost Pills, Best Pills* 2009 (September): 6-8.

Common myths, often spread via the brand name drug companies who lose as a result of competition from lower-priced generic drugs, are discussed and rebutted in this article.

Full text freely available at: www.worstpills.org/public/page.cfm?op_id=47

Reminder: People living in developing countries qualify for a free subscription: more at: www.worstpills.org/http_IPCountryCheck.cfm

• **"La revolució dels medicaments biotecnològics"** *e-farma* 2009 (December); (09) : 1-13.

For this thematic issue of *e-farma* on biosimilars, our colleague Cristina Ibanez Collado from *Butlletí e-farma de la Regió Sanitària Barcelona* used the ISDBweb forum to gather data about the use of biosimilars over the world. This issue was to clarify some aspects that clinicians or hospitals managers do not know about biosimilar drugs, making them reticent to consider their prescription. Just as generics, biosimilars are useful tools to improve efficiency in drug management, with sig-

nificant differences in drug prices.

Full text available at: www10.gencat.cat/catsalut/rsb/farmacia/efarma/efarma_09.pdf

Contact: Cristina Ibáñez Collado (cibanezc@catsalut.cat)

Drug Regulatory Agencies

• **"Legal obligations for transparency at the European Medicines Agency: Prescrire's assessment over four years"** *Prescrire International* 2009 ; 103 : 228.

Findings of the analysis of 80 requests sent Prescrire and of the answers received by the European Medicines Agency.

Full text freely available at: <http://english.prescrire.org/bin/m2/?w=transparency&mid=34073&f=3>

• **"EMA-FDA: due Agenzie a confronto"** *Dialogo sui Farmaci* 2009 ; (2) : 58-61.

EMA and FDA share a common responsibility in the assessment of drugs before approval and in the identification and management of postmarketing critical issues.

The dossier is intended to highlight differences in regulatory actions and in the transparency and completeness of data made available to health operators.

Full text freely accessible online at: www.lascienzainrete.it/files/Dsf_2_09_DossierEmaFda.pdf

• Lexchin J and O'Donovan O **"Prohibiting or 'managing' conflicts of interest (COI)? A review of policies and procedures in three European medicines regulation agencies"** *Social Science & Medicine* 2010 (Mar) ; 70 (5) : 648-51.

Review of conflict of interest policies in three European medicines regulatory agencies: the European Medicines Agency, the Irish Agency, and the UK Agency.

The authors conclude that drug regulatory agencies «presuppose and promote the ideas that COIs cannot and need not be eliminated as the risk of bias can be managed» and add that "Given that much available evidence implies that commercial interests bias regulatory science, we advocate an alternative normative approach based on the precautionary principle».

Contact: Joel Lexchin (Therapeutics Initiatives) (joel.lexchin@utoronto.ca)

Ongoing campaigns

In this section, we report on initiatives taken to support regular long term actions (i.e. transparency, lobbying in Europe) or on regulatory challenges ISDB has to face.

EUROPE/PATIENT-‘INFORMATION’

Towards direct-to-consumer advertising of prescription drugs in Europe? A critical moment



Since the start of this decade, pharmaceutical companies have been lobbying hard for the ban on direct-to-consumer advertising (DTCA) of prescription drugs to be lifted. In the face of stifling innovation, patients are now the target of marketers' efforts to protect the volume of drug sales and foster future growth.

Despite the European Parliament's overwhelming rejection (by 494 votes to 42) of the proposal to lift the ban on DTCA of prescription drugs in 2002, pharmaceutical companies, some press groups and the European Commission have continued to push for this ban to be overturned. Despite our strong mobilisation (read in box page 17), the Commissioner Dalli did not withdraw the controversial proposals. We therefore had to prepare many amendments to improve the proposals (30 amendments to the Directive were prepared and 20 to the Regulation).

End of September 2010, MEPs will be voting on the highly controversial patient «information» proposals (a Directive and a Regulation) (vote in the Environment, Public Health and Food Safety Committee (ENVI)).

On July 13 2010, in a joint briefing paper, the *Medicines in Europe Forum*, *Health Action International (HAI) Europe* and the «DTCA working group» on behalf of ISDB urge Members of European Parliament (MEPs) to vote for amendments aimed at enhancing patients' access to non-promotional, independent and comparative information. Of particular importance are those amendments boosting the transparency of European and national Drug Regulatory Agencies.

We also urged MEPs to uphold the strict ban on direct-to-consumer advertising. For example, pharmaceutical companies must not be allowed to publicly disseminate «information» derived from official information, while selec-

tively highlighting the benefits of the drugs and glossing over potential adverse drug reactions. Experience has shown how skilfully advertisers can exploit this sort of loophole.

Read the full text of the press release on ISDB website at: www.isdb-web.org/documents/uploads/press/En_ENVI_PRInfo_July2010_Final.pdf

More on this topic:

- Our AIM, ESIP, HAI, ISDB and MiEF joint analysis "**Legal proposals on «information» to patients by pharmaceutical companies: a threat to public health**" (March 2009) www.prescrire.org/docus/LegalProposalsInfoPatient_JointPaper_March2009.pdf

This Joint Briefing Paper argues that the European Commission's proposals represent additional bureaucracy and increased cost, while putting patients at risk. These proposals need to be withdrawn.

- Buko-Pharma's Special issue of *Pharma-Brief*: "**Schöne neue Pharmawelt: Arzneimittelwerbung und Desinformation in Nord und Süd**" (in English "Nice new pharmaworld: medicines' advertising and disinformation in North and South") *Pharma-Brief Spezial* N° 1 2010 Freely available (in German only) at: www.bukopharma.de/uploads/file/Pharma-Brief/2010_01_spezial.pdf

EUROPE/PHARMACOVIGILANCE

Pharmacovigilance: vote on the improved European Commission's proposals at the end of September 2010

In December 2008, the European Commission published its proposed Directive and Regulation concerning pharmacovigilance. Despite the recent public

health disasters due to adverse drug effects, many of the proposed measures would have weakened the European pharmacovigilance system, instead of strengthening it extension of premature marketing authorisations; end to the requirement that pharmacovigilance activities be publicly funded; strengthening of pharmaceutical companies' stranglehold on the interpretation and also the gathering of data, which could threaten the member states' public pharmacovigilance systems with extinction; organising the "dilution of data", centralised at the European level in an unusable «mega-database», etc).

Thanks to the ISDB "DTCA working group" mobilisation, the European Commission's proposals were improved. Many amendments that we prepared were adopted during the 1st reading at the European Parliament: patient reporting to Drug Regulatory Agencies and not to pharmaceutical companies, strengthened authority for the European pharmacovigilance Committee, more transparency.

The rapporteur for the European Parliament, Mrs Mc Avan (S&D, UK), and the Spanish Presidency for the Council, agreed on a text that will be voted in plenary session on 22 September 2010 by the European Parliament. If the text is adopted, the legislation should come into force in 2011.

More info:

Our HAI Europe, ISDB, MiEF joint analysis "**Pharmacovigilance in Europe: the European Commission's proposals endanger the population**" (October 2009) is available at: www.prescrire.org/docus/En_PharmacovigBriefingNoteOct2009.pdf

In this joint analysis, we examine the European Commission proposals and make 15 concrete recommendations for improvement.



Ongoing campaigns

EUROPE

'Pharmaceutical package' - List of lobbying actions undertaken

2009 and 2010 were busy in terms of lobbying about patient-"information" and pharmacovigilance proposals, both part of the 'pharmaceutical package': draft analysis, briefing papers, amendments, voting lists, press releases; organisation of 2 events in the European Parliament; etc.

The main actions undertaken since June 2009 are presented below (the more recent first).

Note: The links sometimes refer to texts made available online on *Prescrire's* website because some texts still need to be transferred from the "old" ISDB website to the "new" ISDB website.

- **"Towards direct-to-consumer advertising of prescription drugs in Europe? Upholding patients' rights to reliable information"** (July 2010)

Briefing paper urging MEPs to vote for amendments aimed at enhancing patients' access to non-promotional, independent and comparative information, and to uphold the strict ban on direct-to-consumer advertising.

www.isdbweb.org/documents/uploads/capagne/En_ENVI_Memo_July2010_Final.pdf

- **"Direct-to-consumer communication by pharmaceutical companies? Europeans deserve better"** (March 2010)

Joint press release by 29 organisations asking for the withdrawal of the current Commission proposals, which do not meet the needs of citizens for relevant, independent and comparative health information tailored to users.

www.prescrire.org/docus/PressRelease-Info_20100315.pdf

- Public expert meeting at the European Parliament **"Medicines in Europe - managing risks: A closer look at the legislative proposals on pharmacovigilance"** (January 2010)

On January 27 2010, ISDB co-organised a public expert meeting at the European Parliament hosted by the European Parliament rapporteurs Linda Mc Avam (S&D) and Michèle Rivasi (Greens).

The following presentations were made:

- "Medicines' Adverse Reactions are a public health issue: a proactive approach is needed" by Prof. Joan-Ramon Laporte, Catalan Institute of Pharmacology (ICF), Spain

- "How to deal with adverse drug reactions reports? The role of National and

regional pharmacovigilance centres" by Dr. Thomas Stammschulte, German Medical Association (Arzneimittelkommission der deutschen Ärzteschaft, akdä), Germany

- "The European Commission's Pharmacovigilance proposals: more than a technical issue" by Dr. Florence Vandeveld, Medicines in Europe Forum

- "Direct patient reporting: what works and why it matters. Findings of an international survey" by Dr. Andrew Herxheimer, UK Cochrane Collaboration, United-Kingdom

- "Access to pharmacovigilance information - Patients and consumers' demands" by Dr. Martine Van Hecke, Belgian Consumers' Organisation Test-Achats, and Ilaria Passarani, European Consumers' Organisation BEUC Speakers' presentation and press release available at: www.aim-mutual.org/?page=17&id=201

- **"European Commission places medicines under the DG-SANCO's competence: an opportunity to put public health first"** (December 2009)

Joint ISDB and MiEF press release welcoming the decision of the President of the European Commission to transfer the management of pharmaceuticals and medical devices policies from the Directorate General-Enterprise (DG-E) to the DG-SANCO (Health and Consumer Policy)

www.prescrire.org/docus/Congrats_switchFinal.pdf

- Public expert meeting at the European Parliament **"Relevant health information: making the right choice for Europe!"** (December 2009)

On 2 December 2010, ISDB co-organised a public expert meeting at the European Parliament hosted and chaired by

MEP Dr. Thomas Ulmer (Germany, EPP) and MEP Carl Schlyter (Sweden, Greens).

Following presentations were made:
- "Direct to Consumer "Information" by the pharmaceutical industry - a déjà vu?" by Dr Barbara Mintzes, Assistant Professor at University of British Columbia (Canada)

- "What is the added value of the directive on information to the general public on medicinal products subject to medical prescription?"

Responses from: Ilaria Passarani, Head of Health Department at European Consumers' Organisation (BEUC); Jörg Schaaber, President of the International Society of Drug Bulletins (ISDB)

- "Access to information"

- Patients' and citizens' demands Interventions from: Cédric Diat, from the Association François Aupetit (Crohn's disease) (AFA); Anne-Sophie Parent, AGE - European Older People's Platform Speakers' presentation and press release available at: <http://www.aim-mutual.org/index.php?page=21&id=200>

- **"Future Commission: need for change in health goods governance"** (October 2009)

In a joint open letter to European Commission President José Manuel Barroso, the MiEF and the ISDB argue that EU pharmaceutical and medical device policies and regulations should be under the competence of Health and Consumer protection's Commissioners.

www.prescrire.org/docus/200910_LetterBarrosoDGE_Final.pdf

TRANSPARENCY

European Medicines Agency (EMA) under scrutiny



In 2009-2010, ISDB put pressure on the European Medicines Agency (EMA) at several occasions.

Answers to public consultations. ISDB answered to EMA's public consultations on its draft transparency policy, found to be very disappointing, and on its «roadmap to 2015», which failed to address the independence issue.

More:

• **“EMA transparency policy falls short: a weak and irresponsible project”** (September 2009)

Joint HAI Europe, ISDB and MiEF answer to EMA's public consultation calling for EMA's full accountability to the public. Real transparency is an indispensable prerequisite to restore EU citizens' confidence in EMA's decisions.

Press release:

www.isdbweb.org/documents/uploads/sept2009%20EMA%20transparencypdf

Detailed answer available at:

www.haiweb.org/24092009/24Sep2009JointResponseEMEAtransparencypdf

• **“The European Medicines Agency Road Map to 2015: Independence should be the priority”** (April 2010)

Joint HAI Europe, ISDB and MiEF answer to EMA's public consultation denouncing a number of practices that create conflicts of interest, among them:

- over 80% direct funding by pharmaceutical companies (fees);

- the generalisation of “scientific advices”, advices provided to pharmaceutical companies by the EMA with the payment of fees, presented as a mechanism to reach agreement on how to prepare and submit a successful market authorisation dossier;

- lack of transparency.

The Agency's financial and intellectual independence from pharmaceutical companies should be the priority if the EMA is to improve its accountability to citizens (read in box below).

Encouragements to strengthen EMA's conflict of interest policy. On June 18th of 2010, following the release of a report by Corporate Europe Obser-

Concrete proposals for the EMA's roadmap to 2015

(extracts from ISDB's joint answer)

In its draft roadmap to 2015, the EMA details plans to strengthen its fee-for-service relationship with pharmaceutical companies, which represent a threat to its independence.

To be able to carry out its public health tasks, the Agency needs to:

- **be weaned off a fee-for-service relationship with pharmaceutical companies through public funding from the European Union;**
 - **reconsider its proposal to give systematic scientific advice** that places the Agency in an untenable position in terms of conflict of interest;
 - **concentrate on evidence** (scientific data) from clinical studies that have been designed to meet health needs, and **assess the risk-benefit balance of medicinal products on a comparative basis (therapeutic advance);**
 - improve and **enforce its transparency requirements to effectively prevent conflicts of interest;**
 - encourage the **interaction with independent civil society representatives;**
 - **prevent “conditional” or “accelerated” marketing authorisations from becoming the rule** rather than the exception, if no genuine unmet medical need is at stake, so as to prevent unnecessary exposure to avoidable harm;
 - coordinate the activities from its various committees, coordination groups and working parties, while **guaranteeing the separation of powers among committees that approve medicinal products from the pharmacovigilance committee** (currently, pharmacovigilance decisions are often delayed, the most recent example being the case of Avandia® (rosiglitazone): having licensed the medicine in the first place, licensing committees have difficulties in overturning their original decision).
- Among the working areas in its work plan to 2015, **the EMA should also include a specific chapter on transparency.** As a public supranational regulatory body in the field of medicines, and bearing in mind the major impact its decisions have on public health, EMA must be accountable to the general public. (...)
- The EMA should also include another important aspect in its work plan to 2015: medical devices' evaluation.**

Detailed answer:

www.isdbweb.org/documents/uploads/press/JointAns_EMAFiveYearPlan2010.pdf

vatory (CEO), which revealed that the EMA had failed to implement its policy on conflict of interest at the management board level, the ISDB and the MiEF issued an open letter to the EMA's Executive Director. In that letter, we highlighted how important and necessary it is for the EMA to implement its internal rules on conflict of interest, and to strengthen them.

In fact, the two representatives of patient groups that sit on the EMA Management Board are members of organisations that are heavily funded by pharmaceutical companies, namely the European Federation of Neurological Associations (EFNA) and the European Patients Forum (EPF).

Then, on 9 July 2010, ISDB and MiEF sent an open letter to Commissioner Dalli with copy to Jo Leinen, President of the ENVI Committee of the European

Parliament, following EMA's spokesperson answer to the press (BMJ, APM News) who mentioned “*that the two representatives still sit on the board and could be removed only by the European Commission, which appointed them*”. We asked them to address this problem effectively.

More: Full texts of the letters available on ISDB website :

• Open letter to EMA's Executive Director **«EMA's policy on conflict of interest: improvements needed»** (June 2010)

www.isdbweb.org/documents/uploads/campagne/EMA_COI_Final.pdf

• Open letter to European Commissioner for Health and Consumer Policy **«Action is needed to enforce the European Medicine Agency's policy on conflict of interest»** (July 2010)

www.isdbweb.org/documents/uploads/press/EMA_ManagBoard_LetterCommissionar_Final.pdf

MORE ON TRANSPARENCY

“Handling of the influenza A/H1N1 «pandemic»: European citizens want to know more” (April 2010)

ISDB supported the initiative by more than 200 Members of European Parliament who have signed a call for a parliamentary committee to examine how the influenza A pandemic was handled by the European Union and Community institutions. Unfortunately, the Presidents of the Political groups rejected this initiative in May 2010. **More info:** www.isdbweb.org/documents/uploads/vecchi/press_release/press%2019%20aprile%202010.pdf

INTERNATIONAL

ICH: an exclusive club



During the 2008 General Assembly, an ISDB working group decided to tackle the “International Conference on Harmonisation” guidelines. In fact, ICH guidelines often do not serve public health but big pharma’s commercial interests, and have a major impact on the development of Drug Regulatory Agencies’ guidelines. The 1st step to carry out that long term work is to know better the functioning of the ICH. In August 2010, Prescrire Editorial Staff published an analysis on the ICH in Prescrire International: “ICH: an exclusive club of drug regulatory agencies and drug companies imposing its rules on the rest of the world”.

In short:

- Under the pretext of harmonising regulatory requirements for marketing authorisation of new drugs, the drug regulatory agencies of the world’s wealthiest countries and three pharmaceutical industry trade associations, joined together since 1990 in the ICH, are promoting their own interests by imposing their criteria for evaluating drugs on the whole world.
- The toxicity standards advocated by ICH sometimes promote faster, cheaper drug development over patient protection.
- The drug quality standards advocated by ICH sometimes increase manufacturing costs without providing any public health benefit.

Full text available:

In French (*Rev Prescrire* 2010; **30** (317): 222-225);

In English (*Prescrire International* 2010; **19** (108): 183-186).

In this section, we reprint extracts of papers that seem interesting for strategic reflection. Health personal data are already big business...

Pharma needs to work with non-traditional partners to survive

Reprint of extracts from Kevin Grogan’s article “Pharma needs to work with non-traditional partners to survive” PharmaTimes (11 February 2010).

“Pharmaceutical companies should be working with IT companies, mobile phone firms and other non-traditional healthcare firms if they are to successfully make the switch from being product-focused to customer-centric, claims a new report from Ernst & Young.

The report, entitled *Progressions, Pharma 3.0*, claims that IT companies, large retailers, and telecommunication firms “are strategically poised to capitalise on rapid changes” taking place in health care and pharma is “increasingly looking for innovative ways to collaborate with these new players to reach and improve outcomes for patients”. (...)

The Progressions report describes the shift from the industry’s “long-standing vertically integrated blockbuster-driven model”, dubbed Pharma 1.0, to today’s Pharma 2.0 business model. The latter has seen companies pursue more targeted therapies, broadening their portfolio of products and establish “more independent and flexible R&D units”, due in part to partnerships with biotechs and universities. They are also outsourcing many non-core functions.

However the report claims these efforts may be overtaken by a Pharma 3.0 «ecosystem» “comprised of established industry members, non-traditional companies and an increasingly informed data-empowered consumer” [i.e. e-health, mobile-health and new medical technology firms]. It believes that pharmaceutical companies “remain largely on the sidelines of this revolution, hampered by a regulatory framework governing patient interactions which has been slow to evolve”.

The E&Y study also notes that as pharmaceutical companies expand into emerging markets, “they are increasingly considering alliances with non-traditional partners – from micro-lenders who could bridge the affordability gap to food companies with existing distribution and infrastructure networks to help manage supply chains”.

Google makes no-cost online medical records service available to public

Reprint of extracts from a 21 May 2008 text by the Advisory Board Company and Kaiser Family Foundation which full version is available at <http://www.medicalnewstoday.com/articles/108183.php>.

In May 2008, “Google opened public access to Google Health, an online personal health record service, after about 18 months of development (...).

Google Health allows users to store online their medical records and laboratory test results, as well as information about allergies, vaccinations and prescriptions. Users will have the ability to enter some information, as well as have data pulled from clinical records. In addition, users can decide whether to share information in their PHRs with health care providers. Google Health also allows users to search for medical information and use other online health care tools. (...). As part of Google Health, Google has partnered with hospitals, clinics, pharmacies and lab test companies (...).

The health care industry considers electronic health records «crucial to reducing the cost of providing health care and eliminating medical errors» (...).

© 2008 Advisory Board Company and Kaiser Family Foundation. All rights reserved text

Full version at: <http://www.medicalnewstoday.com/articles/108183.php>.