



ISDB Declaration on therapeutic advance in the use of medicines

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ISDB Declaration on therapeutic advance in the use of medicines

The International Society of Drug Bulletins (ISDB) promotes the publication of good quality independent information about drugs and therapeutics to health professionals and the public in all countries.

ISDB convened a Working Group to deliberate on the issue of what constitutes a genuine Therapeutic Advance as considered from the viewpoint of patients and the Society. The Working Group met in Paris, France on 15-16 November 2001, and on behalf of the Society, made public the following Declaration.

I Purpose and context

The practices of the pharmaceutical industry and regulators that blur the distinction between genuine therapeutic advance and mere innovation were the driving force behind this ISDB Declaration.

'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. A number of ISDB bulletins critically appraise the evidence on all newly marketed drugs, and publish their conclusions on whether, and if so to what extent, these new interventions extend the available options (drug and non-drug). 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.

* We refer to medicinal products (including traditional medicines), their new formulations or indications, and we consider use for treatment or prophylaxis.

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. Policy makers, organisations paying for medicines and regulators should act in the best interest of the public and not accept industry's claims that an innovation is necessarily a therapeutic advance.

II Identifying therapeutic advance

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 interrelated: they must be assessed concurrently and regularly re-assessed as new evidence emerges. Indeed, continuous evaluation of old substances is essential so that drugs which are no longer valuable can be eliminated, and new or better ways of using already approved drugs can be identified. A therapeutic advance should not be seen in isolation: cost and quality must also be considered (see Annex II).

1 - Efficacy

Efficacy describes how far a drug achieves its intended effect (e.g. pain relief, contraception). When considered as a component of therapeutic advance, efficacy should be assessed in ordinary clinical practice: this is often called 'effectiveness' to distinguish this from 'efficacy' in clinical trials.

Controlled trials are accepted as the reference method for testing drug efficacy. Their design and performance however are often inadequate, and lead to unreliable or irrelevant conclusions. The following points raise the greatest concerns:

- a) studies with wrong comparators, which on the one hand expose patients to an inadequate level of care, and on the other are likely to produce results biased in favour of the new drug. Placebo-controlled trials, when a treatment with favourable risk/benefit ratio does exist, are extreme and unacceptable cases in this category;
- b) studies using outcome measures that are unconvincing, clinically irrelevant, or methodologically weak, or exposed to the risk of misrepresentation of statistical significance (e.g. surrogate and not predefined endpoints, scales and measures that are not clinically validated in the specific clinical condition or population, combined endpoints of unequal relevance);
- c) studies conducted in populations and/or contexts that do not represent those where the new intervention would be applied;
- d) especially controversial and worrying are non-inferiority or equivalence trials, which represent a large proportion of industry-sponsored clinical trials. The performance of such trials, often designed for drug registration, poses clear ethical problems:
 - patients included in the trials are misled to expect better care;
 - research is not centred on real needs but is performed as part of the company's marketing plans.

2 - Safety

New drugs are generally approved on the basis of efficacy studies; safety outcomes being considered as a secondary issue.

Safety concerns frequent as well as rare and serious adverse effects. At the time of first approval one must be sceptical of an apparently acceptable safety profile of a new drug, as rare adverse effects can be recognised only when a large population has been exposed to the drug.

Preclinical toxicity studies are rarely published or otherwise accessible. Animal studies may have been determined, but often no one knows. All these data are needed for independent safety evaluation.

Many regulatory bodies and pharmacovigilance organisations publish little or no safety information to professionals and the public.

3 - Convenience: helping patients and professionals to use drugs well

Convenience includes ease of use of medications and related devices, as well as reliability of packaging. An improvement in convenience, resulting in greater adherence to a drug regimen, can in itself be an advance. One should remain sceptical about claims of greater convenience for drug interventions that are not accompanied by the relevant data.

Adherence depends on the convenience of the administration schedule for patients and health professionals, treatment duration, storage conditions (especially in warmer climates), together with the quality and safety of packaging, including patient information and ease of handling the packaging.

But easier use is clearly bad if it makes harm more likely.

Obstacles to the emergence of therapeutic advance

All parties in the field of research and development of new drug interventions share responsibility for shaping therapeutic advances.

1 - Policy makers and drug regulators

Lack of transparency and democratic control of regulatory activities, and the fact that marketing application fees represent often more than 50% of regulatory agencies' budgets, can weaken consideration of public needs. As service providers, national and international regulatory agencies compete among themselves for capturing application fees. This may lead some agencies to be less stringent *vis-à-vis* industry. Moreover, standards of regulatory work and legal frameworks vary internationally. Where a mutual-recognition arrangement exists, the pharmaceutical company may withdraw an application from an agency that detects a problem, and try again with a more lax agency.

It is common to measure a regulatory agency's effectiveness in terms of the number and rapidity of marketing authorisations granted, instead of the quality of decisions. This quality is clearly inadequate when regulators fail to request postmarketing studies for a new intervention supported by too little evidence on efficacy and safety at the time of approval. Such behaviour is unacceptable, even for drugs that target life-threatening conditions.

Industry pressure on regulators to speed up drug approvals in response to harmonisation requirements obstructs the recognition of real therapeutic advances.

The quality and relevance of clinical data required for regulatory submission are inappropriate. Policy makers have watered down the definition of 'innovation'. In Europe the requirement of 'significant therapeutic interest' in Council directive 87/22/EEC of 1986 has not survived in Council Regulation 2309/93 of 1993.

2 - Health-care organisations

The proportion of drug research and development funded by public authorities, public organisations, health-care providers and health insurance systems has decreased over the years.

This means there is inadequate funding of trials unattractive to industry: non-drug treatments (surgery, physiotherapy, complementary and alternative medicine); multi-drug comparisons; comparisons with drugs that are no longer patented; trials of methods of managing chronic or terminal conditions that are commercially unattractive but impose a significant health burden; and trials involving orphan drugs and neglected diseases.

3 - Investigators

Because of the lack of substantial public funding, and of the overwhelming (and economically attractive) pressure of industry-sponsored projects, the academic world no longer has much influence in defining research priorities in the investigation of therapeutic advances.

Short-term, publication-oriented studies are preferred to the evaluation of the therapeutic implications of the many promising new findings of pilot clinical research.

Clinicians looking after the majority of chronic and complex patients' needs (mostly unattractive for the industry) only occasionally have a role in the production of new knowledge on therapeutic and preventive (not only drug-based) strategies.

Health agencies do not recognise that funds for investigating the value of claimed innovations should be considered a productive investment for the routine delivery of care.

With important but marginal exceptions, patients are still playing a very limited role in promoting, actively conducting or participating in, evaluative research on topics where drug intervention competes with non-drug strategies of care.

4 - The pharmaceutical industry

Since the pharmaceutical industry currently dominates the innovation process, this is mainly drug-centred and driven by marketing strategies instead of the needs of patients. In addition, a great part of industry research is aimed at capturing market shares for conditions already well treated. The *de facto* monopoly of research has led pharmaceutical companies to claim that the financial sponsorship of clinical investigations entitles them to full control and ownership of the data. The dangers of direct or indirect manipulation of information to be used in submissions for drug approval must be emphasised. This situation threatens the relevance and the independence of evidence-based medicine: the assessment of the overall efficacy and safety profile of drugs for use in the development of effectiveness-oriented guidelines is thus forced to rely on biased information.

IV Obstacles to recognition of therapeutic advances by health professionals and the public

Honest information on new drug interventions depends on the balance of power between the parties involved: the public, health professionals and their information providers, health policy makers and regulatory authorities, organisations paying for medicines, and the pharmaceutical industry.

- a) Information on new drug interventions comes mainly from the pharmaceutical industry that invests heavily in promoting novelties. Industry's propaganda aimed at blurring the distinction between commercial introduction of a new drug intervention, technological innovation and therapeutic advance leads professionals and the public to succumb to marketing ploys and exaggerated claims by medical representatives and advertisements. By playing down or withholding trial data that do not support their marketing strategy, and by frequently failing to carry out postmarketing studies requested by regulators, not only

does the pharmaceutical industry mislead professionals and the public, but it also prevents them from identifying real advances promptly. Such behaviour does not comply with the 2000 Declaration of Helsinki that stipulates in its 16th clause: "...*The design of all studies should be publicly available.*" And in its 27th clause it says: "*Negative as well as positive results should be published or otherwise publicly available.*"

- b) The pharmaceutical industry's pressure on governments can have a huge impact. In the UK for instance, when the National Institute for Clinical Excellence (NICE) gave an unfavourable ruling on the value of zanamivir (which, unfortunately, it then reversed), the manufacturer made all sorts of threats, including the threat to re-locate its research and development facilities. Through their export-earning and tax-paying potential, the pharmaceutical industry can therefore have a significant impact on official decisions about new medicines.
- c) Regulators are excessively secretive about their decision processes, and fail to release relevant information promptly to professionals and the public; this is partly due to a restrictive interpretation of confidentiality requirements.

- d) Publication and dissemination of information on new drug interventions come up against several obstacles.

The secrecy clause that prevents investigators from publishing study results without sponsor approval is a documented obstacle to honest information and a cause of publication bias.

The dependence of many information providers, as well as continuing-medical- education bodies, on drug advertising resources obstructs honest communication.

Professional bodies are often unwilling to devote sufficient resources to producing truly independent information. Opinion leaders who accept money from industry for launching new products are also to blame.

Lay journalists and press agencies often assist industry's marketing strategy because they are given biased information and lack independence.

The *de facto* relaxation of the ban on direct-to-consumer advertising, sometimes disguised as disease awareness campaigns, provides biased information to the public.

Patient groups are increasingly a source of information about drugs and treatments. Their frequent weakness and dependence on industry funding is worrying.

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V Proposals

Preamble

The parties that define and enforce the rules of drug development and marketing are almost all in the rich countries of the North.

The problems considered so far are much worse in the poor countries of the South, which must unquestionably put the needs of patients and populations before drug and market-centred interests.

Real therapeutic advances coincide with widening inequalities because of economic and logistic inaccessibility; misleading innovations contribute to the pressure of the market on the fragile public health oriented systems.

The recent focus on the constraints of the patent system should not be considered in isolation: the concept and the policies of essential drugs should be expanded and reinforced to cover all therapeutic advances for old as well as for emerging diseases.

The potential implications of the proposals that follow would therefore have even more important consequences in the countries of the South.

1 - For identifying therapeutic advance

Efficacy

The efficacy of a new drug intervention should be assessed in terms of overall mortality where relevant, morbidity, and quality of life as assessed from the patient's perspective. Therapies for chronic conditions require long-term studies. Comparative trials assessing the superiority of an intervention are required when there is an adequately tested treatment. These requirements are consistent with the latest version of the Declaration of Helsinki (October 2000), which requires that *"The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods."* (Section C clause 29)

Safety

Improved safety compared with existing options can qualify a new intervention as a therapeutic advance provided that short-, medium- and long-term pharmacovigilance data are taken into account. All information on drug safety (including pharmacovigilance data) should be public from the date of marketing. For a new drug intervention to be accepted as a therapeutic advance on grounds of safety, several years of active pharmacovigilance are necessary.

The following are required:

- well designed pharmacovigilance studies, such as case-control studies and large cohort studies, to provide a clear picture of safety profiles, including interactions and safety in at-risk groups (such as elderly people, children, pregnant women and patients in renal failure),
- long-term, large, randomised controlled trials with overall mortality as the main endpoint for assessing safety of prophylactic interventions such as antihypertensives and lipid-lowering drugs.

Substances that require intensive monitoring should be listed internationally, with the year of local introduction. The list should be made available to professionals and the public worldwide. In each country, a priority list of drugs to be monitored should be identified, as is done in several countries. Substances on the priority list should be identified as such on the label of the medicine and in the Patient Information Leaflet.

The benefit/harm relationship of a drug intervention should be scientifically re-evaluated at least every five years.

Convenience

Before marketing, studies should be undertaken to show adequate ease of use and adherence to the dose regimen together with studies showing that patients understand and can use the accompanying information. Medicines legislation should incorporate this requirement as soon as possible.

2 - For policy makers and regulators

- a) Regulators must be reminded that they are accountable primarily to the public and not to the pharmaceutical industry, and that their responsibility to public health should take precedence over their responsibility for the welfare of industry. The European Medicines Evaluation Agency, for instance, must be made accountable to Health and Consumer Protection Directorate-General, instead of Enterprise Directorate-General of the European Commission.
- b) Policy makers should actively improve the legal framework for public health so that regulatory agencies will facilitate access to relevant information by health professionals and the public. Regulatory bodies should make available to professionals and the public a register of clinical trials submitted with applications for approved drugs. This should include all trials, completed or not, together with their protocols.
- c) Decisions by regulatory agencies should be strengthened by appointing independent representatives of the public and health professionals to key bodies in their organisation.
- d) All regulatory agencies should report annually how they have implemented their policies on the management of conflicts of interest.
- e) Regulators should publish the data from comparative evaluations so that health professionals and the public can distinguish useful drug interventions from gimmicks.
- f) When a pharmaceutical company withdraws an application from an agency that detects a problem, this should be published internationally, and explicitly declared by the company in any other application for marketing approval.
- g) Regulators should not only consider the public health implications of new drug interventions in the approval process, but should identify them explicitly in the approved product information.
- h) Regulators should improve the post marketing surveillance of new drugs.

3 - For governments and international organisations

International organisations and governments should allocate parts of health care and research budgets to large-scale trials meeting public health needs (drug and non-drug therapies). Health needs for such trials should be based on proposals coming from professionals and the public. In particular, adequate public funding is needed for trials unattractive to industry: unpatentable drugs; non drug treatment; multi-drug comparisons; research on the management of commercially unattractive chronic or terminal conditions; and orphan drugs and neglected diseases.

Public funding should be sustained over several years, and on a scale sufficient to establish a sound balance between industrial and public health research.

4 For health professionals and the public

- a) At national or regional level, health professionals and patients organisations should identify research needs for conditions and diseases requiring therapeutic advances.
- b) Patients should be involved in the design of clinical trials - specifically the choice of endpoints, outcomes (e.g. quality of life, burden of care), and of the information for participants. Communication with participants about trial progress and results should be specified in trial protocols.
- c) Health professionals should be able to compare new therapies with existing ones, so that they can reliably identify therapeutic advances. They should be trained to use the basics of evidence-based medicine (notably systematic reviews, level of evidence, relevant endpoints and outcomes) as well as handling benefit/harm and cost/benefit relationships. When offering a newly marketed treatment, health professionals should have all the information to explain its advantages and disadvantages in comparison with established treatments, so that the patient can make an informed choice, and be aware that any unexpected or unwanted effects should be reported.
- d) The use of sources of independent comparative drug information should be widely promoted. Initial and continuing medical education on medicines should be carried out independently of the pharmaceutical industry.
- e) Ethics committees should not approve a study unless it is stated in writing that the full results will be made publicly available as soon as the product is approved for marketing.
- f) Health professionals should accept their responsibility to give official bodies and the media well-informed and impartial advice, openly disclosing the limits of their knowledge.
- g) Journalists, editors and publishers should be encouraged to check their sources with impartial and informed experts, to avoid being unwitting agents of commercial campaigns related to health. This has become topical with current pressure for the relaxation of the ban on direct-to-consumer advertising.

ANNEX I

About the word consumer

The word *consumer*, instead of 'patient', is used increasingly in medical publications. In reality a consumer is 'A person who purchases goods and services for his own needs' (Collin's dictionary). The word *consumer* therefore is more than a euphemism and a soothing word for 'patient'. Indeed using the term tends to negate the role of doctors and pharmacists and the patient-professional relationship. The term *consumer* assumes the patient is independently and reliably informed, and can choose from the medicines on offer to treat any health problems: this is rarely the case.

The word *consumer* has clear commercial connotations. It puts implicit and sometimes inappropriate emphasis on the role of drug treatments, and tends to overlook non-drug options (surgery, watchful waiting, psychotherapy, etc.). Those with vested interests prefer the term *consumer* since it is consistent with the concept of direct-to-consumer advertising, e-commerce of medicines, and the industrial strategy of bypassing health professionals who are viewed as barriers to expanding drug markets.

Making the patients and the public informed and committed partners in health care is a desirable aim. But the word *consumer* should be avoided when describing the relation between patients and medicines. It should be replaced by 'the public' or 'patients'. Occasionally the word 'individuals' may be more appropriate since those taking medicines to prevent some events (e.g. pregnancy or malaria) are not 'patients'.

ANNEX II

Drug pricing

Access to therapeutic advance in developed as well as in developing countries depends on the affordability of drug interventions and on the quality of dispensing systems.

Therapeutic advances that the target population cannot afford are of little value since they cannot achieve the necessary health benefit.

The supposedly rising cost of research and development of new drugs has long been industry's excuse for increasingly high drug prices demanded by industry. But the price of a drug is less related to the cost of research and development or to therapeutic advance (witness high prices for me-too drugs), than to the rising cost of promotion, and the *laissez-faire* of policy makers and organisations paying for medicines.

National policy makers and organisations paying for medicines should ensure transparency of drug pricing and research and development costs. They should resist pressures from drug companies towards the maximum international price acceptable by rich countries. Price is a major barrier in the transfer from efficacy as assessed in clinical trials to therapeutic advance for the patients and the public.

About the International Society of Drug Bulletins (ISDB)

Background

The International Society of Drug Bulletins (ISDB) is a world wide network of bulletins and journals on drugs and therapeutics that are financially and intellectually independent of pharmaceutical industry. It was founded in 1986, with the support of the WHO Regional Office for Europe.

The rationale for the Society is that drug bulletins independent of funding from industry experience problems not faced by editors and publishers of other journals.

Membership

The main requirements for membership are editorial and financial independence, and the quality of the information published. ISDB has two categories of members: full members who meet all membership requirements as set out in the Constitution; and recognised correspondents. Recognised correspondents are institutions or individuals who do not meet all criteria for membership, but who are sympathetic to the aims of the Society.

Aims

The overall aim of ISDB is to encourage and assist the development of independent drug bulletins in all countries and to facilitate co-operation amongst them.

ISDB's priorities are:

- to help all independent drug bulletins achieve the highest professional standards,
- to support the development of new drug bulletins,
- to identify independent drug bulletins that are not part of the ISDB network and develop a relationship with them,
- to encourage members to help health professionals communicate more effectively with patients and the public,
- to work with producers of formularies and people in drug information centres,
- to campaign for drug regulatory authorities to serve public health first and foremost.

Work of the Society

ISDB holds a General Assembly every three years, which provides an excellent forum for members to meet and exchange information. In addition, this allows ISDB members to meet with other attendees, such as producers of formularies, people in drug information centres and other publishers of independent drug and therapeutic information that are not already part of the ISDB network.

To help independent drugs bulletins achieve high professional standards, ISDB organises regional workshops where people working on long established bulletins can share their experience with those starting new ones. Such meetings have been held in Algeria, Hungary, Italy, Japan, Philippines, Italy, Holland and Spain.

To support the development of new drug bulletins, ISDB members also host

visits from editors starting up new bulletins to help them gain experience. ISDB publishes newsletters which are distributed free to all members and recognised correspondents. This newsletter serves: to keep members and recognised correspondents informed of current editorial standards for the development of articles and information, to keep members and recognised correspondents informed of current issues and activities, and to facilitate communication between members.

Through its meetings, workshops and newsletters, ISDB also encourages and facilitates discussion on sources of information, organisational structure, ways that bulletins can help health professionals communicate more effectively with patients and the public, financial support for member bulletins, and any other support for bulletins faced with particular difficulties.

To address public health and drug information issues, ISDB has developed links with many relevant organisations with members being involved in various activities and campaigns. Topics of particular interest are: access to information about medicines, including access to unpublished data held by drug regulatory agencies; identification of truly innovative drugs; the impact of undue promotion by the pharmaceutical industry; resistance to direct-to-consumer advertising of prescription medicines. Other ISDB activities include the exchange of information on new drugs, adverse effects, and drug promotion and regulation.



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