DRUG INFORMATION

WORLD HEALTH ORGANIZATION
Regional Office for Europe
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TARGET 31

ENSURING QUALITY OF CARE

By the year 1990 all Member States should have built effective mechanisms for ensuring quality of patient care within their health care systems.

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DRUG INFORMATION

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ABSTRACT

Drugs can be rationally used only if health professionals and the public have up-to-date information on them. National drug bulletins are the best channel for new information on the properties and use of drugs. Experts from 17 countries of the WHO European Region met to draw up guidelines on the production of such bulletins. They gave not only general principles but also practical advice on the accomplishment of such tasks as: securing editorial independence, staffing a bulletin, determining its content, selecting articles, discussing new drugs, adverse reactions and the costs of treatment, cooperating with other bulletins, and promoting a bulletin and assessing its impact. The participants concluded by making recommendations to all parties involved – the pharmaceuticals industry, government, health professionals and other interested bodies – on how to help establish and operate national drug bulletins that promote the rational use of drugs.

Keywords

DRUG INFORMATION SERVICES – organization/admin
DRUGS – adverse effects
EUROPE

CONTENTS

INTRODUCTION

The Meeting on Drug Information was held in Madrid from 16 to 18 October 1991. It was organized by WHO and the Ministry of Health and Consumer Affairs in Spain, with assistance from the Ministry of Health, Welfare and Cultural Affairs in the Netherlands. An earlier meeting on the same topic had been held in Madrid in 1986. This meeting saw the birth of a group that named itself the International Society of Drug Bulletins (ISDB). ISDB became WHO's partner in preparing for the 1991 Meeting.

The participants at the Meeting came from 17 countries of the WHO European Region, and included the staff of government health authorities, organizations and institutes concerned with the use of drugs, and the editors and staff of drug information bulletins. The working papers and participants of the Meeting are listed in Annexes 1 and 2, respectively.

The use of drugs requires that both health professionals and the public have accurate, balanced and comprehensive information on their properties and use. National drug bulletins offer the best channel for the prompt dissemination of new knowledge about drugs and their optimal use. The purpose of the Meeting was to develop practical guidelines on the production and operation of such bulletins.

The existence of bulletins, however, did not obviate the need for regulatory authorities to be obliged to issue to health professionals comprehensive and objective information on each licensed drug. This information should be updated as required and at regular intervals.

DISCUSSION

Editorial independence

To provide objective scientific information, drug bulletins need to be editorially independent of the pharmaceuticals industry, official bodies concerned with drug regulation or the financial aspects of health services, and special interest groups such as professional associations of physicians or pharmacists. Good communication with all of these is

necessary, however, and financial and organizational independence is usually difficult to achieve.

Editorial independence is perhaps easiest to attain if a bulletin is financially self-sufficient, paid for entirely by its subscribers. In most countries, however, only a relatively small proportion of physicians and pharmacists is willing to subscribe to bulletins. This means that the information, no matter how excellent, will benefit only a small part of the population. On the other hand, subscribers who pay for a bulletin are more likely to read it than the recipients of free copies.

A bulletin may receive financial support from a health ministry, a social security organization or a professional or consumer organization. The editorial independence of such a bulletin is best assured by secure long-term arrangements for funding. In any case, the funding of a bulletin should be clear to its readers. Bulletins funded by official sources should nevertheless to be free to discuss, for example, decisions on drug regulation and reimbursement, because regulatory authorities are often unable to discuss background details that allow prescribers to understand the context of new measures. Informed discussion in bulletins and in more public media can help to improve regulatory decisions and their implementation. This will be even more important when such decisions affect a number of countries, as will be the case in the European Community.

Staffing

The staff of a bulletin should include physicians, preferably clinical pharmacologists, and pharmacists. They must work as a team because every article requires the specialized skills of each. Articles must be so clear and direct that the reader not only understands them but also uses them to improve his or her practice.

To meet the needs of readers, bulletin editors must know their habits and preoccupations, what they consider to be their priorities and their most pressing problems. Editors must also note the promotional messages aimed at their readers and help the readers to assess these objectively. In a national bulletin, articles will address general

practitioners, pharmacists and specialists, and must therefore be written in a way that all these groups can understand.

Articles written by a specialist for others in the same field are unsuitable for drug bulletins, except those intended for a specialist readership such as psychiatrists or ophthalmologists. All physicians, however, should be aware of what their patients may experience when treated by a specialist. For example, general practitioners need to know enough about anaesthetics to able to discuss their effects with patients, and to look after patients returning home after day surgery.

Content – general considerations

The articles published in bulletins must be reliable and balanced. They must compare real alternatives that the prescriber must weigh up such as the use of alternative drug or non-drug treatment, and benefits and risks or costs. This requires that drafts be critically revised by several members of the editorial team and preferably by outside commentators. These would be people whose opinion is judged to be valuable and who represent the main categories of readers and experts on the subject under discussion. In principle, this process is very similar to that of constructing a drug formulary.

Since pharmaceuticals companies know more about their drugs than anyone else, all possible relevant information should be obtained from them for the preparation of an article. In some circumstances it may be useful to send a draft article to the companies concerned to check the facts. Giving companies the chance to express their views after publication of the article, however, is often a satisfactory alternative.

The author of the first draft of a bulletin article may face certain problems. For example, the original wording may be extensively changed and the writer may get no public recognition for the work because many others contribute to it. It may therefore be helpful:

- to pay the author for the work;
- to name all contributors, including editors and commentators, in the bulletin; and
- to certify officially that the author did the work and is entitled to list it among his or her publications.

In addition, comments from readers are valuable for editors and often interest other readers. Publishing such comments when possible is therefore worth while. Often space will not permit this, however, and it may be worth while to explore the use of electronic bulletin boards. They can accommodate an unlimited number of comments that can be read by anyone interested.

It is useful to discuss in an occasional article how prescribers can best cope with promotional information and other communications from pharmaceuticals companies. The issues here include how to conduct a useful conversation with a company representative,[a] and how to evaluate advertisements and other promotional materials.

Selection of articles

The choice of topics for bulletin articles should depend on the needs of the readers. These topics include assessments of individual drugs and groups of drugs (including their benefits and risks), and the management of disease and other health problems. Readers vary greatly in their medical education; for example, a newly qualified physician and one who has been practising for 30 years will differ greatly in knowledge. Aspects of clinical pharmacology discussed in articles must be understood and usable by both. Regular exchanges of opinion and information with members of the profession, whether within or outside an editorial board, are necessary to guarantee that the contents of a bulletin are up to date and of immediate practical interest to prescribers.

Surveys of readers emphasize the need for practical advice about the use of drugs and for more general updating, also with emphasis on the practical aspects. Many doctors want prompt

[a] Getting good value from drug reps. *Drug and therapeutics bulletin*, **21**: 13 – 15 (1983).

information about new products and how they relate to existing ones. One problem is that most new products are uninspiring and negative articles about them irritate readers. A compromise must be reached, probably by making negative assessments as brief as possible and balancing them with helpful positive material, perhaps in the same issue.

Identifying problem areas through data on drug use

Drug utilization data are very useful for identifying the apparent under- and overuse of particular drugs or groups of drugs. These issues deserve discussion in a bulletin. Such a discussion can be constructive, however, only if the particular patterns of and reasons for suboptimal prescribing have already been identified. It is therefore very desirable that any drug utilization data collected be promptly made available to the editors of drug bulletins. Comparing the data on different hospitals, regions and countries can give important clues about patterns of prescribing. For such comparisons to be possible, drug utilization data must be expressed in a standard way, using, for example, the anatomical therapeutic chemical (ATC) classification[a] or internationally defined daily doses.[b] In countries in which the medicines market and prescribing patterns are changing rapidly, drug utilization studies are especially important.

Drug utilization data can also be a valuable indicator of the effectiveness of activities to educate and inform prescribers through articles in bulletins and other means. Changes in prescribing behaviour caused by such activities, however, are much harder to detect than changes in sales caused by commercial promotion. Unfortunately, sales statistics are treated as commercial secrets in most countries. The European Community is preparing a directive that will oblige wholesalers to provide regular sales statistics to the registration

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[a] *Guidelines for ATC classification*. Oslo, WHO Collaborating Centre for Drug Statistics Methodology and Nordic Council on Medicines, 1990.

[b] *Guidelines for DDD*. Oslo, WHO Collaborating Centre for Drug Statistics Methodology and Nordic Council on Medicines, 1991.

authority, but it is unclear whether these will be available to people outside the regulatory framework.

The most useful drug utilization information is market research data linked with morbidity data. As yet, however, research has paid insufficient attention to the need for morbidity data.

Sources of information on drugs and treatment

Information can be obtained from textbooks, specialized monographs, medical journals, drug bulletins, the pharmaceuticals industry, computer databases and informal sources. Computer information is available either on line or on CD-ROM systems; each has advantages and disadvantages. Personal databases are a cheap although time-consuming alternative; their information yield can be very satisfactory. They also have the important advantage of allowing the full text to be included with an evaluation.

Editors of drug bulletins should regularly scan journals such as the *Lancet*, the *British medical journal*, the *New England journal of medicine*, and if available, *Scrip*. The most important monthly journal is *Annals of internal medicine*, with its excellent new ACP (American College of Physicians) Journal Club, which summarizes and comments on therapeutic publications. The three leading journals of clinical pharmacology also contain important material. A number of national bulletins on drugs and adverse reactions, and those journals published by WHO provide very useful information. Over the last six years the amount of practical therapeutic information in general medical journals and clinical pharmacology journals has gradually decreased. Meanwhile, information in review journals, which is mostly derived from the pharmaceuticals industry, has increased.

It is notable that papers on the first one or two representatives of a new therapeutic class of drugs are very numerous and provide remarkably full and diverse information. Far fewer papers are published about later members of the same therapeutic class. The difficulty or impossibility of finding adequate information about these later drugs hinders a balanced judgement of their efficacy and safety. Pharmaceuticals companies compound the problem by treating unpublished comparative studies as commercial secrets.

The concealment of clinically important information is against the public interest. Comparative information on recently licensed drugs is regularly published in Sweden in *Information från Läkemedelsverket*, the bulletin of the Swedish Medical Products Agency. In Norway, it is proposed that such data be made available to the public. A more comprehensive approach to the problems of commercial secrecy and publication bias would be most desirable: all clinical trials could be registered at inception, with a brief statement of their aims and design and the names and addresses of the sponsors and principal investigators.

The role of electronic communication in the work of drug bulletins is still largely unexplored, but this medium offers a cheap and fast method by which countries and colleagues could obtain and exchange information bulletins. This would be particularly useful in preparing up-to-date articles on rapidly changing topics, such as the withdrawal of a drug in one country and the urgent reconsideration of its value in others. It would therefore be worth while to try out a system for electronic communication between bulletins for a year, to see what advantages it offers over telefax, which many bulletins now use.

Assessing new drugs

Much of the material that prescribers receive from drug companies promotes new drugs. It is therefore important to provide independent information on these products as early as possible after their launch. Even minor products, about which little is known, need evaluation; such information is particularly important to pharmacists, who have to advise patients about the medicines they sell. Nevertheless, many bulletins cannot deal with all new drugs because their staff and space are limited. What is said about a new drug in a bulletin must be reliable and relevant. The information should help professionals to compare the drug's effectiveness, safety, convenience and cost with those of alternative drug and non-drug treatments, and to decide whether to use it. If the drug is to be used, the professionals need to know how best to do so.

An article about a new drug should not be a more elaborate version of a data sheet and should not simply report clinical trials. It should not describe pharmacological mechanisms or hypotheses that have no clear clinical relevance, nor should it reflect the personal opinion of a particular specialist. Obtaining adequate data on a new drug may be difficult. The main sources are the manufacturer, published articles, promotional material and informal data from experts acquainted with some of the unpublished trials of the drug. Persistence and skill are needed to obtain the required information from manufacturers. Those who provide useful information can be publicly acknowledged, for example by presenting them with an award, as is done by *La revue prescrire*.[a]

An assessment of a new drug is the work of a team. It requires a thoroughly briefed clinician to write the first draft, and contributions from general practitioners and other physicians, pharmacists (in both the community and the hospital), pharmacologists and often specialists in the field concerned, as well as those familiar with the relevant experimental methods. The bulletin editor coordinates the work of this team, and must ensure that the structure, titles, conclusions and summaries are clear and correct. Articles on new drugs are best published anonymously; they are the work of a team and it is important to protect the author of the first draft from harassment or blandishments from the pharmaceuticals industry. After publication, comments from manufacturers or their competitors and from readers may often have to be considered and important points published as a postscript, with or without an editorial rejoinder. Good documentation and thorough fact finding will prevent adversarial attitudes, although industry tends to take such matters to court more readily in some countries than in others.

New drugs are often launched with relatively little published information and insufficient details in the data sheets and other product information. Many registration authorities think that data sheets do not need revision more than once a year, but this is not acceptable for prescribers and their patients. Data sheets must be promptly updated whenever significant new information becomes available. This is the

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[a] Herxheimer, A. France: the Golden Pill and Red Lantern awards. *Lancet*, 1: 604 – 605 (1991).

responsibility of the manufacturer and the registration authority. Whenever such changes are made, health professionals must be specifically informed: they will not notice an unannounced change in a data sheet.

Manufacturers may wish to distribute articles favourable to their own drugs or critical of their competitors' products. Whether a bulletin permits this depends on whether patients and prescribers are ultimately likely to benefit. If a bulletin permits the commercial use of its articles, it should explain to readers that the reprints are not supplied to make a profit.

Writing about adverse reactions

Many countries have some bulletins that deal only with adverse reactions and are published separately from bulletins that discuss the choice and use of drugs. Because such choices must clearly be based on risk–benefit assessments, however, all bulletins have to consider adverse reactions in relation to likely benefits. Although detecting, reporting and analysing adverse events is a separate activity, it is performed by physicians who make therapeutic decisions in their everyday work. Further, too much emphasis on the negative aspects of the use of a drug can distort opinions about its usefulness. Thus, discussions of adverse reactions and drug choice and use should be linked as far as possible rather than separated.

Bulletins should encourage their readers to report significant adverse effects, and provide feedback to them. Unfortunately, many national adverse reaction registers do not make their data freely available to bulletins. Bulletins must nevertheless have this information if they are to help their readers make the best use of it, that is to encourage them to look out for and report suspected reactions, and to revise their therapeutic choices in the light of current reports. Quarterly updated reports should be provided on all suspected adverse reactions to recently marketed drugs. In the United Kingdom, these drugs are identified in the British National Formulary by a black triangle.

In the absence of satisfactory official information on adverse drug reactions, establishing alternative unofficial reporting systems may be valuable. These could give prompt feedback to contributing

practitioners and rapidly publish up-to-date analyses of reports. Having several different reporting systems in one county, as in Germany, however, can cause confusion through the unwitting duplication of reports and partial disclosures. Adverse reactions to different drugs in the same therapeutic group can only be assessed if their incidence is related to sales figures. This is another reason why bulletins need such data. In some countries, such as France, prescribing data appear to be better guarded than military secrets, while in Germany, for example, complete sales data are freely available.

Before a bulletin publishes an article about an adverse reaction, it is important to consider the possible therapeutic consequences. This includes trying to predict what alternatives physicians might prescribe. Sometimes the disadvantages of using the alternatives would be greater than those of continuing to use the drug under suspicion.

How often should educational messages be repeated in bulletins? Clearly, they cannot be repeated even annually. Including such messages in formularies and therapeutic guides may have a more permanent effect. Another method of reinforcing messages is used in Sweden, where pharmacists from the Swedish Corporation of Pharmacies visit physicians, with concise summaries and graphs, to discuss important therapeutic messages from the Medical Products Agency.

Discussing the costs of treatment

Clinicians and other health workers need to consider the costs of treatment whenever they choose a treatment policy. Many bulletins routinely inform their readers about the cost of the medicines that they discuss, but making meaningful comparisons can be difficult. A good rule is to compare only treatments that have similar efficacy, safety and acceptability, and then to compare the cost of the amounts of drug required for the same period, for example one month.

Determining equivalent doses of the various drugs may be difficult. If a wrong equivalent is chosen, the cost comparison will be misleading. In addition, the cost of a drug may differ in the hospital and the community; then a decision must be made on how to explain this to readers. Further, the comparison of more than a few alternative treatments is apt to be burdensome for readers.

A greater difficulty concerns the indirect costs involved in the use of a medicine. For example, extra visits to health professionals may be required to determine the correct dose of the drug and to monitor its effects; these costs include the time of physicians, other health workers and patients and the cost of laboratory tests. Adverse effects, if they occur, have costs to the patient and the health care provider who treats them. In the past, serious damage from drugs has often been discovered only many years after their use. Chronic renal failure from phenacetin is an example. Its enormous cost could not be included in the balance sheet for phenacetin until long after the drug ceased to be used.

When a treatment policy involves the use of several different drugs and procedures, the calculation of costs can become quite complex. Recently manufacturers have begun to use economics in their promotional strategies, employing health economists to present sophisticated arguments that the use of a certain drug saves money. Bulletins must learn to evaluate such claims critically, and will need the help of health economists in doing so.

Collaboration

The International Society of Drug Bulletins (ISDB) was established in 1986. It is a forum for contact and collaboration between editors of the world's independent drug bulletins.[a] The aim of ISDB is to improve the quality of existing bulletins, to encourage the development of new bulletins and to promote the international exchange of good high-quality information on drugs and therapeutics. It facilitates the sharing of skills between bulletins (for example, by the temporary exchange of staff) and organizes training in summer schools, for example, for people working or intending to work on bulletins.

ISDB publishes an internal newsletter for its members and recognized correspondents, and in 1991 began to publish *ISDB review*, containing articles of wider interest that are relevant to the work of bulletins. *ISDB review* is published in English and, when possible, in other languages, too; at present it appears at irregular intervals. The

[a] Information about ISDB can be obtained from the Coordinating Secretary, 103 Hertford Road, London N2 9BX, United Kingdom.

exchange of information is facilitated by translations of important articles from journals such as *La revue prescrire*, *Pharma-Kritik* and *Ricerca & pratica*. Different opinions among bulletins on a particular subject often reflect a healthy pluralism and encourage scientific debate.

Promotion

Drug bulletins need to be actively promoted if they are to reach – and be read by – the people for whom they are intended. Promotional activities are essential for the launch of a new bulletin, but are also needed later.

The promotion of a new bulletin can be very expensive. To save money, a parent organization may help with this task. Association with a parent organization, however, may threaten the independence of a bulletin. Many therefore chose to put a time limit on any contract with such organizations, allowing them to stop the arrangement should problems arise.

University teachers and other opinion leaders can be of great help in promoting bulletins to students, physicians, pharmacists and others. It is therefore important to make the bulletin known and recognized among opinion leaders. This can be achieved by such means as including them in editorial committees or sending them articles for review. Promotion to medical and pharmacy students is important, since they will be responsible for the prescribing and use of drugs in the future.

Special attention must be paid to the appearance of a bulletin. An attractive and distinctive layout and use of colour can be very helpful. Once a bulletin is established, its quality will determine its success. Even high-quality bulletins may need active promotion, for example, by offering certain extra products to subscribers, such as bargain sales of earlier issues, binders and bound volumes, indexes, booklets and volumes on diskettes or other electronic material.

Good contact with readers is an important element in promotion. Such contact can be established by drug information activities such as educational meetings. The presentation of bulletins at professional meetings is also valuable. Many of the topics dealt with in

drug bulletins (such as adverse drug reactions and important new drugs) are of interest to the mass media. This interest could be explored as a means of delivering messages and encouraging desirable changes in drug prescribing and use. Contact with the mass media will also make bulletins better known.

Evaluating impact

For bulletins sold by subscription, the circulation and the annual renewal rate are valuable indicators of acceptance by readers, not impact. The influence of a bulletin on prescribing is difficult to measure reliably, because many other influences are also at work. Nevertheless, such measurement is necessary. Randomized surveys of recipients and non-recipients of a bulletin have occasionally been made, but the response rates have tended to be low and the respondents comprise a self-selected and therefore possibly an unrepresentative sample.

Questionnaires about articles in past issues can assess what interest readers and what they remember. The *Drug and therapeutics bulletin* carries out such a questionnaire survey annually. The simpler and shorter such questionnaires are, the higher the response rate. The answers can help to improve a bulletin and make it more relevant to the different groups among its readers, such as hospital physicians, general practitioners and pharmacists. The relationship between recalling an article, remembering an important point in it and the effect on prescribing behaviour, however, is complex and requires more detailed investigation.

A different and more ambitious approach is to invite readers to test themselves to assess whether they have regularly and assiduously read and digested the material in a bulletin. Since 1988, *La revue prescrire* has published multiple-choice questions about material in previous issues. Readers can send their answers to be scored independently and, if they pass, receive a certificate as *Lecteur émerité*. This certificate contributes to official accreditation for continuing education in general practice. In 1990–1991, out of 20 000 subscribers,

656 physicians, pharmacists and students took a year-long series of tests, and 439 passed.[a]

RECOMMENDATIONS

1. Independent information on drugs should be developed, with the contribution of all parties: the pharmaceuticals industry, governments, the medical community and other interested bodies.

2. The pharmaceuticals industry should make available data on the studies conducted for registering a drug, as well as those initiated after registration. The industry should provide all information, whether positive or negative, published or unpublished.

3. Governments should provide complete summaries of the clinical evidence used as a basis for their decisions on drugs, including those on whether to register a drug or a new indication, or to withdraw a drug from the market. Governments should require:

- the pharmaceuticals industry to disclose information – both published and unpublished – on clinical trials that have been used for drug registration;
- all pivotal clinical studies of a drug to be registered before they are started, so that a summary of the results and, if desired, the complete results will be accessible to all interested parties after the drug has been marketed.

As a rule, any data on the side effects of drugs should be made available without delay to all interested parties.

4. Bodies in the medical community should acknowledge the role of independent drug bulletins by increasing collaboration between

[a] Nory, J.P. Tests de lecture à *La revue prescrire*, 1990 – 1991: les résultats. *La review prescrire*, **11**: 625 – 628 (1991).

editorial committees and clinicians, academics and particularly clinical pharmacologists.

5. The medical community should consider carefully the need to study important therapeutic questions that may not be of interest to the pharmaceuticals industry. Independent research on such questions requires public support.

6. Data on drug consumption (or drug utilization data) should be readily accessible; they should be presented as recommended by the WHO Drug Utilization Research Group in its guidelines on ATC classification and defined daily doses.

Annex 1

WORKING PAPERS[a]

ICP/DSE 168/6	What do we mean by independent bulletins? by A. Arias & J. Recalde
ICP/DSE 168/7	The editorial committee by G. Bardelay
ICP/DSE 168/8	What to write about? How can we find out what prescribers and other health workers need? by M. Bogaert
ICP/DSE 168/9	How can data on drug use help to identify problem areas? by A. Iñesta
ICP/DSE 168/10	Where to find background documentation/ literature? by L. Offerhaus
ICP/DSE 168/11	New technologies in drug information by M. Polman
ICP/DSE 168/12	How to present new drugs by D. Bardelay
ICP/DSE 168/13	How to update adverse drug reactions by U. Moebius

[a] Copies can be obtained from the Pharmaceuticals unit of the WHO Regional Office for Europe, 8 Scherfigsvej, DK-2100 Copenhagen Ø, Denmark.

ICP/DSE 168/14	How to include pharmacoeconomics in a drug bulletin by A. Herxheimer
ICP/DSE 168/15	How can drug bulletins help each other? by A. del Favero
ICP/DSE 168/16	Promotional activities and relationship with readers by E. Gysling

Annex 2

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