

The 39th Annual General Meeting of the Pharma Documentation Ring was a continuation in the line of successful meetings.

Multinational Pharmaceutical Companies Gather in Berlin

by Y. Dubosc, A. Mullen
and C. Otto

The 39th Annual General Meeting (AGM)¹ of the Pharma Documentation Ring (PDR), held in Berlin, Germany, September 26, 1997, was arranged by Dr. K. Specht and his staff from Schering AG. As in previous years, attendance was kept to a manageable size (40 delegates) in order to ensure an intimate atmosphere conducive to open, frank discussions. These PDR AGMs, in which in-depth presentations take place from the industrial user perspective, are attended only by members of the organization.²

Reports on the activities of this corporate-based organization, whose representatives stem from the scientific information departments of major pharmaceutical companies and conduct an exchange of experience in nonconfidential areas of mutual interest, have already appeared in this journal.²⁻⁴

Summary

The 39th Annual General Meeting of the Pharma Documentation Ring (PDR) was held in Berlin, Germany, on September 26, 1997. Common themes reported on included the impact and widespread use of intranet technology; expansion in end-user searching; experience with electronic journals; and programs for the development of electronic archiving and document management systems. Other sessions discussed aspects of chemistry systems; copyright; drug information systems on development products; information management, in-house management of databases; Intranet/Internet activities; and patents. The core topic presented at the meeting involved an overview on document delivery/electronic journals. There is considerable activity in this area by primary and secondary publishers with real momentum seen in the area of electronic document delivery services on the Internet. The 40th anniversary of the PDR will be celebrated at the upcoming AGM, to be held in Montpellier, France, September 30–October 2, 1998.

Due to ongoing mergers in the pharmaceutical industry and a stricter assignment of the member companies to corporate groups, consolidated membership of the PDR now stands at 26, as depicted in Figure 1. The membership reflects the present pharmaceutical industry scene, which has been subject to takeovers, mergers and consolidation over the last few years. Virtually all major pharmaceutical companies with R&D activities in Europe are members of the PDR, and these now account for some 48% of

the estimated \$225 billion worldwide ethical drug turnover.

The main European R&D sites of the member companies are presented in Figure 2. This figure highlights the wide geographical spread of PDR members across Europe and the expansion in growth compared to an earlier report.² The current PDR membership is presented in Table I.

As can be appreciated from the table, PDR membership² opens up a



Fig. 1. Development in the membership of PDR.

TABLE I: PDR CORPORATE MEMBERS^a

Asta Medica	Novartis
Astra	Novo Nordisk
BASF/Knoll	Nycomed
Bayer	Organon
Boehringer Ingelheim	Pfizer
Boehringer Mannheim	Pharmacia & Upjohn
Byk Gulden Lomberg	Rhône-Poulenc Rorer
Glaxo Wellcome	Sanofi
Grünenthal	Schering
Hoechst Marion Roussel	SmithKline Beecham
Hoffmann-La Roche	Solvay Duphar
E. Merck	Wyeth
Merck Sharp & Dohme	Zeneca

^aStatus: November 1997

first-class network of personal contacts within the information scene of the pharmaceutical industry, which can be invaluable for the exchange of information and experience (in non-confidential areas) between member companies.

Special meetings over the last 12 months

Intranet technology

One of the main events over the last 12 months was a specially convened Intranet meeting in April 1997

where PDR members exchanged their experience with the implementation and operation of intranet technology, which has made a major impact on Information Management. The PDR Intranet Task Force, one of the goals of which is to promote the availability of databases and other services in formats suitable for corporate intranets, reported on its work.

Disappointingly, the task force concluded that there was still a relatively slow response by publishers and database producers to the PDR request that they provide a comprehensive range of databases and other services in formats suitable for corporate intranets—at realistic prices.

Over the last year, all PDR companies have introduced, or are about to launch, intranet-based services to enhance corporate information management processes: besides the use of intranet Web browser technology as a standard, user-friendly front-end to corporate databases and other services, some 90% of PDR companies plan to migrate their CD-ROM applications to an intranet environment in order to overcome the known problems associated with networking CD-ROMs. Several PDR companies reported that they had already made substantial progress in this areas.

PDR TRIP-Fulcrum initiative

Early in 1997, a special PDR meeting was held devoted to the continuation of maintenance of the TRIP text retrieval system beyond the year 1999, after which the owner (Fulcrum Technologies, Inc.) originally planned to discontinue support for the system. There was strong support for an extension of maintenance for a three- to five-year period beyond the present envisaged termination date. PSI, which represented Fulcrum at the meeting, agreed to present these views to the new owner. A subsequent meeting was held in May 1997 at which a list of companies which had confirmed their strong interest in a maintenance agreement after 1999 was presented to Fulcrum. Shortly before the PDR AGM in September, where this



Fig. 2. Main European R&D sites of PDR member companies.

topic was on the agenda, Fulcrum contacted the PDR with suggestions for continuing support for the system, assuming there was a viable financial case (i.e., a suitably sized customer base). Endeavors are currently under way to arrange a meeting with Fulcrum and the members of the PDR TRIP-Fulcrum Initiative to reach a satisfactory agreement for the continuation of TRIP support beyond 1999.

Highlights from the 39th PDR AGM

As in the previous years, where the PDR AGMs focused on Internet (1995) and Information Management/Intranet (1996), the core topic of this year's venue was *Document Delivery/Electronic Journals* (see below).

In fact, in some ways, it was a year of consolidation, during which companies put into practice the fast-moving technologies recently developed. Nevertheless, there were numerous interesting presentations made by PDR members as well as by guest

speakers. Representatives from Ashley Publications, BIDS, Derwent Publications, Elsevier Science and NT Software presented their upcoming projects and latest developments.

A current overview of PDR topics²⁻⁴ is presented in Table II. A new topic—Competitor Intelligence—evolved over the last year and is jointly coordinated by Glaxo Wellcome and Novartis.

The PDR topics² undergo continuous revision to reflect those issues of major interest/concern as well as new trends and developments. PDR topic coordinators are expected to provide a current critical overview of their areas, supplemented, if need be, by a survey of the PDR membership. Topics that are particularly "hot" generally crystallize out as the core session of the AGM lasting for half a day.

Company reports session

This slot is the most important of the AGM where each company

reports on its activities in the information management area over the previous year. Common themes which emerged from the 1997 company reports were:

- Impact and widespread use of intranet technology;
- Expansion in end-user searching;
- Experience with electronic journals; and
- Programs for the development of electronic archiving and document management systems.

Selected PDR topic sessions

Chemistry systems

This year's PDR survey on reaction databases indicated that Beilstein Informationssysteme's CrossFireplus-Reactions is now firmly established as a main database for PDR companies (21 installations out of 26). Many companies still continue to subscribe to MDL Information Systems, Inc. databases under REACCS/ISIS and to purchase thematic databases, such as those from Synopsys. An overview of the patent content in reaction databases was also presented.

An Elsevier Science representative gave a presentation on the rationale behind that company's strategic acquisition of MDL Information Systems and the possible consequences for users of systems from both Elsevier Science and MDL.

Copyright

Important activities relating to copyright in 1997, such as the WIPO Treaty, EC Database Directive, EC Green Paper on Copyright and the ABPI initiative involving STM publishers, were reported and their possible impact discussed. Special emphasis was placed on the developing issue of Electronic Copyright Management Systems (ECMS), which will allow the identification, tagging and control of the use of copyrighted material. This topic is steadily increasing in importance for PDR members and could well form one of the focal points of next year's meeting.

TABLE II: OVERVIEW OF PDR TOPICS

TOPIC	COORDINATORS
Biological Science Systems/Databases Biomedical literature, biotechnology	Boehringer Mannheim Byk Gulden Lomberg Merck Sharpe & Dohme
Chemistry Systems and Databases Chemical literature, including chemical reactions, new products	Hoffmann-La Roche Pfizer Zeneca
Competitor Intelligence Definitions, structures within organizations, role of information specialist	Glaxo Wellcome Novartis
Copyright Copyright law, intellectual property, electrocopying	Glaxo Wellcome Wyeth
Drug Information Systems on Development Products Critical overviews and comparisons of commercial sources/databases, producers, quality, prices, software, coverage, trends, PDR usage	Bayer Schering
Information Management Total quality management, end-user support, training, education, marketing of services	Novartis Solvay Duphar
In-House Management of Databases In-house installation of commercial and proprietary databases, including CD-ROM, hardware and software systems company drug papers	Asta Medica Astra Charnwood BASF/Knoll
Internet/Intranet World Wide Web tools, security, encryption recommended sites, Home Page design issues, deployment in PDR companies, Intranet	Boehringer Mannheim Nycomed
Library Affairs and Document Delivery General library services and systems, document delivery systems, electronic books/journals, staffing	BASF/Knoll Novo Nordisk SmithKline Beecham Karl Thomae
Medical Economics Sources and services covering pharmacoconomics, epidemiology, incidence and prevalence data	Astra Arcus Grünenthal
Patents Commercial files/products, producers, quality, comparison, coding systems, PDR usage	Hoechst Marion Roussel Rhône-Poulenc Rorer
Records Management Archiving, document management, imaging, electronic archiving	Boehringer Ingelheim Merck Pharmacia & Upjohn

Document delivery/Electronic journals

This main topic session involved an overview of the area by a representative of BIDS (Bath Information and Data Services) on the internal and ex-

ternal information markets, covering the various solutions offered to users by the publishers through various routes. As there is considerable activity in this area by primary and secondary publishers as well as journal subscription agents, the PDR is plan-

ning to convene a special meeting devoted to this topic in 1998.

Various aspects of this topic were covered by the PDR coordinators, such as:

- Status of the electronic library project involving access, in one case, to over 150 electronic journals in full text. This prototype, probably soon to be overtaken by the availability of electronic journals at the desktop, provided valuable information on the behavior and economics of electronic journals' provision.
- Overview of electronic document delivery resources on the Internet, concluding that there is a real momentum in the scene, due to the uncertainties as far as scope, access, pricing and licensing policies are concerned.

Drug information systems on development products

Some overviews on PDR work in this area were recently published.^{5,6} The 1997 survey on licensed-in drug development product files within the 26 PDR member companies indicated that the Pharmaprojects file now leads with 23 installations, followed by R+D Focus (19), MDDR (14) and R+D Insight (14). Numerous PDR companies are testing the IDdb file from Current Drugs.

Chemical Abstracts Service has responded to a PDR request to provide specialized database producers of the above type with CAS® Registry Numbers^{5,6} and chemical structures in suitable formats for in-house use, thereby ensuring top quality and accurate chemical structures, in order to alleviate the present QA problems associated with these sources.

A PDR survey indicated that currency of data, coverage of CAS® Registry Numbers, accuracy of chemical structures and reliability of development status information are at the top of the priorities for these files. A possible activity for the PDR in this area in 1998 could well involve a

study of the relative reliability of these files.

Information management

The session on information management, which was the main topic last year, concentrated on the results and comments from two surveys on archiving and information management inside PDR companies.

Regarding archiving, paper is still the most commonly used medium; even with the advent of electronic archiving systems there is still a strong need to have backups of document files in paper or on microfilm.

Concerning information management, the survey showed interesting results about the varying sizes, tasks (information retrieval services *and* library) and "hot" topics (intranet/Internet, information technology, global information management plans, backcharging, outsourcing) of the I&D departments of PDR companies.

In-house management of databases

The outcome of a recent survey was a clear movement away from CD-ROM networking (which is, however, still expanding) toward intranet-based integration of database resources. There is also a trend to involve external vendors or hosts in the provision of information sources for the corporate intranet system via so-called extranets. The advantages and disadvantages of this new approach must be carefully studied over a period of time.

Intranet/Internet activities

The PDR Intranet Task Force initiated last year presented the results of the contacts between this group and major database producers/publishers urging them to offer their databases/services in structured HTML formats at realistic prices for immediate integration into corporate intranets.

This session was a follow-up of the special PDR Intranet meeting in April 1997, the conclusion being that

publishers and database producers are reacting relatively slowly and consequently PDR activities in this area must be continued.

Patents

The patent session included the results of three surveys along with two presentations by external speakers. The follow-up study on the timeliness of patent databases showed a general improvement in the Derwent and Chemical Abstract databases by up to one month for the in-depth indexing. This is due, at least in part, to work conducted by the PDR in this area.

A survey on how competitor patents are tracked by PDR companies showed that information departments are involved in 15 companies and researchers themselves in 18 companies. Paper media are still very popular for alerting services, Derwent databases being the most widely used source (Patents Preview/World Drug Alerts progressively replacing WPIL).

PDR Board election and internal affairs

The four-member PDR Executive Board is elected for a two-year period, and at this AGM the proposal submitted by the existing PDR Board for the new Board was endorsed by the membership. The PDR Board members for the period October 1997–October 1999 are:

- President: A. Mullen (Bayer)
- Vice-Presidents: M. Levenbach (Solvay Duphar) and D. McNeillie (Zeneca)
- Secretary: H.U. Häussermann (BASF/Knoll)

Emphasis was also placed on plans for suitably celebrating the 40th anniversary of the PDR. The celebration will take place in Montpellier (September 30–October 2, 1998) during the next PDR AGM, which will be hosted by Sanofi.

PDR host companies for future AGMs have been provisionally arranged up to the year 2002: 1998, Sanofi (France); 1999, Novo Nordisk

(Denmark); 2000, Zeneca Pharmaceuticals (U.K.); 2001, Pfizer (U.K.); and 2002, SmithKline Beecham (U.K.).

Concluding remarks

The 39th PDR AGM was a continuation in the line of successful meetings. A high level of quality was evident in the presentation and content of most topics, as was reflected in the very positive outcome of an evaluation conducted among members on the relevance and quality of the meeting. The core topic, Document Delivery/Electronic Journals, was particularly well appreciated. A very pragmatic approach to the different topics was strongly evident, helping to make these PDR meetings one of the annual highlights of the information calendar in the pharmaceutical sector.

Our active year in 1997 will hopefully be matched by a comparable level of activity in 1998—there is an urgent need, expressed at the meeting, for the PDR to reach out much more and influence events before they become facts.

As well as the PDR AGM next year, special meetings were foreseen for the following topics:

- PDR Trip-Fulcrum Initiative (with interested partners)—December 1997
- Document Delivery/Electronic Journals—May 1998

Over the coming year we once again look forward to continuing to work closely with service providers in order to help improve information and documentation tools, as well as to maintain the high standard of participation of members in the work of the PDR.

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Y. Dubosc is the former PDR Vice-President and can be contacted c/o Rhône-Poulenc Rorer, Centre de Recherche de Vitry-Alfortville, F-94403 Vitry-sur-Seine, France. A. Mullen, Ph.D., is PDR President and

can be contacted c/o Bayer AG, Pharma Research Center, D-42096 Wuppertal, Germany; e-mail: alexander.mullen.am@bayer-ag.de. C. Otto, Ph.D., is the former PDR-Secretary and can be contacted c/o Fachhochschule Darmstadt, FB Information und Dokumentation, Schöfferstr. 3, D-64295 Darmstadt, Germany; e-mail: otto@www.iud.fh-darmstadt.de.

PHASE III RESULTS REPORTED FOR PROSORBA

Cypress Bioscience, Inc. reported January 26, 1998, results from its recently completed pivotal phase II study of the *Prosorba* column for the treatment of severe rheumatoid arthritis (RA). The study was stopped early two weeks ago upon the recommendation of an independent data safety and monitoring board after an analysis of the data showed that the *Prosorba* column had achieved both statistically significant efficacy and favorable safety results.

This study, which began in 1996, had expected to enroll up to 268 patients, with completion by late 1999. The first interim analysis involving data from 60 patients occurred in July 1997. The second interim analysis was performed in January 1998 on 91 patients, at which point the trial was stopped on the basis of having achieved statistical

significance for the primary endpoint. The patients involved in this trial suffered from advanced RA and had previously failed an average of over five different second-line treatments known as DMARDs, including methotrexate in almost all cases, as well as newer biological inflammation modulators (BIM) in some cases. The trial demonstrated that the *Prosorba* column is safe in this patient group. The frequency of adverse effects in the treatment group was no more frequent than that in the control group.

Of the 91 patients analyzed in January 1998, 48 had been assigned to the active treatment group. Of these, 16 (33.3%) responded to the *Prosorba* column. Of the 43 in the placebo group, only four (9.3%) responded, a statistically significant difference. Of patients who completed all treatment and follow-ups, 45.7% of the patients who received

the *Prosorba* column treatment were responders versus 13.3% for the group treated with apheresis alone. Of the 16 responders within the treatment group, four achieved a greater than 50% reduction in symptoms, based on the American College of Rheumatology composite score (ACR50), versus none in the control group. Overall, the mean decrease in swollen joints was 57% and in tender joints 64% for the responder group. While many patients are still within the six-month follow-up period and cannot yet be evaluated for duration of response, the average to date has been 32 weeks. The open-label phase of the study continues.

Cypress has marketed the *Prosorba* column for several years for the indication of idiopathic thrombocytopenic purpura. A PMA seeking FDA approval is expected to be filed by mid-1998.

XERECEPT SHOWS PROMISE IN PATIENTS WITH BRAIN TUMORS

Neurological Technologies, Inc. reported January 29, 1998, data from its open-label pilot phase I/II trial of *Xerecept*TM, a synthetic preparation of **human corticotropin-releasing factor** (CRF), in patients with brain swelling associated with brain tumors

(peritumoral brain edema). These data were published in the January 1998 issue of *Annals of Oncology*. In this trial, 10 of 15 patients treated with the drug experienced clinical improvement in neurological symptoms such as seizures, muscle weakness, loss of coordination and double vision. In September 1997, Neurobiological Technologies began

a randomized, double-blind phase I/II clinical trial of *Xerecept* in this patient population. This trial, which is expected to enroll 90 patients with malignant brain tumors, will evaluate the efficacy of *Xerecept* for controlling neurological symptoms caused by peritumoral brain edema.