

WORLD CONGRESS OF PHARMACY AND PHARMACEUTICAL SCIENCES

# Input of genomics, proteomics and bioinformatics to drug discovery

*Our coverage of the International Pharmaceutical Federation Congress, which took place in Sydney, Australia, continues*

**W**e are not yet in the post-genomic era, according to Dr Mark Ross, senior group leader, Wellcome Trust Sanger Institute, United Kingdom. Since 2001, public effort has been directed towards generating the finished sequence and in this year, which marks the 50th anniversary

of the humane genome project, it is recognised that the sequence is essentially finished in a highly polished state. However, a variety of problems exist and until these are solved, we are not in the post-genomic era. The more serious of these lie in the fact that while 24,500 protein-coding genes have already been predicted, we do not know how many exist in total. It is also not known how many RNA genes exist; 16,388 complete mRNAs have been found in the sequence. Thirty to 60 per cent of genes undergo "alternative splicing" and this phenomenon also adds to the complexity of gene prediction as different combinations of transcripts can be produced. The regulatory gene and chromosome elements directing this activity have also not been adequately described.

Dr Ross stated that although it may take a long time to find solutions to these issues, much work is currently being done in the novel area of comparative genomics, eg, comparing human and mouse genes to identify functional and non-functional elements — functional elements converge; non-functional elements are expected to diverge. This type of investigation also facilitates better understanding of species evolution. When comparing the human genome to that of other vertebrates, it has been suggested that there is good conservation between human and chimpanzee as well as chicken genes. This algorithm is now being used to test the prediction of regulatory elements and shows great promise for the future.

Investigations are ongoing in the area of comparing human genes to detect rare, causative sequence variations in monogenetic disease. Around 2,000 have been identified and the major outcome of this work has been the development of a catalogue of the most common variants, which are mainly single nucleotide polymorphisms (SNPs). There



are currently over five million SNP sites: 46 per cent within genes, 2 per cent in coding regions and 54 per cent between genes.

Traditional methods for investigating monogenetic disease, eg, linkage, are not suitable within association studies (in relation to mapping genes involved in complex chronic dis-

eases). Linkage provides information related to susceptibility to disease rather than actual incidence. In most common diseases, a large number of genes are implicated and environmental factors, such as diet, exercise, etc, also play a role, and these issues cannot be predicted at gene level. It is also not economically or technically viable at the moment to type all common SNPs in association studies so the approach adopted to overcome this is to use linkage disequilibrium (LD). However, knowledge in this area is limited and pilot projects are difficult to compare with each other as they use different densities of SNPs,

investigate different areas of the genome or use different measures for LD. Despite this, it is known that LD varies considerably between genomic regions and even LDs in the same regions vary between populations (Black, Asian, Caucasian) to produce a "population bottleneck" effect.

Several projects support the idea that the genome may be composed of haplotype blocks, where approximately six SNPs are aligned together and exhibit high levels of

recombination between each block. Most of the human population can be described by just three haplotype blocks. It is important to know how much of the genome can be described in this way, how much recombination is occurring within and between these blocks and how this translates into susceptibility or incidence of chronic disease. The international HAPMAP project aims to define patterns of LD and haplotypes across the genome. Participants from China, Japan, UK and the United States will be sampled. The researchers will investigate around 600,000 SNPs and it is hoped that this project will generate tools to enable efficient and comprehensive studies for the association of genetic variation to disease risk and drug

response. Dr Ross concluded: "We still have one foot firmly stuck in the genomic era and we will have for some time. Nevertheless, the mass of data and reagents available do permit post-genomic studies now."

## BIOINFORMATICS — FISHING FOR PROTEINS

"Tell me who you interact with and I'll tell you who you are." This is the philosophy behind the tool developed by Hybrigenics in France. Professor Donny Strosberg, president and chief executive of Hybrigenics, explained the difference between the company's approach to discovering novel drugs and the classical approach. The classical approach to screen for new drugs is to identify a target, extract the proteins and then use these directly as screening tools. Many companies are doing it this way so, to compete in this market, Hybrigenics had to find a successful niche strategy. It "expanded the box" and decided to concentrate its efforts on exploring protein interaction pathways leading to better specificity and exposure of toxicity-related pathways. Technology currently in use is fraught with issues of false negatives and false positives. Hybrigenics wanted to reduce these events and also produce a better set of codes to build up databases for use by itself and its pharmaceutical company clients. The essence behind the technology is simple — go fishing.

Using one protein molecule as bait, we need to fish in a gigantic library of polypeptides to find the prey plasmid. To prepare the bait, large databases of prey are trawled, interactions are scored and then very few (five to 10) fragments of protein are chosen and converted to bait. The bioinformatics used are highly sophisticated and although competing technologies exist, such as mass spectroscopy, these are less superior in effect. The tools are extremely powerful technologies to investigate protein-protein interaction pathways; they are relatively inexpensive, fast and simple. Quality assurance, quality control and validation are consistently monitored with robot technology used in as much of the process as possible. The libraries are highly extensive and complex, containing 30 to 50 million gene fragments. Some good results have been achieved in the area of oncology and wound healing. Much of the work is ongoing and Professor Strosberg concluded that the tremendous advances made in this area were due to the technological advances and sophisticated mathematical and bioinformatics tools available to researchers and drug developers today.



*Donny Strosberg: looking to reduce false positives and negatives*

## CHEMOGENOMICS — COMBINING INFORMATICS AND BIOCHEMISTRY

Dr Edgar Jacoby, team head of molecular and library informatics, Novartis Switzerland, confirmed that there is much still to be discovered about protein-protein interactions. The focus for industry is drug development, ie, how to go from a target to compound selection. Using knowledge-based design strategies enables a systems-based approach to drug development. In looking at protein families, ligand databases and target databases need to be integrated. It is important to use chemical structures and then to fingerprint these in generic search strategies. The crystal structure of a compound is only one picture of many possible interactions of that compound with a protein. Ligand design is an active field of research — there is a need to understand the ligand architecture and molecular recognition at an atomic level. If reference compounds exist, we can characterise these and build libraries, which can lead to new combinations, new compounds and new profiles. These are all highly valuable activities that lead to discovery and development of new drugs. Modelling is a valuable exercise in relation to mutagenesis. In the mid 1980s and early 90s mutation work was of a high quality. Dr Jacoby concluded that mutation studies are not performed to such high quality nowadays, although it is a powerful tool combining existing knowledge in the area of chemogenomics.

## ADME AND TOXICITY MODELLING

The areas of high throughput screening (HTS) and ADME (absorption, distribution, metabolism and excretion) technologies have been around for some time. So why are pharmaceutical companies keen to integrate these for drug development? According to Dr Mary Bradley, senior research associate and head of scientific computing group, Pfizer, United States, it all comes down to efforts to reduce costs.

Drug development costs have doubled in the past 10 years and the time to market for drugs is also increasing. Many companies turned to technology as the answer to their prayers but technology adoption has not led to the hoped for reductions. Bleeding of company profits into the drug discovery process is a major area of concern for many within the pharmaceutical industry. The traditional methods of drug discovery are proving expensive. Chemistry typically drives the success or failure of projects and pharmacokinetics (ADME profiling, toxicology, etc) usually comes later on in the process. There is a major emphasis now on team-working across disciplines at the start of projects to reduce some of the costs and discoveries of failures that occur at later stages. Strategies employed include high throughput screening of drugs with a bias towards searching for failures (the “fail fast” principle). Compounds are investigated using screening libraries for high pK profiles then filtered and optimised, prioritising hits during the process. Compounds that are

accepted for further development have to pass a “rule of 5” (or 4 or 3.5, depending on the company criteria). If a compound has poor absorption or poor permeability or is too large, it will not pass. This may not be a hard and fast rule for some companies but is the usual criterion for project decision-making as to whether to go with a compound or fail it.

There has been concern about computational ADME and toxicology modelling within the industry. Dr Bradley suggested that it is lagging behind the traditional predictive modelling used in lead optimisation programmes due to lack of data. Typically, in pharmaceutical companies those who have the data are in different departments and operate under different conditions and rules regarding data access. This type of data is not readily available to those within the drug development areas, producing more barriers to improving product design. She emphasised that drug developers would realise improvements in costs if they optimised ADME toxicology and potency early on in the development process.

Dr Bradley concluded that although the strategy used in companies was now one of “fail faster” the candidate pool coming through was much larger so companies could afford to be choosy in their drug development investment decisions.

## EDUCATE, EDUCATE, EDUCATE

“Pharmacists may be letting themselves down with regard to pharmacogenomics,” according to Professor Ross McKinnon, College of Pharmacy, University of South Australia. Various factors influence drug response such as genes, environmental exposure, dose, diagnosis, patient factors and compliance. He could not think of one pharmacogenomics association studies paper that had investigated the influence of patient compliance on outcomes. Therefore, all research in this area assumes full patient compliance whereas we know that in reality patients do not comply. This needs to be borne in mind when evaluating association studies.

The main problem lies in how to translate basic pharmacogenomic research into positive health outcomes within clinical practice. The implications for pharmacists are emerging as more research is conducted in this area. Prescribing in the near future will necessitate incorporation of genomics information. Pharmacists need to be comfortable with association studies and genetic profile testing in order to answer patients’ queries about why the doctor did not prescribe them a certain drug, why a doctor performed such a test, etc.

Professor McKinnon reminded participants that genomics is all around us. Internet companies are already offering genetic



Mary Bradley: drug development costs have doubled

profiling but the question arises as to the quality of the information they are providing to the consumer. What are they basing their association studies on? Do they take into account environmental and compliance factors, especially in relation to chronic diseases? How reliable and reproducible is the test result? If alternative therapies are not available to the patient, what is the impact on the health outcomes?

Much of the adverse drug reaction incidences (approximately 50 to 60 per cent) are due to medicines mismanagement and not to genetics. Pharmacists therefore have a major role to play in counselling patients and working alongside other health care professionals in implementing the research in practice. The ability to take on this role depends greatly on education and a real effort is needed to introduce postgraduate and undergraduate courses of sufficient breadth and depth.

Professor McKinnon suggested a restructuring of the pharmacy curricula in all countries into an integrated model based on pharmaceutical care, which would include a component of pharmacogenomics and pharmacogenetics as part of this “patient-centered teaching approach”. He concluded by reminding pharmacists that inclusion of pharmacogenomics into mainstream health care will increase treatment options and this, by its very nature, will increase the risk of errors. It was up to pharmacists to work alongside health practitioners and attain sufficient competency within this area to ensure this does not happen.

## ETHICAL DILEMMA

Dr Pat Buckley, head of physiology, school of molecular and biomedical science, University of Adelaide, Australia, told participants that “pharmacogenomics is a ‘sleeping giant’ ethically speaking and it should get properly integrated into the science and practice of genomics”. Within pharmacy education in the US, the majority of schools surveyed recently undertook no teaching of ethics in this area or limited it to a one-hour session. Areas to be considered under the ethical framework include equitable provision of health care, issues surrounding orphan drug development and possible explosion in the number of orphan drugs, respect for communities and different races, ethnicity, genders as well as consent, privacy and access to database information.

She concluded that these discussions were not theoretical and events were developing such that many of the issues are being played out in the public arena already. Pharmacists have a responsibility to invest their professional expertise in this area. She urged participants to rid themselves of vested interests and discuss the ethical challenges posed by this new field of health care. — Contributed by Sonia Sanghani.

# Who pays for better outcomes?

Opening a symposium organised by the FIP Administrative Pharmacy Section on outcome research in pharmacy on 8 September, Professor Marion Schaefer, of Humboldt University, Berlin, Germany, said that the performance of pharmacists and the acceptance of that performance by patients, professionals and managers of health care systems is crucial for the future of pharmacy. Acceptance will be generated from evidence of value, which is what makes outcome research so important, she added.

Two speakers from the University of Sydney, Australia, described different aspects of a study in community pharmacy, which investigated outcomes of a disease state management service for type II diabetes mellitus.

The first speaker, Dr Ines Krass, focused on what the study had demonstrated in terms of adherence to medication. Type II diabetes is a chronic disease which requires intensive treatment to optimise control of blood glucose, blood lipids and blood pressure, she said. To achieve this control, the patient must pay attention to diet and exercise, maintain adherence to a drug regimen that is often complex, and also monitor blood glucose. This is a challenging task.

## ADHERENCE IN DIABETES POOR

She went on to point out that adherence to medication regimens in type 2 diabetes is generally poor. Two recent US studies, using pharmacy records as evidence, have shown compliance rates averaging 70–80 per cent, while a Dutch study using medical records found that compliance was 74 per cent. Although overall adherence in a recent Scottish study was higher at 90 per cent, compliance in taking sulphonylureas and metformin was 31 and 34 per cent, respectively.

The aim of the study Dr Krass described was to optimise adherence to medication in a disease state management service in type II diabetes. Other interventions, such as attempting to enhance monitoring of blood glucose and attention to diet and lifestyle were made, but adherence to these was not measured in the study. The study was of a parallel group design, consisting of a control and an intervention group and took place in three settings — a diabetes clinic, a rural pharmacy and an urban pharmacy. There were three pharmacists trained in the management of diabetes in each setting and 135 patients were enrolled in the intervention group. Baseline data were collected at the start of the study and after two weeks the patients returned to see the pharmacist after which the service began. Monthly follow-ups continued for nine months at which point the final data



were collected. The control group was of a similar size, and data were again collected at nine months, but the patients received only the pharmacists' normal service instead of the additional service.

Dr Krass explained that adherence to medication was measured using two methods. The first was from a self-reported, brief medication questionnaire (BMQ). This tool has been validated by Swedish workers and asks the patient about drugs taken during the past week, how well the medication is working, any side effects and also any difficulties they have had in relation to taking the medicine. She explained that a score of zero on this tool means adequate adherence and more than zero indicates risk of non-adherence.

The second method used to measure adherence was dispensed medication history (DMH). Six months of dispensing data were analysed and if the patient collected between 85 and 110 per cent of prescribed medication, this was judged to reflect adherence. Complete data were obtained from 87 subjects and 67 controls.

The new diabetes service resulted in an overall reduction in risk of non-adherence to medication, but this was most evident with the antihypertensive therapy rather than the antidiabetic medication. Moreover, 100 per cent adherence was not achieved in this study. There was fairly close agreement between the two measures of adherence, although BMQ has greater sensitivity. DMH is of limited value in that it does not report use of over-the-counter medicines. In addition, patients use more than one pharmacy and also may not take all the collected doses.

Dr Krass concluded by saying that the introduction of a diabetes service had led to a reduced risk of non-adherence. Unfortunately, however, the study lacked power to show statistically significant changes because of the small numbers of patients. Further work using larger numbers is needed.

## ECONOMIC OUTCOMES

The second speaker, Dr Susan Taylor, went on to describe the economic outcomes of the study. Two analyses were conducted — a cost-effectiveness analysis and a cost-benefit analysis. A cost-effectiveness analysis is important for government and a cost-benefit analysis is important for the patient. The evaluation included one initial patient visit and six follow-up visits over nine months together with one medication review.

Change in glycated haemoglobin (HbA<sub>1c</sub>) levels with the new disease management service compared with the pharmacists' normal service was chosen as an indicator for the cost-effectiveness analysis. This indicator was chosen because, accord-

ing to a large body of research, reduction in HbA<sub>1c</sub> leads to avoidance of complications, improved cost savings and better disease control. It was expected that the new service would cost more money, and it was important to know if there would be more benefit.

For the analysis, 53 patients from the intervention group and 46 from the control group were eligible. In other words, the analysis involved a sub-set of patients, but the demographics of the eligible participants were sufficiently similar to those of the group as a whole, Dr Taylor said.

## COSTS

Dr Taylor said that the total cost of the new service, including the time spent by the pharmacist, the time spent on telephone calls to the patients, the time spent on medication reviews and the cost of information print-outs for the patients, amounted to A\$1,857 per patient. This compared with A\$1,465 per patient in the control group.

A 0.43 per cent reduction in HbA<sub>1c</sub> was achieved in the intervention group, but there was little change in the control group. By calculation, the cost of achieving this 0.43 per cent reduction was A\$391 per patient in this study, Dr Taylor said. However, US research has linked a sustained reduction in HbA<sub>1c</sub> with cost savings over one to two years, and the UK Prospective Diabetes Study found that a 1 per cent reduction in HbA<sub>1c</sub> is linked with a 21 per cent risk reduction for any endpoint related to diabetes mellitus. The health benefits may therefore outweigh the costs, she added.

Dr Taylor went on to describe the cost-benefit analysis. This investigated patients' willingness to pay for a diabetes service offered by community pharmacists and provides a measure of the value patients place on the new service compared with the normal service.

A questionnaire was sent to all the patients involved in this part of the study, and the response rate was 77 per cent. Of those receiving the new service, 84 per cent professed themselves to be satisfied or very satisfied compared with 58 per cent receiving the standard service and patients were willing to pay for the extra service. However, of the additional cost of providing the new service, which amounted to A\$40 per month, patients were willing to pay only A\$10.

Continuing, Dr Taylor explained that the question is who should make up the shortfall of A\$30 per month — the government, the pharmacist or both? The reduction in HbA<sub>1c</sub> is likely to result in reduced complications and a similar, but larger scale study is now being conducted in the hope of getting a firmer estimate of cost savings and a greater reduction in HbA<sub>1c</sub>. The likelihood is that the service will be more cost-effective in younger patients and those with higher HbA<sub>1c</sub>, she concluded. — *Contributed by Pamela Mason.*

# Pharmaceutical clinical technology: — an opportunity pharmacists should ensure they do not miss

Professor Albert Wertheimer, centre for pharmaceutical health services research, Temple University, Philadelphia, United States, said that if pharmacists do not watch out, involvement in pharmaceutical clinical technology could be yet one more opportunity that they miss. Professor Wertheimer was speaking on 9 September at a symposium organised by the FIP Administrative Pharmacy Section.

He went on to define pharmaceutical clinical technology as “the rational, effective, safe and economical use of medical technologies (eg, devices, instruments, single use items, biotechnology and diagnostics) and medicines in the prevention, diagnosis and treatment of disease”. Chemistry-based drugs are being replaced by clinical technologies and pharmacogenomics, he added.

Although pharmacists in many countries already conduct near-patient testing or sell test kits for home use, they are, in the near future, going to have to be able to do more than dip a stick in a biological sample and read a colour change. How many pharmacists know much about bone scanning technology, he asked. It is not enough to be aware of dual energy X-ray absorptiometry (DEXA), for example. Pharmacists should understand the different types of DEXA, together with the risk scores and their interpretation.

Schools of pharmacy, however, are not preparing pharmacists for a future which will include a vast range of new diagnostic tests and drug delivery systems, not to mention pharmacogenomics. Currently, faculties have no foundation for teaching pharmaceutical clinical technology and no immediately obvious place to put it in the curriculum. Should it be taught as a discrete subject or incorporated into the more traditional pharmaceutical subjects? As for teachers — it might be better to use industrial colleagues because they are the ones with the most up-to-date experience of these new technologies, he pointed out.

## A DISCIPLINE-BASED APPROACH TO TEACHING AND PRACTICE

Dr Ari Heller, also from the US, emphasised the need to take a discipline-based approach to the teaching and practice of pharmaceutical clinical technology. Making comparisons with clinical pharmacy, he went on to say that pharmacists' widening role in clinical pharmacy has been achieved in part through the development of a large body of research and the creation of concepts such as drug utilisation review. This is what is needed to develop pharmaceutical clinical technology, he said. Moreover, its

theoretical and conceptual framework should be used to guide practice.

In his opinion, pharmaceutical clinical technology should be anchored and taught within the context of existing disciplines in schools of pharmacy. In the US — and it is similar in many other countries — the pharmacy curriculum is divided into three basic categories. First, there is basic sciences, which include pharmacetics, pharmacology and pharmacokinetics. The area of pharmaceutical clinical technology which could be included at this stage is biomedical engineering. The second category is clinical science, such as clinical pharmacy, clinical epidemiology and medicines information. The subjects to include at this stage include clinical technology, clinical epidemiology and clinical technology information. The third category is social and administrative sciences, such as social pharmacy and pharmacy administration. From a pharmaceutical clinical technology perspective, the areas of technology management, human factors and ergonomics would slot into this category.

## WHY DO WE NEED SPECIALISTS?

Dr Heller went on to describe what pharmaceutical clinical technology specialists do and why we need them. They are the health professionals who “systematically address the clinical, scientific, rational use, technology information analysis, patient safety, epidemiological, economic and managerial issues for clinical technologies and drugs used in medicine”. Performing these tasks will reduce costs and maintain a high level of patient care. It should not be forgotten that the process of patient care includes technologies. It is not just about drugs, he emphasised.

In his opinion, there is currently a void in this area. No single group of health professionals is seriously engaged in the management of clinical technologies. And although anyone could do it — not just the pharmacist — the pharmacist is already involved in the management of medicines, so why not include the clinical technologies being used by the patient? Pharmacists already have some involvement — for example they advise on the appropriate use of blood glucose meters, nebulisers and inhalers. But clinical technologies are becoming increasingly varied and complex, and overall management in this area is currently poor, he said.



There is therefore a large unmet need, which represents a huge opportunity for pharmacy. Pharmaceutical clinical technology is, moreover, an extension of what pharmacists do in the care process around medicines. In other words, pharmaceutical clinical technology and clinical pharmacy go hand in hand. Pharmacists can — and in some cases already do — advise patients not only on their medication but also on any devices, equipment or drug delivery systems they may be using.

Practising pharmaceutical clinical technology involves a set of well-defined tasks. These include: discussing with the patient and the doctor the appropriate use of clinical technologies; monitoring and identifying problems and risks/benefits in relation to clinical technologies; and conducting biological and chemical analysis of physiological samples. Much of the role involves providing information. This information, like medicines information, must be unbiased, critically evaluated and evidence-based so that rational and informed scientific, clinical and economic decisions related to all clinical technologies can be made.

In his conclusion, Dr Heller said that pharmaceutical clinical technology enables pharmacists to expand their range of services and also increases their role in patient care and with medical practitioners. It is a win-win situation, he said, bringing benefits to patients in terms of rational diagnosis and improved therapeutic outcomes and to the healthcare system in reduced costs and enhanced patient safety. Pharmaceutical clinical technology should be practised in a systematic manner and anchored in schools of pharmacy teaching programmes in existing scientific fields.

“Pharmaceutical clinical technology is an integral part of pharmaceutical care, and the pharmacist is the health professional who should provide this service,” he declared.

## A CHALLENGE FOR THE PHARMACEUTICAL INDUSTRY

In the final presentation, Dr Tom Sam, of NV Organon, the Netherlands, described the growth in new clinical technologies as a challenge for the pharmaceutical industry and discussed the value of pharmaceutical clinical technology from an industrial point of view. Innovative technologies such as controlled and targeted drug delivery systems and diagnostic devices and equipment

are transforming today's medicine, he said. The pharmaceutical industry is focusing more on near-patient tests and new emerging medical technologies and rather less on new drugs.

Pharmaceutical companies need to deliver these technologies to the patient, and for the industry, the important question is what can the pharmaceutical clinical technology specialist add to this process. Clearly, the patient needs to have the right technology and use it in an appropriate manner, otherwise it will achieve nothing in terms of health outcomes and the technology might be deemed a failure. This will affect sales and profits, so focusing on patient information is vital, he said.

He went on to point out that new technologies demand more than clinical knowledge. So, whoever is advising the patient must have an understanding of medical and biomedical engineering too. The patient, moreover, tends nowadays to be better informed, accessing knowledge from the internet, for example. And with the shift from compliance to concordance, the industry is now treating the patient as an equal partner. Industrial thinking is also focusing not only on safety, efficacy and quality of its products, but also on their effectiveness in real life. Health economics and risk assessment are playing a bigger part too, with

companies wanting to compare their drugs with other similar drugs and treatments.

So, how can pharmaceutical clinical technology specialists support the industry in relation to advanced drug delivery systems and diagnostics? Such specialists have to be able to advise patients on these devices, because it is they, the professionals, not the industry, who are at the interface with the patient. Near-patient testing, such as glucose monitoring, pregnancy and fertility testing, testing for hepatitis, drugs of abuse, infections including human immunodeficiency virus (HIV) and anticoagulant therapy monitoring is becoming increasingly popular. The PCT specialist must be able to introduce such technology to patients, interpret results and give appropriate advice.

#### REAL POSSIBILITIES

Molecular diagnostics, genotyping/phenotyping and DNA/protein sequencing represent real possibilities for near-patient testing in the pharmacy in the not-too-distant future. Devices for the analysis of



gene regulation will effectively provide the patient with a passport for individualised pharmacotherapy. The pharmaceutical clinical technology specialist should be able to advise on these technologies and deal with the implications of personalised medicine. All these new technologies will have an impact on health care. The

industry wants to improve outcomes and reduce risks, and with medicines and new technologies alike, this can only be achieved in the setting where the patient is located.

The pharmaceutical clinical technology specialist can therefore best support the industry with these innovative technologies by counselling the patient on their optimal use, acting in an advisory capacity to health care organisations and feeding back instances of non-optimal performance to the industry. This involves specialists integrating all their knowledge — pharmaceutical, medical and biotechnological. The need is for them to become a single authoritative voice, speaking on behalf of all professionals in matters concerning medical devices, Dr Sam concluded. — *Contributed by Pamela Mason.*

## Medicine labels and leaflets — implementing an evidence base to improve outcomes

Introducing a symposium organised by the FIP Pharmacy Information Section on 8 September covering the dissemination of drug information to patients, Professor Theo Rayner, University of Leeds, United Kingdom, said that informing consumers about their medicines is now a high priority across the world. Regulations and guidelines on labels and leaflets are being introduced and these should be based on good evidence.

David Sless, of the Communication Research Institute of Australia, said that design of medicine labels and leaflet information has not been based on any research. However, during the past 10 years considerable progress has been made in developing evidence-based guidelines for the industry to follow and benchmarks to allow the assessment of effectiveness of labels and leaflets. In Australia and Europe it is now mandatory for medicines pack insert leaflets to be provided by manufacturers. In the United States there is a voluntary system with much shorter information leaflets being generated in the pharmacy as required.

Parisa Aslani, of the University of Sydney, Australia, explained that consumer information for prescription medicines has



*Theo Rayner: regulations and guidelines on labels and leaflets that are being introduced should be based on good evidence*

been available in Australian pharmacies for a decade. Although the provision of such data is not mandatory pharmacists have a duty of care to ensure patients take their medicines correctly. Research has shown that verbal

information reinforced by individualised written material as part of the counselling process is an effective way of getting the message over. There is a particular benefit in providing suitably translated information for patients whose first language is different from the language of the country in which they live. Consumer medicines information is important for new medication, when ongoing medication is changed and from time to time during long term chronic medication.

Janne Graham, of the Australia Pharmaceutical Advisory Committee, speaking on behalf of consumers complained that although the Australian government was offering a grant of A\$3,000 towards the cost of a laser printer, and 10 cents a prescription to generate consumer information for prescription medicines, relatively few pharmacists are actually responding to this initiative. Further, there has been no attempt to check whether those pharmacists who have signed up to the scheme are in fact providing consumer medicines information. Ms Graham said that consumer groups are becoming increasingly vocal on this matter and want to see medicines information provided in all pharmacies. — *Contributed by Steven Kayne.*