THE EACPT IS IN A PRIME POSITION TO FOSTER AN ENVIRONMENT OF EXCHANGE BETWEEN RESEARCH AND POLICY WITHIN THE FIELD OF CLINICAL PHARMACOLOGY AND THERAPEUTICS, AS **PEN** FINDS OUT

Policy and pharmacology

The European Association of Clinical Pharmacology and Therapeutics (EACPT) includes all the national scientific and professional organisations and societies for clinical pharmacology and therapeutics in Europe. It aims to provide educational and scientific support for the more than 4,000 individual professionals interested in clinical pharmacology and therapeutics throughout the European region.

All medicines have risks of adverse effects, in addition to their expected health benefits. The EACPT is very well placed to provide up-to-date briefings and recommendations to policy makers on how pharmacology can contribute positively to human health and wealth, through a clear understanding of the clinical and cost benefit/risk ratio of medicines.

The EACPT is also in a strong position to advise on the support needed for clinical pharmacology and therapeutics, and its underpinning pharmacology, to ensure that established experts and emerging CPT professionals in academia, the clinical domain, governance, industry and other roles can continue to develop and use medicines effectively to meet current and new challenges to human health.

Development and growth

The EACPT [1] was founded in 1993,[2] and is now entering its third decade of activities. Fundamentally, the EACPT provides a growing resource of expertise and experience to provide education, scientific and clinical expertise, and to inform policy across the increasingly complex clinical pharmacology and therapeutics sector. Reasons for this complexity include a progressive expansion of the portfolio of licensed medicines and their supporting diagnostics and biomarkers of effectiveness and safety;[3] conventional medicines are now increasingly complemented by sophisticated biological agents, with a growing need to consider pharmacogenetic, proteomic and other biomarkers when selecting medicines; tests both for prediction of likelihood of beneficial action, and to avoid predictable serious adverse effects.

Furthermore, advances in research technology, and increasing engagement by life scientists and health professionals in research and development in new personalised approaches to therapeutics, are leading to the affordable translation of new tools, such as pharmacogenomics, from research approaches to clinical practice, as new ways to improve treatment of patients. This is resulting in the need to educate prescribers in how to interpret these new tests and how to explain the implications of false positive and false negative results to patients when discussing new prescribing choices.

These developments have been mirrored in an increasing complexity in establishing, understanding and communicating the clinical and cost-effectiveness of medicines to the overlapping communities of stakeholders interested in these issues: from policy makers to regulators, health professionals from the clinical to the biotechnology and pharmaceuticals sectors, and not least to patients and the public.

The EACPT was some years in gestation, arising from a working party in the 1980s supported by the World Health Organization – Europe. The EACPT now includes all the national organisations and societies for clinical pharmacology in Europe, from Scandinavia to the Mediterranean, and from the United Kingdom to recent accession countries to the European Union, and to the Baltic States and Russia (see Fig. 1).

Education and training

The key aims of clinical pharmacology and therapeutics are that appropriate medicines are available for the right patients at the right dose, at the right time, and for the appropriate duration, with treatment monitored to make sure that it is both effective and safe. Achieving this requires combining traditional good practice in medicine with new approaches to drug discovery. It also needs reliable monitoring of drug safety, effectiveness and health impact,

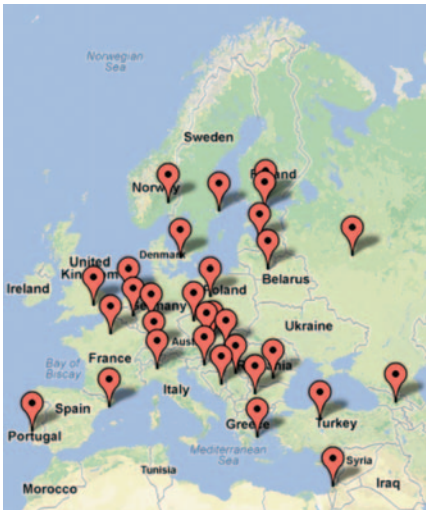


Fig. 1 Map showing countries with EACPT member societies

supported by excellence in drug regulation, pharmacovigilance and clinical toxicology.

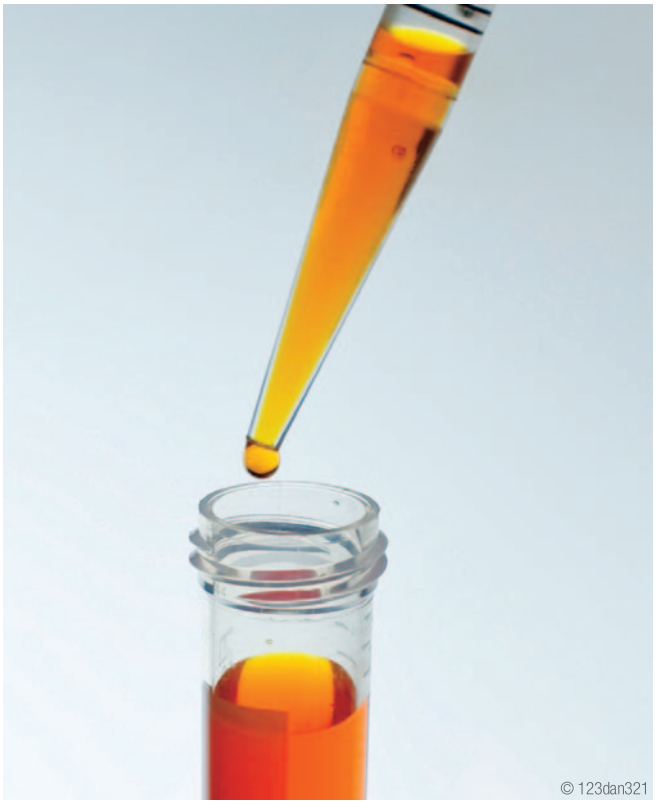
The EACPT has a major interest in promoting the safe use of medicines across Europe and internationally, through education on the effective use of medicines in the best interest of patients, the public and health services, addressing health priorities for the public and for health services, and by combining classical with new approaches to ensuring efficient translation of research from concept to clinical and cost-effective use.

Since its inception, the EACPT has played important roles in supporting the education and training of clinical and research professionals interested in drug discovery, the safe and effective selection, prescribing and use of conventional medicines, the risks and benefits of using generic *versus* branded medicines, new internet sources of treatments, and the new world of coupling designer medicines with specifically tailored tests – known as companion diagnostics – throughout Europe and internationally.

New medicines

Although effective treatments are now available for many common and serious diseases and their risk factors, active international organisations such as the EACPT are vital for meeting unresolved challenges in clinical pharmacology and therapeutics. These include:

- Personalising the understanding and treatment of disease so that individual patients are not disadvantaged by genetic variability in disease causation or in drug handling. Across the European continent perhaps 25% of people will have one or more genetic variants in the proteins that determine how drugs are handled by the body;[4]
- It is also vital that expertise across the spectrum in clinical pharmacology and therapeutics is maintained to address the many remaining unmet current challenges both in the developed world and in less and least developed countries; and
- A further important need for protecting public health in Europe and globally is to maintain the infrastructure and expertise needed to deal with future epidemics of infectious disease.



Congresses and workshops

The EACPT has supported the above aims since 1995, through holding bi-annual international scientific congresses, alternating with educational summer schools, with delegates attending and presenting from around the world. Conferences and summer schools organised by the EACPT have a global reach, both in terms of delegates and speakers.

Summer schools provide an intimate forum where experts and young clinicians and scientists discuss, in informal settings, new developments in the discipline. Bursaries are provided for young scientists to support their attendance, based on abstracts submitted for presentation.

The Tenth EACPT Summer School for young clinical pharmacologists will be held in Edinburgh from 4-6 July 2013.[5] A faculty of 23 speakers will cover themes from new research on medicines, to safety in prescribing and communicating science with policy makers and the public. Keynote discussants will include the chair of the UK's National Institute for Health and Clinical Excellence, Professor Sir Michael Rawlins, Professor Sir Kent Woods, chair of the UK Medicines and Healthcare Regulatory Agency; and on research and clinical themes Professor Ingolf Cascorbi from Kiel in Germany, Professor Adam Cohen from Leiden in Holland, and Professor Garret FitzGerald from Pennsylvania, USA.

EACPT congresses are typically attended by 800-1,200 delegates and provide excellent opportunities to showcase issues of topical international concern to the CPT community, through timely and accessible original research presentations and commentaries to policy makers, health and industry professionals, health technology providers, patient groups and academia.

The 11th biennial EACPT congress will be held from 28-31 August 2013 in Geneva.[6] This will bring together a wide range of international

delegates, including health professionals, clinical and life scientists, policy makers, professionals from the biotechnology and pharmaceutical communities and others interested in the spectrum from basic to clinical pharmacology and pharmacotherapy, and from drug discovery to regulatory affairs.

Key themes at the Geneva congress will range from bedside pharmacology for special patient groups, to pharmacology and toxicology and pharmacology and society. Further sessions will include new biological agents, translational medicine and pharmacogenetics, advances in personalised diagnostics to improve the safety and effectiveness of medicines, updates on new biological approaches to ocular disease, therapeutics of cardiovascular, cancer and inflammatory disease, clinical trial design and regulation, drug safety and toxicology, clinical trial design and governance, health policy, communicating with the public, and safe prescribing. There will also be sessions on the safety of drugs, and on the European and international regulatory environment.

Further EACPT international scientific and educational congresses are planned for Madrid in 2015 and Prague in 2017, with further summer schools planned for alternate years.

Promoting EACPT aims

The EACPT is now extending its international reach through a new affiliation with the international journal *Clinical Therapeutics,* in partnership with the major international publisher, Elsevier.[7]

Clinical Therapeutics provides an excellent way for the EACPT to continue to develop and enhance its international contributions to the development of policy and practice within clinical pharmacology and therapeutics and related disciplines, aided by the large community of experts in clinical therapeutics and pharmacology in Europe and their global collaborators in academia, clinical health services, industry and the health policy communities.

Clinical Therapeutics will, in this partnership with the EACPT, provide an extended cross-disciplinary forum, in print and online, for an international audience to discuss case studies and strategy for the engagement of clinical pharmacology and therapeutics, in supporting and leading the development of health policy in relation to medicines in Europe and beyond.


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Table 1. EACPT member society countries and their 4,361 national members

COUNTRY	MEMBERS
Austria	102
Belgium	120
Bosnia & Herzegovina	62
Bulgaria	36
Croatia	100
Czech Republic	60
Denmark	175
Estonia	6
Finland	157
France	607
Georgia	15
Germany	453
Greece	54
Hungary	154
Israel	57
Italy	150
Lithuania	5
Netherlands	419
Norway	63
Poland	50
Portugal	40
Romania	105
Russia	100
Serbia	108
Slovakia	65
Spain	290
Sweden	130
Switzerland	138
Turkey	55
United Kingdom	667
Total	4163

Health policy

It has been argued that some areas of activity have felt the influence of clinical pharmacology

less than others, despite the fields being indispensable for the development both of new treatments and the proper understanding and practice of contemporary medicine.

EACPT is increasingly supporting the safe and effective clinical development of drugs by providing advice to health policy makers, including the European Medicines Agency, on criteria for approving drugs and for regulating medicines after they are licensed for clinical use. This is applicable both for established and evolving areas of interest, including the evaluation of medicines for children, with extension of patent life being a trade-off to incentivise interest from industry, and the increasingly complex area of using companion diagnostics to optimise the selection of as safe and effective as possible anti-cancer and other therapies.

Two major issues that have potential for positive interactions between the pharmaceutical industry and experts in clinical pharmacology and therapeutics are drug selection and reimbursement,[8] and clinical research. As part of the solution to accelerating cost-effective and timely drug development, the EACPT favours increased collaboration among academic researchers, clinical centres and industry, coupled to constructive discussion on resolving aspects of the EU Clinical Trials Directive that have had a major impact on the ability of European researchers to engage in research more on medicines.

Future areas of policy engagement and educational initiatives for the EACPT will include the clinical place of non-medical prescribers, e.g. clinical pharmacists and nurse specialists, and their training and governance, as well as effective strategies to educate patients and the public in order to improve adherence and to reduce the risk of serious adverse effects of medicines.

References

1 Website for the European Association for Clinical Pharmacology and Therapeutics. http://www.eacpt.org/

2 Singer DRJ. Professor Gonzalo Calvo and the European Association for Clinical Pharmacology & Therapeutics. Health Policy and Technology 2012; 2:115-6.

3 Crabb N, Marlow M, Bell H, Newland A. The NICE Diagnostics Assessment Programme. Health Policy and Technology 2012; 1:5-7.

4 Sim SC, Kacevska M, Ingelman-Sundberg M. Pharmacogenomics of drug-metabolizing enzymes: a recent update on clinical implications and endogenous effects. Pharmacogenomics J. 2013 Feb; 13(1):1-11.

The European triangle

Following a legal act passed by the European Commission in March 2013, an inverted triangle will now begin to appear on the inside leaflet of certain medicinal products on the EU market.

It is hoped that the symbol will allow patients and healthcare professionals to easily identify medicinal products that are undergoing additional monitoring, and its accompanying text will encourage them to report unexpected adverse reactions through national reporting systems.

Tonio Borg, European Commissioner for Health and Consumer Policy, said: "The symbol is easy to recognise for patients and healthcare professionals. It will help to obtain more and better information from them on possible side effects of a medicine which then can be thoroughly analysed. Stronger involvement of patients in the reporting on side effects is an integral part of Europe's pharmacovigilance system and – once in place – the new symbol will contribute to strengthen what is already one of the most advanced systems in the world."

The EU pharmacovigilance system (the process and science of monitoring the safety of medicines and taking action to reduce the risks and increase the benefits of medicines) is widely held as one of the most advanced and comprehensive systems in the world, and ensures a high level of public health protection throughout the Union.

EU pharmacovigilance legislation underwent a major review that lead to the adoption of new legislation in 2010 to strengthen and rationalise the system for monitoring the safety of medicines on the European market and to improve patient safety and public health through better prevention, detection and assessment of adverse reactions to medicines.

The adoption of the new regulation is an implementing act of this legislation.

5 Website for the EACPT Summer School in Edinburgh: 4th-6th July, 2013. http://www.bps.ac.uk/meetings/139ba11a3ad

6 Website for 11th EACPT Congress, Geneva, 28th – 31st August, 2013. http://eacpt2013.org

7 Singer DRJ and Calvo, G. Clinical Therapeutics and the European Association of Clinical Pharmacology and Therapeutics: a new international partnership. Clinical Therapeutics. 2013; 35: (in press).

8 Quinn B. Payers and the assessment of clinical utility for companion diagnostics. Clin Pharmacol Ther. 2010; 88:751-4.

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