

A tour around pharmacy regulation

A recent meeting looked at how issues of governance, regulation and ethics are influencing the future of pharmacy. Alan Nathan reports

Julie Stone, deputy director of the Council for Healthcare Regulatory Excellence, said that public protection is the CHRE's mission, and that regulation is about maintaining public confidence in the professions and setting out and upholding proper standards of conduct. The CHRE, which oversees health profession regulators, is an independent body accountable to Parliament. Professor Stone said that there is an increasing shift towards regulation of teams providing health services rather than individual professions, citing the Pharmacists and Pharmacy Technicians Order of the Health Act 1999, currently out for consultation, as an example.

She explained that the CHRE has statutory powers, and its general functions include promoting the interests of patients and the public in relation to the performance of the health regulatory bodies (RBs), promoting best practice and formulating principles relating to good professional self-regulation, and encouraging co-operation between RBs. The CHRE has powers to do anything necessary in connection with its functions, including investigating regulators, comparing their performance and recommending changes in the way they perform their functions. If it considers that action taken by an RB regarding professional misconduct by or fitness to practise of a practitioner has been too lenient, the CHRE can, and has, referred the case to court for reconsideration.

Professor Stone went on to consider the possible implications of the Foster and Donaldson reviews, which are looking at the regulation of non-medical health care professionals and doctors, respectively. Issues being examined included a review of the number of regulators and a possible harmonised approach to regulation, which raises a further question: is "one size fits all" the best policy since there may be legitimate differences between RBs? On the other hand there are attractions in whole sector regulation, which could reduce the regulatory burden and achieve economies of scale. Another possibility is consensus working between RBs with sharing of standards where appropriate. Currently, there is considerable variation in the way RBs operate and the sanctions available to them. Suggestions that might be considered for the future include: indicative sanctions guidance derived from RBs', the CHRE's and High Court decisions and actions; having evidence of what sanctions work best; and the possibility of out-sourced adjudication. Other issues that could come out of Foster and Donaldson include revalidation of practitioners, something that pharmacy has not yet moved towards, and the

new and extended roles being taken on by pharmacists and the regulation of the support staff needed to allow them to fulfil them.

Finally, Professor Stone considered harmonisation of regulation through Section 60 Orders. Their purpose is to speed up changes in legislation, but delays in implementation were hampering reform. A role that the CHRE can play is to work with regulators and the Department of Health to prioritise S60 orders in terms of optimal public protection. There are also opportunities for harmonisation through use of orders which would apply across health professions.

Section 60 Order

Points made by Professor Stone were borne in mind when members present considered the Pharmacy Law and Ethics Association's views on the proposals in the consultation on the Section 60 Order. Several issues were discussed, the first being the use of a S60 order as a device to regulate the pharmacy profession. It was suggested that control is being moved from primary legislation (the Pharmacy Act 1954) to a ministerial order under the general authority of the Health Act 1999, removing the possibility of Parliamentary scrutiny, contrary to the democratic process. However, it was pointed out that use of S60 orders as an implementation device is nothing new and has operated for many years in several areas, including health and safety legislation. Nonetheless, the meeting believed that it was undemocratic and resolved to express its view in its response to the consultation. Another matter of concern was that the Order would provide the Royal Pharmaceutical Society with power to require anyone with information regarding a pharmacist's fitness to practise to "inform" on them under pain of a court order. This would mean that pharmacists under investigation would be unable to consult friends, family, defence organisations, the Society's own Listening Friends scheme or take general advice, unless the provider could claim legal privilege, and this was considered contrary to human rights to privacy and confidentiality. On the suggestion in the consultation that registration requirements should in future include "appropriate attitudes and behaviours", it was considered this was an issue that required much deeper consideration before it could be implemented. For one thing, considerable additional resource would be required to provide students with sufficient clinical experience to follow role models in practice and to inculcate attitudes. Unlike other health professionals, pharmacy students currently spent little time in clinical placements before graduating.

The regulation theme was continued by Lynsey Balmer, head of professional ethics at

the Society, with an update on the review being undertaken on the Code of Ethics. She said that the code had traditionally been rules-based, but that the style and approach had changed in recent years. The current version, operative since 2001, had moved towards a principles-based approach. The latest review was necessary due to changes in pharmacists' roles and responsibilities (eg, medicines use reviews, prescribing), in working practices (eg, multidisciplinary and more patient-centred working) and in regulatory requirements (eg, changes to supervision regulations). Problems identified in the present code included a lack of flexibility and a need for application across all sectors of the profession. In its current form it had quickly become outdated. There was a need to promote professional judgement more, and it was considered not particularly "user friendly". A review group, including representatives from different sectors of pharmacy and from the public, is working on a new code. It has proposed that it should be based on a set of overarching principles supporting a culture of accountability and professional judgement, be a single code for both pharmacists and registered technicians, and not contain detailed technical requirements. It is aimed to complete the revision in time for approval and implementation at the Society's annual general meeting in May 2007.

One of the principles included in the new code will be "respect", an issue covered in a presentation by David Badcott, a pharmacist working in the Centre for Applied Ethics at Cardiff University, on dignity in the elderly. He reported on a three year, pan-European research project exploring the views of people aged over 65 years, health and social workers, and young and middle aged adults on the concept of dignity in old age. Its aims were to increase awareness of its importance in the lives of older Europeans, advance a more positive portrayal of them, and improve the quality of their lives and health care. Substantial agreement was established on the need for respect and recognition, participation, and dignity in care for older people. Health professionals' views on what constitutes dignified care were gathered, and an analysis made of what leads to failure to afford dignity in care for older people and what needs to be done to remedy it. The project's final report to the European Commission urged that older citizens be afforded their full rights as citizens with legal protection from harm and discrimination, that the culture of ageism be combated in all its forms, and that care for the elderly be adequately resourced to ensure that professionals can carry out their work without compromising their moral integrity and responsibilities for those under their care.

The annual seminar of the **Pharmacy Law and Ethics Association** took place in London on 24 May