

UNLICENSED MEDICINES

Demand for disclosure of patients' names

From Mr R. J. S. Shaw,
MRPharmS

A number of pharmaceutical manufacturers continue to demand the disclosure of patients' names before allowing supply of certain medicinal products. Typically the products concerned will be unlicensed or used "off label".

We believe that it is normally illegal, in terms of patient confidentiality, for a member of National Health Service staff ever to disclose patient details to an outside organisation. Indeed, the former Medicines Control Agency's own guidance on the interpretation of the relevant Statutory Instrument to this section of the Medicines Act 1968 (GN14) clearly states: "There is no legal requirement for individual patients' names to be supplied."

This practice puts procurement staff in the difficult situation of having to choose between breaking patient confidentiality or denying the patient essential treatment.

We would welcome a clear statement from the pharmaceutical industry that patient names will not be requested as a condition of supply unless specifically required as a condition of the marketing authorisation.

Bob Shaw
Chairman,
NHS Quality Assurance Committee

ALAN HUNTER, director of law, regulatory and intellectual property and secretary to the Association of the British Pharmaceutical Industry, replies: We write to respond to Mr Shaw's letter and offer our comments upon the labelling issues raised, although we should point out that it is the Medicines and Healthcare products Regulatory Agency that has responsibility for the regulation of medicines labels and for enforcement under the Medicines Act 1968 according to its interpretation of the law.

The rules relating to the supply of unlicensed medicines by pharmaceutical companies are complex but, in principle, if a doctor makes an unsolicited request for the supply of a product with a particular specification

that is not licensed in the UK, a company can obtain it and supply it to that doctor for administration to particular patients of his and on his direct personal responsibility. This is the case whether or not the product is specially manufactured (the products to which Guidance Note 14 mentioned by Mr Shaw applied) or is a finished product licensed elsewhere that is specially imported (products in part covered by old Medicines Act Leaflet 30).

Although in the UK such supply has sometimes been described as "named-patient supply", there has never, in fact, been a requirement that the patient actually be named to the company. This would be difficult when supplies are made to a practitioner to compose stock which may then be used for particular patients — whose names may not be known when the initial stock is supplied.

However, the company is required to keep records of the names of the health professionals to whom the unlicensed product is supplied. In MAL 30 the licensing authority also stated that, although not a requirement, it welcomed being informed (presumably by the relevant doctor) of the prescribing of unlicensed products, including the name and address of the patient, the condition to be treated and the drug to be administered.

Although the UK's implementation of EU pharmaceutical law has created some uncertainties as to how such products should be labelled by the company, there appears to be no statutory requirement for the company to put the name of the patient on the label. However,

there is no obligation upon companies to supply unlicensed medicines and, therefore, it is open to them to make it a condition of supply that the name of the patient be supplied to them, whether for product liability or other reasons.

Supply of the patient's name without the patient's consent would be a breach of confidentiality by the patient's doctor. Nevertheless, it is generally considered good practice for doctors to counsel patients on the fact that treatment with an unlicensed product is proposed and if, as part of this process, consent is given by the patient for supply of his or her name to the company in question, no problem ought to arise. Of course, the receiving company would be required to maintain confidentiality consistent with prevailing data privacy rules.

As regards off-label use, manufacturers cannot promote products in a way inconsistent with the approved prescribing information. However, the use of products off-label by doctors is not addressed in the pharmaceutical legislation because it is essentially a matter for the clinical judgement of health professionals. Certainly, unless a requirement arises from a special monitoring scheme in force pursuant to obligations contained in the marketing authorisation (of the type, for example, imposed in relation to use of Clozaril [clozapine]), there is no general obligation imposed upon a company to require information from doctors as to the names of patients for whom a company's licensed product has been prescribed off-label.

BRANDING

Collaboration should extend beyond borders

From Ms H. J. Evans, MRPharmS

Robert Lowe writes about the confusion surrounding the use of the name Benadryl for different ingredients (*PJ*, 7 June, p792). I can add another to his list. Benadryl capsules and liquid in the United States contains diphenhydramine.

Although I realise that this form is unlikely to appear on the shelves of a British pharmacy, imagine the confusion to tourists from each country. It would be reasonable for a British tourist purchasing Benadryl in the US not to expect drowsiness as a side effect if they have used either form of Benadryl available in the United Kingdom.

In the US many over-the-counter products are available for self selection so it is highly likely that there will be no pharmacist intervention and hence no verbal warning of the likelihood of drowsiness occurring.

I agree, therefore, that one brand name should be associated with one particular drug and that, in this age of international travel, collaboration on this issue should extend beyond borders.

Hilary Evans
Pembroke, Bermuda

PATIENT PACKS

Too much common sense

From Mr C. J. Cairns, FRPharmS

I thoroughly enjoyed John Wilson's "Broad Spectrum" article on patient packs (*PJ*, July 5, p12). Every word made sense and his suggestions were completely practical. Appropriate bodies — Prescription Pricing Authority, Pharmaceutical Services Negotiating Committee, National Pharmaceutical Association, etc — should act now to call for immediate implementation of his suggestions. The only barrier I see is that they are based on too much common sense.

Chris Cairns
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Anonymity will only be accepted in exceptional circumstances. These circumstances will be at the discretion of the editor and the decision made in consultation with the correspondent.

WORKFORCE

Do vacancies exist through lack of interest?

From Mr S. M. Koumis,
MRPharmS

Anyone sifting through the back pages of *The Journal* might be forgiven for thinking there is a recruitment crisis in community pharmacy. The large number of vacancies at first sight might appear to be related to a shortage of pharmacists. But surely, if that were the case, then would not most if not all these pharmacies/dispensaries close or cease to function normally without a qualified pharmacist? Since I am not aware of such problems, I can only assume that there must be at least one pharmacist present at any time for each of these vacancies.

According to the recent Pharmacy Workforce Census, carried out by the Royal Pharmaceutical Society (*Pfj*, 1 March, p314), 36 per cent of community pharmacists prefer to work as self-employed locums. This figure represents around 8,000 out of the 22,000 community pharmacists, which is well over a third. So am I right in assuming, then, that these vacancies exist, not through the lack of manpower, but through lack of interest?

Resorting to importing European pharmacists (along with their language difficulties and cultural differences) will not help matters. The Government's planned skill mix policy, the aim of which is to introduce highly skilled technicians who could perform the duties of a pharmacist without direct supervision, is also unhelpful.

If community pharmacies, and notably the large multiples, are to resolve the vacancy problem, they need to entice some of the 8,000 self-employed pharmacists into permanent employment, even if it is part-time employment. However, gimmicks such as child care facilities, company bonuses and pharmacy associations are unlikely to coax anyone into making this transition.

Self-employed pharmacists enjoy autonomy and freedom in their jobs and are unlikely to give it up for the straight-jacket restrictions imposed by most retail multiples. Companies need to look hard at their terms of employment for pharmacists and

their management policies, and become less autocratic in order to attract some of the highly qualified workforce that is available.

Sotirakis Koumis
Ilford,
Essex

VETERINARY PHARMACY

Why has the diploma been suspended?

From Mr A. Potbecary,

The Marsh report recommended that pharmacists should have greater involvement in the supply of medicines (purchased and prescribed) to animals. I hope to join the register next month and believe that I do not have the necessary knowledge to respond to symptoms in animals, or to become involved in the larger scale dispensing of veterinary prescriptions that the report envisages. The only teaching in this area I received as an undergraduate covered the legal necessities involved in supplying products against a veterinary prescription.

This is an area that particularly interests me and represents another new role for community pharmacists. It is a role in which we would not compete with other practitioners for the right to offer the new services we are best qualified to provide, and which all community pharmacists could provide, independent of the agenda of their local primary care trusts. Furthermore, it would improve the image of the profession and could be a valuable additional source of income. In addition, the National Pharmaceutical Association has been encouraging members to consider becoming involved in this area of practice.

Bearing all this in mind, I decided that I would like to undertake some further training in this area, and so contacted the Royal Pharmaceutical Society to ask about the Diploma in Agricultural and Veterinary Pharmacy. I was informed that the Society had suspended the course and that if it is reinstated, this will be advertised in *The Journal*. To my knowledge, this is the only course of its kind on offer and I believe that it is not a wise move on the part of the Society to suspend it, bearing in mind that it is

expected that the proposals of the Marsh report will be implemented soon. The diploma was and could be a valuable resource to those members of the profession who want to start practising in this area, and I fear that we will be unprepared when customers approach us for advice on the care of their animals.

I am curious to know why the diploma has been suspended.

Andy Potbecary
Portsmouth

LIZ GRIFFITHS, secretary, Veterinary Pharmacists' Group, replies: During the past six years, the Society's Veterinary Pharmacists' Group (VPG) has been committed to promoting veterinary pharmacy at every opportunity. Although the group is relatively small, it nevertheless plays an active role in all animal health related matters — both in the United Kingdom and in the European Union.

The VPG has committed a great deal of time and resource into promoting the pharmacy profession to the recent Marsh and Competition Commission inquiries. The recommendations, subsequently proposed by both inquiries, will offer not only an improved service to the public but exciting new opportunities to pharmacists wishing to become involved in veterinary pharmacy in the future.

The Society recognised the need for specialised training in veterinary pharmacy many years ago. The Society wishes to assure its members that it has remained committed to the diploma ever since. However, the VPG identified a need to revise the syllabus and agreed to make it more user friendly at the same time, by converting the companion animal module into a distance learning package. The new diploma will also complement a new textbook, dedicated to veterinary pharmacy, that will be available from the Pharmaceutical Press from 1 December.

All this has taken time. However, the Society is delighted to announce that the new updated and revised Diploma in Agricultural and Veterinary Pharmacy will be available in January 2004. It will provide pharmacists with an invaluable knowledge base with which they can venture confidently into the field of veterinary pharmacy.

Readers interested in the diploma or wanting additional advice and information relating

to veterinary pharmacy matters, can contact me on 020 7572 2409 (e-mail lgriffiths@rpsgb.org.uk).

MODERNISATION

Pharmacy has never been viewed more positively

From Mr H. Patel, FRPharmS

Michael Burden rightly quotes me asking, "where is the bogeyman?" and he answers the question by saying that "the bogeyman, like the devil, is in the detail" (*Pfj*, 12 July, p46).

But what does this mean? He says that he is struggling with the complex difficulties and that the Royal Pharmaceutical Society's Council's plan may need to be "reviewed and refined, even groomed" and he hopes that the Council will do that.

The Council will do that because it has been forced to do that by the membership and the new President has indicated that the Council must listen to the membership. The tone has changed, the timetables have been modified to a certain extent, complexities are breaking down and action to find a new solution has begun in earnest. The members must note it and thank those who raised the alarm.

However, Mr Burden says that "until and unless the profession puts the patient and the public at the centre of our thinking we shall rightly be accused of self-interest, and we will not enjoy the support of the public or Government — which we seem desperately to want and need".

This is nonsense. Some 24,000 community pharmacists and 5,000 hospital pharmacists are putting patients and the public first every day. If this were not the case, there would already have been an outrage since six million people visit our pharmacies daily. Public and parliamentary support for community pharmacy and against the Office of Fair Trading report has been unprecedented. Not a single parliamentarian has spoken out against community pharmacy in the press, in the Houses of Commons and Lords, or in committees.

Pharmacy has never been viewed more positively. Pharmacy will have a strong future as an independent profession free from

Government meddling, but that independence will not remain if people are allowed to surrender it voluntarily.

New models for the Society as a representative and regulatory body will be produced that meet pharmacists', parliamentarians' and the public's expectations. More significantly, pharmacy has a good opportunity to capitalise on the goodwill it has generated.

Pharmacists seeking alternatives to "the prescribed medicine" are not reckless but they are proud, passionate and intelligent. Mr Burden, it is time to stand tall and go forward boldly in the knowledge that the public and their elected MPs are not in a mood to be booted around.

There is an expectation that the profession will improve its standards, and become more open, integrated and community spirited. It must embrace newer ideas on developing efficient and sustainable communities by getting increasingly involved in public health and community development.

While change is essential, there is a difference between a confident, proud and independent profession and a spineless Government lackey. Thankfully, most members of the Society appear to know the difference.

Hemant Patel

Member, Royal Pharmaceutical Society's Council and Modernisation Steering Group

Missing the point

From Mr M. Koziol, MRPharmS

Those pharmacists who attended this year's annual general meeting and special general meeting will not be surprised that Michael Burden continues to miss the point with regard to the modernisation of the Royal Pharmaceutical Society (*PJ*, 12 July, p46).

As a body that sets and maintains standards, the Society is inherently an organisation that serves the public interest and it joins the ranks of literally hun-

dreds of standard setting organisations in this country that do the same. However, as a body that maintains the honour and promotes the interests of all pharmacists it is unique, since there is no other organisation that singularly performs this role.

Little surprise then that the members believe strongly that the Society's original proposals are a pup. Let us all hope that when the Council announces its "soon to be revamped" proposals it succeeds in securing the broad support of the membership.

For if it does not then the Society will be unable to proceed.

Mark Koziol
Birmingham

THE SOCIETY

It is more of a college than a society

From Dr P. M. Worling, FRPharmS

The article by Anthony Cox on changing the name of the Royal Pharmaceutical Society (*PJ*, 12 July, p44) may well raise a few eyebrows. However, it is for similar reasons the National Association of Pharmaceutical Distributors (NAPD) changed its name same years ago to the British Association of Pharmaceutical Wholesalers (BAPW) in order to make the activities of its members absolutely clear.

If this suggestion is to find merit, perhaps it is worth considering the word "society" also. This gives the impression that we are a social organisation — more of a club than a serious body of professionals. An alternative is the word "college" — a body of persons having certain rights and privileges devoted to common pursuits. The "Royal College of Pharmacists of Great Britain" has an air of authority to it.

Peter Worling
Edinburgh

PJ ONLINE

The Pharmaceutical Journal's website, *PJ Online*, can be found on the internet at www.pjonline.com. At the site, pharmacists can take advantage of a daily news services and can view the contents of the current weekly issue. The site also contains a searchable archive of *PJ* material and a searchable database of current job advertisements. There is also a feedback facility, whereby browsers can send e-mails to the editor and to the advertisement manager.

CPD

Can I serve on a careers panel?

From Mr K. G. Bridger, MRPharmS

Dr Robert Dewdney's response (*PJ*, 5 July, p13) to David Shenton's comments about voluntary health care advice given by retired pharmacists was clear and definitive. However, Mr Shenton's letter prompts me to raise a further point about a similar issue.

I, too, am a retired pharmacist and from time to time I have been asked to represent pharmacy on a careers panel conducted at a local school. These occasions are conducted on an informal basis with a "What's my line?" question-and-answer structure. I am sure many other pharmacists provide this kind of service for young people and, like me, do so on a voluntary, unpaid basis. I have no intention of being involved with continuing professional development when it becomes mandatory for practising pharmacists. Does this mean, when the time comes, I will no longer be able to offer my services in this way, even though my responses to questions never include specific medical advice?

Ken Bridger
Ringmer, East Sussex

Dr ROBERT DEWDNEY, head of education, Royal Pharmaceutical Society, replies: Mr Bridger will have to judge for himself whether or not his giving this form of advice, ie, information about pharmacy as a career, is consistent with a statement/undertaking (to gain categorisation as "non-practising") that he is not engaging in the science or practice of pharmacy in the widest sense.

Not going to be encumbered with the burden of bureaucracy

From Mr E. A. Silverberg, MRPharmS

I should like to add my support to Dr Norman Harris's remarks (*PJ*, 12 July, p48). I registered in 1958. My career has been varied, from owner of my own community pharmacy for 35 years to group senior pharmacist for a 40-branch company until my semi-retirement two years ago.

During that time I have developed and set up residential and nursing home dosage systems. I have been responsible for the induction and training of pharmacists joining the multiple that I have been associated with for the past 12 years in addition to supervising the development of the company electronic patient medication record systems. None of these activities could have been performed without the necessary ongoing training. I also provide emergency locum cover in my area.

I have no intention of being encumbered with the burden of bureaucracy necessary to record my ongoing continuing professional development once this becomes mandatory. If this necessitates my resignation from the register, then so be it.

Eric Silverberg
Swansea

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CPD

Should industrial pharmacists remain on the register?

From Mrs A. B. V. Chalmers,
MRPharmS

Bamboozled by all the close print concerning the modernisation of the Royal Pharmaceutical Society and, as a rather disinterested industrial pharmacist, I thought I might get some understanding of whether the Royal Pharmaceutical Society represented me if I attended a Charter roadshow. So, I attended the one at the Society's headquarters on 30 June.

I am grateful to the Secretary and Registrar for a clear presen-

tation directed at the audience and then the bonus elucidation from Marcus Jolley, a non-pharmacist, as to the "regulatory" and "professional" remit of the Society and the mechanisms controlling them. Those on the Council and steeped in the Charter bandy these terms around, as well as talking about "regulating the profession". I find it all very confusing; clear definitions are called for. I dare say they may have been given in the *PJ* but I would rather skip the pages than plough through turgid material looking for them.

Many in the audience, particularly women, would have liked more discussion on an understandable matter closer to our hearts — the proposed active and non-active sectors of the future register. Please may we have a definition of "practising" pharmacist? I may be the proud pos-

essor of a continuing professional development certificate but I know not whether I am "practising". I do not dispense, an activity for which only a pharmacist may be responsible. We in industry do jobs which call upon our pharmacy education and knowledge but these jobs may also be done by non-pharmacists. Even the demanding role of a Qualified Person is not exclusively the domain of registered pharmacists.

Will the Society please indicate for which of the sectors I should be putting myself forward? If it is the active sector and presuming the annual registration fee to be higher for active than for non-active folk, what will I be getting for my money? I do not find convincing the argument that membership fees for other professions allied to health are much greater. Why did ours rocket up by such a large amount

this century? Will the reorganisation and new Charter come with an ever higher annual registration fee? What will be the precise justification? Will it be worth an industrial "pharmacist" remaining on the register at all?

Antonia Chalmers
London W6

Dr ROBERT DEWDNEY, head of education, Royal Pharmaceutical Society, replies: The Council's proposal document (insert, *PJ*, 8 February) went into this issue and the consultation that followed certainly elicited answers to directly relevant questions (*PJ*, 29 March, p456). The outcome is that it will be for the "non-practising pharmacist" to make, and if called upon (on evidence to the contrary) to sustain, a statement/undertaking that he or she is not engaged in any

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aspect of the science or practice of pharmacy. This can be taken to mean any activity or advice-giving to do with medicines or health care. (A false statement/undertaking will be a disciplinary matter.) All other pharmacists will be deemed practising and subject to the mandatory CPD requirement.

Wrist-play!

From Mr J. B. Paige, MRPharmS

Until I read the letter from M. J. Moon (*PJ*, 12 July, p48) I thought I was the only one who had been singled out for a "special" login password by the education division of the Royal Pharmaceutical Society.

As a critic of the Council and its policy on continuing professional development, I assumed

that someone was trying to send me a message when I was given the password "wrist-play"!

Barrie Paige
Guernsey, Channel Islands

THE JOURNAL

Absence of evidence is not evidence of absence

From Dr P. H. Rowe

A recent news item in *The Journal* (12 July, p39) provides a nice example of the way in which non-significant statistical results can be misunderstood. The item concerns a study of oral contraceptive use and stroke. The study

result was reported as a 95 per cent confidence interval for the odds ratio. The null hypothesis (exactly equal risk of a stroke in users and non-users of oral contraceptives) would be represented by an odds ratio of 1.0. The upper and lower limits were 0.86 to 3.61. The magic figure of 1.0 is therefore included within this range and we are forced to conclude that the null hypothesis cannot be discounted.

However, the title of the article claims "Study dispels fears over contraceptive pill use and stroke". This implies that safety has been positively demonstrated — an extension that cannot be justified. If we wanted to go that extra step and "dispel fears", the correct approach would be to agree upon what odds ratio would be small enough not to be a source of fear and then inspect the upper limit of the confidence interval. If, for example, we had agreed that any-

thing less than a four-fold increase in the odds was acceptable, then the upper limit of "only" 3.61 would be tolerable and our fears would truly be dispelled.

The general point is that any non-significant result only means that we have not shown an effect to be present, it does not mean that we have shown it to be absent. Or, as is frequently said in bars up and down the country, "absence of evidence is not evidence of absence".

Phil Rowe
*Reader in Pharmaceutical
Computing
John Moores University*

E-MAIL

E-mail correspondents are asked to give a postal address or membership number.