REPORT OF MEETINGS OF THE NPA BOARD OF MANAGEMENT, ASSOCIATED ORGANISATIONS AND SUB-COMMITTEES

October 2004

Electronic Signatures on prescriptions

The NPA has responded to the MHRA consultation – MLX 310 – to amend the POM Order to allow the use of advanced electronic signatures on prescriptions that are transferred electronically. Legislation had been amended in 2001 to allow electronic signatures to be used for the three ETP Pilots in England. These concluded in 2003 and there is now a need for a permanent change to the legislation to facilitate the introduction of universal ETP commencing in 2005.

The NPA agrees that it is necessary to amend the Prescription Only Medicines (Human Use) Order 1997, so that the electronic prescription used in ETP can be legally dispensed. It recognises the characteristics of advanced electronic signatures as being a fundamental safeguard to the authenticity and originality of electronic prescriptions and so fully supports the use of an advanced electronic signature. In agreeing to the amendment the NPA made the following additional comments:

- There should be a single standard agreed for the advanced electronic signature, which is adhered to by all prescribers. In saying this, the NPA recognises that the standard will be updated from time to time, to take account

of technology advancements or security risks. It is essential that in implementing the proposal, provision is made for this.

- Pharmacists dispensing prescriptions are under an obligation to ensure that the prescription is genuine. As part of this, pharmacists will need to be satisfied that the prescriber has the authority to prescribe. It is not clear from the proposals how pharmacists will know this. The NPA has asked for clarification on whether the existence of an advanced electronic signature is in itself confirmation of authority.

- The NPA is pleased to see that the proposal does not oblige prescribers to transmit prescriptions electronically, nor to print an electronic signature onto a paper prescription. The NPA believes that a transitional period will be helpful in allowing both prescribers and dispensers make the preparations necessary to move to universal ETP. During this period it is essential that those pharmacies that do not have the necessary equipment to receive electronic prescriptions are not disenfranchised from dispensing them. This would hinder patient access to care and would be in direct conflict with the principles of equity and fairness referred to in the draft regulatory Impact assessment. During the transitional period, the NPA has suggested that prescribers be encouraged to sign all prescriptions so as not to hinder patient care. This will be particularly important in the case of "tokens". Patients are likely to assume that tokens are prescriptions and will suffer a delay in receiving medicines if unsigned tokens are presented at a pharmacy that is incapable of handling ETP. Accordingly, the NPA suggests that tokens be signed by the prescriber during the transitional period.

- Comprehensive guidance on the use of advanced electronic signatures must be issued to healthcare providers and to Primary Care Trusts and all other

stakeholders affected by ETP so that the implications of the use of advanced electronic signatures and their operation in practice is fully understood.

- The NPA believes that all prescribers, supplementary or independent, and from whichever health discipline, should be able to use an electronic signature and thus issue prescriptions by electronic transmission. Further, the procedures for issuing electronic signatures should be such as to ensure that signatures are issued as soon as prescribers acquire this status.

- The NPA notes the intention that Controlled Drugs in Schedules 1, 2 and 3 will not be included in the proposals. Whilst recognising the need for separate consideration of controlled drugs, the NPA believes that consideration should be given to including CDs in the arrangements. The prescribing and supply of CDs is currently the subject of major overhaul as a consequence of the Shipman Inquiry. The NPA believes that the opportunity should be taken to include the use of electronic signatures for CD prescriptions within this review.

RPSGB retention fee

The NPA has responded to the proposals for an increase in the personal retention fee. The personal retention fee is to increase by 25%. This is well ahead of both cost of living and wage inflation which are currently running at around 1.8% and 3.8% respectively. Whilst this very large increase will fall on individual pharmacists, it will be met by pharmacy owners either directly, where the employing or engaging pharmacy agrees to pay the fees, or indirectly through salary increases or engagement costs.

The RPSGB says the increase is needed to create a firmer financial foundation for the Society's core activities, to establish healthy reserves and to support the Charter Objects of professional leadership, development and representation. Further, the Society says there is a need to look to the retention fee to provide a secure income base that would underpin all the Society's core professional and regulatory activities. The NPA supports fully a strong Society; there can be no doubt that if the Society is to be an effective and modern regulator/professional body it needs to be properly resourced. However, like any other organisation it needs to engage in careful and prudent budgeting. It is not clear from the limited published detail, how the proposed increase is to be apportioned between the various activities or to exactly how the proposed increase will be deployed. Accordingly it is impossible to say whether the increase is justified.

The detail given in the *Pharmaceutical Journal* of 14 August 2004 states that the activity of the Society has grown but the registration fee has failed to keep pace: to the extent that it is now the lowest of the UK health professions. This ignores the fact that there have already been significant increases in the retention fees over recent years. In fact the overall increase in retention fee since 2000 has been 49% - i.e. around 12% per annum. This contrasts with underlying price inflation which was around 8% over the same period. If the proposed increase is approved, this will amount to an 86% increase in fees since 2000.

The RPSGB retention fee has been compared with that paid by other health professions. A comparison with other healthcare professions is only meaningful if the comparison is like for like. Whilst there is clearly a convergence in the regulatory agenda as amongst healthcare professions, each regulatory body will pursue its own objectives and will charge a fee that reflects this and associated infrastructure costs. Further, the fee level will inevitably reflect the relative earning potential of the registrants.

The Society has hitherto relied upon surplus income from its publishing activity. This is a perfectly legitimate means of subsidy. However, it now suggests that it is not prudent to do this given that publishing is a "risk market" and will instead use any profit from publishing will be used to bolster reserves to an "appropriate level". No indication is given as to what will amount to an appropriate level – but it is to be assumed that the Society must have some idea of this level and of the projected level of profitability from publishing because it states that the appropriate level will be reached in five years. The Board are concerned that without firm detail as to how the increase in fees will be deployed by the Society, and its policy on reserves, the membership may be exposed to successive increases in registration fee as Society workload increases.

Included in the Society's proposals is the creation of a split register – practising and non practising. This will, by default, abolish the part-time registration. Part-timer registration will therefore face a 220% increase in fee from £116 to £256. Many part-timers will consider this increase (particularly when coupled with mandatory CPD) as simply too much to warrant their remaining on the practising register to allow them to engage in the occasional locum. If this happens, there could be a significant drain from the Register particularly when it is considered that around 30% of the current Register is "inactive" and of the remaining 70%, around one third are engaged part-time. The impact of withdrawal from the Register could thus have a significant financial impact on the Society. It would be a paradox indeed if the effect of the proposed increase in retention fee resulted in a reduction in income for the Society. The NPA Board urges the Society to factor this into its proposals.

But the impact of pharmacists de-registering will not simply be financial. Any reduction in the number of pharmacists willing and able to practise will have significant impact on service provision. Community pharmacy in particular is looking to take on more roles. There is currently a shortage of pharmacists. Any exacerbation of the pharmacist

shortage will frustrate the objectives of the profession to enhance pharmaceutical care to local communities.

The NPA believes that the Society must be properly resourced to carry out its regulatory and professional functions to best effect. And members of the Society must be prepared to pay the appropriate fee associated with registration. However, increases to this fee must be reasonable and supported by a properly costed budget.

Premises retention fees

In collaboration with the PSNC and CCA, NPA has also responded to the proposed increase in the premises retention fees. As part of this response the NPA cannot agree that the reasons given in support of the proposed increases for the registration, retention and restoration fees provide sufficient justification for such an unacceptable rises in fees.

As it occurs annually, the retention fee has the most significant impact upon pharmacy owners. The proposed increase to the retention fee - 20% - is far greater than would have been expected and is out of all proportion to underlying price and wage inflation (currently running at around 1.8% and 3.8% respectively). It should also be noted that this proposed increase follows a large increase of 24% last year. If allowed therefore the combined increase over two years will be 44%.

A number of "issues" have been given as contributing to the proposed increases. However, a list of issues is not the same as a detailed budget reflecting how any increased revenue will be applied to dealing with these issues. Further, no account appears to have been taken of the proposed increase in the personal retention fee of 25% for 2005. It is the view of respondents that there must be at least some "double-counting" associated with the proposed increases in premises fees. Against this background we cannot see any justification for increasing the retention fee at a rate higher than inflation.

The lion's share of pharmacy turnover comes from the provision of NHS pharmaceutical services – around 80% for the typical pharmacy. Accordingly, the cost of fees for registration and retention should be included as part of overall pharmacy remuneration. The global cost of the retention fees is not insubstantial (if the proposed increase is approved the total cost will be around £1.5 million for English pharmacy contractors). A new contract structure and remuneration framework has been agreed between PSNC, Department of Health and NHS Confederation and contractors are shortly to be balloted toward accepting this. The new contractual framework is founded upon reimbursing the cost of service and providing fair funding. The registration and retention fees are in the view of respondents fees that should therefore legitimately be included in overall pharmacy funding and thus added to pharmacy's global sum.

Regulatory Impact Unit (RIU)

The NPA has been approached by the Regulatory Impact Unit (RIU) with a view to examining the regulatory burden facing pharmacists. The RIU is based within the Cabinet Office and works with other government departments, agencies and regulators to ensure that regulations are fair and effective, and help reduce bureaucracy and red tape. Pharmacy's core business centres on the safe and effective supply and administration of medicines - and so, by its very nature, pharmacy operates in a highly regulated environment. However, it is the NPA's view that the regulation and its enforcement as it impacts on day to day pharmacy practice must be both necessary and proportionate. The NPA will be asking its members for examples of legislation that is unnecessary or over burdens members with red tape.

Review of waste regulations

The NPA has responded to a consultation on a review of the Special Waste Regulations 1996 in England. The principal proposal is that POMs be no longer classified as hazardous waste (with the exception of cytotoxics and cytostatics). The NPA supports this proposal. It recognises that no longer classifying POMs as special waste would resolve some of the day to day practical difficulties facing community pharmacists in dealing with waste medicines.

The NPA's response highlights the important public health role played by community pharmacists in collecting, storing and then safely disposing the large quantities of out-of-date and unwanted medicines returned by the public. Indeed, the safe disposal of unwanted medicines is to become an essential service under the new contract. Without this readily available conduit for safe disposal, it is likely that medicines would constitute a major hazard through pollution of the sewage system or through accidental and non accidental poisoning.

The current regulations cause a number of problems for pharmacists:

- Special waste (POMs) cannot be mixed with non-special waste (GSLs)

- Pharmacists can receive huge volumes from patients (it is not unusual to receive bin liners full of unwanted medicines mixed with other items such as medical devices, appliances and dressings). Returns need to be sifted to ensure different types of waste are segregated. This is time consuming and problematic

- Pharmacists are required to denature Schedule 2 Controlled Drugs

- Some activities carried on by pharmacies in conjunction with the disposal process (such as denaturing CDs, removing medicines from strips etc for disposal, transporting medicines for disposal or operating syringe and needle exchange schemes, may require the licensing of pharmacists either as “waste processors” or “waste carriers”

For all of these reasons the NPA believes that it is inappropriate to classify all POMs as special (hazardous) waste and supports the proposal that only cytotoxics and cytostatics be classified as hazardous.

ends

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