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Modernising the NHS Community Pharmacy in Scotland

I wish to make several comments on the contents and intentions contained in the Consultation paper issued under the above title. My comments are as follows: -

1 General Observations

(a) The proposals succeed in moving the "community branch" of the profession from a "sale and supply" profession to one where the cognitive elements of the body of knowledge available (but not used by the NHS) in the profession is formally recognised. This movement began with clinical pharmacy in the USA in the late 1950s to early 1960s and ward/clinical pharmacy in Scotland in the middle to late 1960s. These movements were essentially hospital based and in my view the legal and philosophical strong adherence to sale and supply delayed a similar movement in retail pharmacy. The advance of pharmaceutical care as a concept has assisted in removing this blockage or obstacle.

(b) It would be advisable to define "Community pharmacy" in the NHS Acts since at present there is no legal definition nor is the term contained in any of the major and relevant Health or Medicines Acts. It was an invention of the RPSGB and however much it has become part of common parlance the term still has no legal standing or definition.

2 Specific Comments

(a) Section 1

This is a reasonable but not complete summary of the current position. For example, it does not fully describe "the origins of the global sum" nor how the Government decides the increase which is acceptable to it year on year. In later sections of the Consultation paper it is suggested that the introduction of new and upgraded services is likely be cost neutral even although the negotiations are not yet completed. Does that mean that the immediate future total of the "global sum" is already known to the Executive?

(b) Section 2

The standard of the qualifications of support staff needs to be defined either by the profession or the Health Department and given some sort of legal standing.

In addition the standard, the number and the location of premises available for the provision of out - of - hours services needs to be firmed up. With the new arrangements

for GP services similarly new administrative and legal arrangements are required for pharmaceutical services.

(c) Section 3

In this section two questions are posed. Comments on the first question are as follows: -

- (i) The simple answer is "not quite". No indication of how "care and access needs" are to be objectively measured is given. Detailed consideration must be given as to how these are to be assessed. To lean simply on how each and every Board will determine this, a parallel situation to "post-code prescribing" will certainly arise. As you know the Executive has already condemned this latter situation. It would be better to have parameters now than later condemn what Boards decide. Left as it is to the Boards (as the Consultation paper seems to suggest) will certainly be interpreted differently in Wester Ross than in Shettleston. That in itself is not to be condemned. However, if this results in gross deprivations in aspects of patient care in a Board area the decision of the Board will be condemned by the public and the profession and the Executive put into a difficult position. Better for the Executive to give targets to the Boards that arrows to the public and the profession.

It follows, therefore, that how Boards objectively measure care and access needs to be done in such a way as to provide a degree of equality which is acceptable to the public and well as to the profession and the Boards. This will require more study, guidance and possibly legislation than the Consultation paper reveals.

Comments to the second question are as follows: -

- (ii) Yes. There are many more models and it is a hostage to fortune to suggest (as the question implies) that there is not. The first question to be put before suggesting alternatives is "what other models have been considered and rejected and why?" For example, it is easy to suggest a salaried service but I presume it has been rejected because the profession would strongly oppose that and the inhibitive costs such a change would incur. It is noted that the Consultation paper states that if a Board has a need that the private sector cannot or will not meet then it will have the authority to meet that need by other means. How else than by a salaried service; particularly if the need cannot be met from the private sector in a neighbouring Board for the geographical and logistical rather than ideological reasons.

What are the objective assessments which are to replace "necessary and desirable". Will the PCSP Plan (PCSP) be for one, two or five years or forever? What factors will induce change if change is necessary and over what time scale? How often is "periodic" review envisaged?

Applications for Core Services and/or local services are to be advertised. Will applicants have to pay a fee as in Eire? And if not why not?

(d) Section 4

It would be sensible to build in some mechanism which would require employee and/or locum pharmacists to feed back to the Board and its advisors comments on the standard and quality of the premises and service provided by principals. Such a provision should be legally enforceable if such pharmacists are, rightly, to be held responsible for their own acts and omissions. In such circumstances they must have a say (and an acceptable outlet for such a say) on the conditions under which they are required to provide a professional pharmaceutical service.

(e) Section 5

Before attempting to answer the question posed in this section, it is necessary to comment that in the Consultation document "direct patient Care" is not defined nor is there any attempt to give clear guidance on what is to be regarded as "indirect patient care" and how this differs from the direct version. There is in logic a legitimate argument that all care provided by community pharmacists is "direct patient care". The Executive should, therefore, spell out the care given (or to be given) by community pharmacists, which it regards as "indirect" and why.

The proposal to replace direct supervision by a description of supervision of a more "modern" approach is to be welcomed. However, it must be noted that such supervision is not defined in the Medicines Act 1968. Indeed in the formulation of the Medicines Bill the term and the context was directly lifted without question or debate from the Pharmacy and Medicines Act 1941 which in turn lifted it from the Pharmacy and Poisons Act 1933 [s18 (a) (iii)], again without question. In all of these Acts supervision refers to the sale or supply of a substance controlled by the relevant Act (and/or regulations made thereunder). In this context it should be noted that NHS dispensing is not a sale. Section 52 of the Medicines Act applies to sale and supplies made in the course of a business. The provision of services under the NHS is treated as the carrying on of a business [s 131(5)]. However, the dispensing of a medicinal product (as defined by the Medicines Act 1968) on a NHS prescription is not a sale but a 'supply in circumstances corresponding to a retail sale' (Appleby & Sleep [1968] 2 All ER 265). It should also be noted that the only current definition of supervision in the context of the provisions of the Medicines Act 1968 and its predecessors (see above) is that given by Lord Caldecote in 1943. This opinion resulted from an appeal in the case of Roberts v Littlewood, Mail Order Stores Ltd. I quote it in full below for the sake of completeness.

"... the man who was upstairs might have been a person who was exercising personal control of a business, but I do not think that, while he was upstairs and therefore absent, he could be a person who was supervising a particular sale. It has been suggested that a man can supervise a sale without being bodily present. I do not accept that contention.... Each individual sale must be, not necessarily effected by the qualified person, but something which is shown by the evidence to be under his supervision in the sense that he must be aware of what is going on at the counter, and in a position to supervise or superintend the activities of the young woman by whom each individual sale is effected' [1943 1 All ER 271].

I have received an informal opinion that that definition by Lord Caldecote would be that which would be currently accepted under the Medicine Act 1968. I think it was common knowledge at the relevant time that the insertion of the adjective (or is the adverb?) "direct" before the word supervision in the 1948 Health Acts and consequently in the 1978

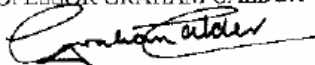
[28(20) Act, quoted in the Consultation document was inserted as a "direct" consequence of the 1943 judgment.

The Noel Hall Report of 1970/71 on the NHS hospital pharmaceutical service in the United Kingdom addressed this problem head on and suggested that instead of supervision or direct supervision, three levels of involvement of pharmacists in care/work practices should be adopted. At that time the professional bodies were against definitions if applied to Community pharmacy. Some hospital pharmacists and virtually all Community pharmacists would have also preferred to rely on "direct supervision". Never-the-less the hospital service now successfully uses these three levels of supervision. These should now be legally adopted by the NHS Acts. In my view it is necessary to so legally authorise (as the Consultation document suggests) the "setting up of safe systems of work". For the above reasons it would be negligent and perhaps cause endless court battles if the presence of "supervision" and not "direct supervision" in the Medicines Act 1968 were to be solely relied upon for the purpose of NHS dispensing.

[As a side issue it is interesting to note that the hard-line taken by Lord Caldecote (and which the Scottish Executive is now doing something about was not taken by the High Court in 1927 in a not dissimilar situation. The relevant case was *Kingsbury v Director of Public Prosecutions* [(1927), 136L.T.312]. In construing regulations, which the Dangerous Drug Regulations now replace, the High Court held in that case that the administration of a dangerous drug (as defined) "by or under the direct personal supervision of a duly qualified practitioner" did not involve the personal presence of the medical practitioners when each dose was taken.]

My comment, therefore, is that the Scottish Executive should incorporate into the NHS Act and the regulations made thereunder the "Noel Hall" definitions of "supervision" since that is what is now required for the present day and in the future of community pharmacy. Perhaps the Community pharmacy section of the profession will oppose this for economic and job security reasons as it did in 1970 - 1971. The hospital pharmaceutical service has since 1971 shown that such reasons have proven to be totally unfounded. I am sure it was the Executive's intention in composing Section 5 of the Consultation document that it had in mind to construct such a definition to appear in future NHS legislation. I cannot believe it intended anything other than that.

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