

THE MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY'S
CONSULTATION ON "SALE, SUPPLY AND ADMINISTRATION OF MEDICINES BY
ALLIED HEALTH PROFESSIONALS UNDER PATIENT GROUP DIRECTIONS"

1. Executive Summary and Recommendations

The Medicines and Healthcare Products Regulatory Agency (MHRA) published a consultation paper (attached) on 31 July 2003 on extending "Patient Group Directions" (PGD) more widely among the HPC's registrant professions and throughout the UK.

The Council is asked to support the proposals in the MHRA consultation paper

2. Review of Patient Group Directions

The full title of the MHRA consultation is,

**"SALE, SUPPLY AND ADMINISTRATION OF MEDICINES BY ALLIED
HEALTH PROFESSIONALS UNDER PATIENT GROUP DIRECTIONS**

- (i) Amendments to the Prescription Only Medicines (Human Use) Order 1997**
- (ii) Amendments to Medicines (Pharmacy and General Sale – Exemption) Order 1980**
- (iii) Amendments to Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 "**

Its proposals are to, " enable Dietitians, Occupational Therapists, Prosthetists and Orthotists and Speech and Language Therapists to sell, supply or administer medicines under such directions and ensure that PGDs for such professionals comply with specified legal criteria. This would be achieved by amendments to the Prescription Only Medicines (Human Use) Order 1997 (the POM Order), the Medicines (Pharmacy and General Sale – Exemption) Order 1980 and the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980. "

This, in effect, brings these four professions up to the same level in PGDs as is currently enjoyed by Orthoptists, Radiographers, Paramedics, Chiropodists/Podiatrists and Physiotherapists. An extract from a briefing note on PGDs is annexed to explain more fully what they are. For completeness, Operating Department Practitioners (ODP) are also already covered by PGDs. There is a section on this in the current DH consultation paper on ODPs.

The DH and the Allied Health Professions (AHP) strongly support this development, and the Council may like to note the Chief Health Professions Officer's briefing on it from the AHP Bulletin for July 2003,

" **Supply of medicines by AHPs**

The number of professions which can supply medicines under Patient Group Directions is to be expanded.

At present, all AHPs can supply a medicine to a patient under a patient-specific direction – a written instruction by a doctor or dentist.

In addition, chiropodists, orthoptists, physiotherapists, radiographers, ambulance paramedics and optometrists can supply medicines to patients under a Patient Group Direction (PGD) – a written instruction for the supply or administration of medicines to a group of patients not individually identified.

The department has made it clear that the majority of clinical care should still be provided on an individual, patient-specific basis and PGDs should be reserved for those limited situations where there is an advantage for patient care without compromising patient safety.

However, it is now looking at extending the list of AHPs that can use PGDs to dietitians, prosthetists, orthotists, occupational therapists, and speech and language therapists. "

3. **Relationship to the Prescription Only Medicines (Human Use) Order, 1997**

At the additional meeting of the Education and Training Committee on 28 May 2003 it was noted that this consultation was imminent. Members asked the Executive to investigate whether it would have any implications for the Chiropodists/Podiatrists position under the Prescription Only Medicines (Human Use) Order, 1997 (the POMs Order). After studying the consultation, holding discussions with the Society of Chiropodists and Podiatrists and in the light of the Health Professions Order 2001 (Consequential Amendments) Order, 2003, it is clear that there is no correlation. The Consequential Amendments Order makes all the necessary changes to the POMs Order.

4. **Recommendation**

- That the Council should respond to the MHRA consultation paper on Patient Group Directions, supporting the proposals (and the consequential option 2 in Annex D).

Annex

Extract from a Briefing Note on PGDs from the Society of Chiropractors and Podiatrists

A Patient Group Direction (PGD) is a specific written instruction for the supply and administration, or just the administration, of a named medicine in an identified clinical situation. It applies to groups of patients who may not be individually identified before presenting for treatment.

PGDs are drawn up locally by doctors, pharmacists and other health professionals, signed by a doctor or dentist, as appropriate and approved by an appropriate healthcare body.

Within the health service, the practice of using PGDs has allowed podiatrists, nurses and other health professionals legally to supply and administer medicines in accordance with the requirements of sections 55 (1)(b) and 58 (2)(b) of the Medicines Act 1968.

There are a number of reasons for their use. These include providing timely access to treatment, reducing waiting times and appropriate use of professional skills. A frequent use of a PGD by podiatrists is for drawing up an emergency drug administration protocol for the administration of, for example, adrenaline by the intramuscular route in the treatment of anaphylaxis.

It is possible for any drug scheduled as a Prescription Only Medicine, with the exception of controlled drugs, to be included in a PGD. The guiding principles are essentially that the podiatrist must restate in writing the general professional responsibility not to undertake treatments that lie beyond the individual's personal level of experience and skill and that they will abide by the limits of authority within the direction.