Royal Pharmaceutical Society of Great Britain

Law and Ethics Bulletin

Non-medical prescribing and mixing of medicines in palliative care

Following a number of enquiries, the Medicines and Healthcare products Regulatory Agency (MHRA) has issued a statement[1] regarding the prescribing of licensed medicines intended to be mixed together before administration via a syringe driver.

Legislation[2] defines what would be considered as the manufacturing of medicines. The mixing of two licensed medicines, where one is not a vehicle for the administration of the other, falls within the definition of "manufacture" and results in a new, unlicensed, product being produced. This is the result when two licensed medicines are mixed together prior to administration via a syringe driver in palliative care.

The mixing of substances with, for example, water for injection before parenteral administration does not fall within the definition of "manufacture".

Legislation[3] only allows doctors, dentists and supplementary prescribers to prescribe unlicensed medicines. Pharmacist independent prescribers and nurse independent prescribers cannot lawfully prescribe unlicensed medicines.

The Society and the MHRA are aware that it is long standing accepted practice in the area of palliative care to mix a number of licensed medicines together for administration via a syringe driver. The MHRA is currently seeking provisional advice on the possible options for changes to medicines legislation, in advance of the usual public consultation procedures required under legislation[4].

The Society and the MHRA recognise that palliative care requires special consideration and do not wish to obstruct safe practice and the provision of effective pain relief to patients.

Until such time as legislation is amended, the MHRA has stated that it will not consider taking enforcement action for breaches of medicines legislation by a

pharmacist (or nurse) independent prescriber engaging in the long standing accepted practice of prescribing and administering (and providing directions to others to administer) a mixture of licensed medication via a single injection or a syringe driver unless it would be in the public interest to do so. This also applies to those supplying, mixing and administering medicines in accordance with the directions of the prescriber. However, each case would be considered individually.

The Society is of the same view in that it reserves the right to take action if it would be in the public interest to do so, based on the individual facts of a case.

Patient Group Directions (PGDs)

The MHRA statement, and this Law and Ethics Bulletin, does not apply to patient group directions (PGDs). This is because the legal framework[5] for PGDs excludes unlicensed drugs.

Because the mixing of two licensed medicines, (where one is not a vehicle for the administration of the other), results in an unlicensed medicine, such a process cannot be included in a PGD.

Notes:
[1] MHRA "Statement on non-medical prescribing and mixing medicines in palliative care": www.mhra.gov.uk/Howweregulate/Medicines/Medicinesregulatorynews/CON025660.
[2] Section 132 of the Medicines Act 1968.
[3] Sections 9 and 10 of the Medicines Act 1968 and Schedule 1 of the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994.
[4] Section 129 of the Medicines Act 1968.
[5] Article 12 of the Prescription Only Medicines (Human Use) Order 1997.