

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations amend the Human Medicines Regulations 2012 ([S.I. 2012/1916](#)) (“HMRs”) which govern the arrangements across the United Kingdom for the licensing, manufacture, wholesale dealing and sale or supply of medicines for human use. The amendments extend to the whole of the United Kingdom.

Regulations 214(1) and (2), 220 and 221 in Part 12 (Dealings with medicinal products) of the HMRs impose prohibitions on the sale, supply and administration of prescription only medicines, general sale and pharmacy only medicines. Chapter 3 (Exemptions) of Part 12 of the HMRs contains exemptions to those prohibitions for certain individuals to sell, supply and administer certain medicines. These Regulations introduce amendments that enable suitably qualified registered dental therapists and hygienists and registered pharmacy technicians to sell, supply and administer certain medicines relevant to their professional practice in reliance on the applicable exemptions in chapter 3 to the prohibitions.

Regulation 3 inserts a new defined term of registered pharmacy technician into regulation 213(1) of the HMRs.

Regulation 4 adds registered pharmacy technicians to the list of registered healthcare professionals in Schedule 16 to the HMRs. The effect of this amendment is to add registered pharmacy technicians to the list of health care professionals who may supply and administer medicines under a Patient Group Direction (commonly referred to as a ‘PGD’) in the course of their professional practice.

Regulation 5 amends Parts 2, 3 and 4 of Schedule 17 to the HMRs in relation to registered dental therapists and registered dental hygienists. These amendments enable registered dental therapists and hygienists who are qualified to supply and administer the medicines listed in column 2 of the amendments to sell, supply and administer them to individuals whom they are treating in the course of their professional practice in accordance with the exemptions contained in regulation 235 (Exemption for sale, supply or administration by certain persons).

Impact assessments relating to this instrument have been prepared and copies can be obtained from the Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU and are available on the [www.legislation.gov.uk](http://www.legislation.gov.uk) website.