

Legal and ethical implications of independent prescribing

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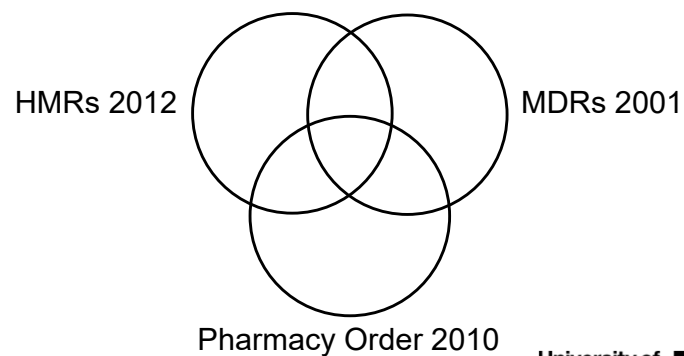
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Outline

- Legislation and guidance
- Roles and responsibilities
- Liabilities and sanctions

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Relevant legislation



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Relevant legislation

- Human Medicines Regulations 2012/1916
- Misuse of Drugs Regulations 2001/3998
- Pharmacy Order 2010/231
 - Relevant rules made under the Order
- General Pharmaceutical Council (Registration Rules) Order of Council 2010/1617

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Human Medicines Regulations

8 “appropriate practitioner” means an appropriate practitioner within the meaning of regulation 214;

214(3) The following are appropriate practitioners in relation to any prescription only medicine ...

(e) a pharmacist independent prescriber

8 “pharmacist independent prescriber” means a person who

(a) is a pharmacist; and

(b) is noted in the relevant register as qualified to order drugs, medicines and appliances as a pharmacist independent prescriber

Misuse of Drugs Regulations

6B ... a pharmacist independent prescriber may prescribe any controlled drug specified in Schedule 2, 3, 4 or 5

Pharmacy Order

- What (legally) makes a pharmacist an independent prescriber?

27(1) The Council may make ... provision in rules ... in connection with annotations to entries in the Register to denote specialisations, and may in particular make provision with regard to ... (e) the standards of proficiency ... necessary for a registrant to achieve in order for an annotation ... to be made

Registration Rules

12(1) ... a registrant ... may apply ... to have an annotation in respect of a specialisation made to the registrant's entry in the relevant part of the Register

12(3) The application form must ... (a) require the applicant to ...

(v) provide evidence which is sufficient in the opinion of the Registrar to demonstrate that the applicant meets such standards of proficiency ... as are set in rules under article 27(1)(e) of the Order

- How does one demonstrate that one has obtained these standards?

Standards for...

- Standards for the education and training of pharmacist independent prescribers (January 2019; revised October 2022)
 - GPhC/PSNI
- Standards for the initial education and training of pharmacists (January 2021)
 - GPhC (adopted by PSNI)

Routes into independent prescribing 1

1. GPhC-accredited IP program
 - Currently offered by 49 universities
 - Formerly requiring two years' appropriate patient-orientated experience post registration, in a relevant UK practice setting
 - 26 days of teaching and learning activity
 - 12 days (90 hours) of learning in a practice environment whilst being supervised by a designated prescribing practitioner (DPP)

Routes into independent prescribing 2

- Since 2021-'22 all new MPharm students will qualify as independent prescribers (i.e. graduating in 2025; qualifying in 2026)
 - Teaching and learning activity integrated into the MPharm
 - 90 hours of "learning in practice specifically related to prescribing" during the foundation training year

Roles for independent prescribers

- Primary care
 - GP surgeries
 - Mental health services
 - Addiction
- Specialist secondary care
 - Paediatrics, oncology, HIV, etc.
- Internet

Prescription charges

- Current NHS prescription charge? £9.65
- 1971? 20p
- If CPI-linked? £3.56
- Private
 - Cost + mark-up + dispensing fee

Business model



Two separate businesses

1. Website that invites people to upload their US prescriptions
 - Prescriptions accessed from website by PIP, who transcribes them and posts them to...
 2. UK-based pharmacy, which dispenses these prescriptions and couriers them overseas
- PIP is the bridge between the two

Munawar Iqbal (2059871)

- 3-9 May 2022
- Pharmacist independent prescriber
 - Contracted to transcribe prescriptions from overseas jurisdictions (US) to be dispensed in the UK (ca. 7,000/month)
 - He was paid £1,000/month for this (14p per prescription)

Allegations

- Inadequate checks for suitability of medications
- Acted outside the scope of competency
 - Prescribed medication for animals

RPS Framework

- Royal Pharmaceutical Society Competency Framework defines independent prescribing as “prescribing by a practitioner, **who is responsible and accountable for the assessment of patients** with undiagnosed or diagnosed conditions and for decisions about the clinical management required, including prescribing”

Expert witness testimony

- Experienced PIP
 - “It is therefore my opinion, based on the evidence I have seen, that the registrant prescribed indiscriminately, irrationally, and unsafely without the necessary clinical assessment/checks and suitable monitoring expected within the RPS competency framework, and thus far below their scope of practice and competency as a pharmacist independent prescriber”

Outcome

- Principal hearing (9 May 2022)
 - 4 months suspension with review
 - Interim measures
- Review (4 October 2022)
 - 6 months conditions with review
- Review (7 March 2023)
 - Conditions to lapse on 8 April 2023

Two separate businesses ???

1. Website (Medimart; <https://www.medixrx.com/>) that invites people to upload their US prescriptions
 - Prescriptions accessed from website by PIP, who transcribes them and posts them to...
2. UK-based pharmacy, which dispenses these prescriptions and couriers them overseas
 - Medix Pharmacy, Stevenage

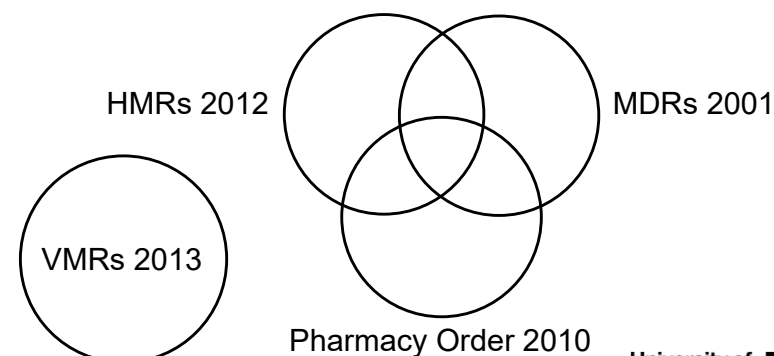
Companies House

- Infohealth Ltd
 - PATEL, Rajive Shailesh (struck-off; August 2016)
- Medimart Health Ltd (dissolved August 2021)
 - PATEL, Rajive Shailesh
 - STRANSKY, Roby
- MDX Healthcare Ltd T/A Medix Pharmacy, Stevenage
 - CHEUNG, Daniel Chun Ying (2056659)
- 74 Miles Ltd; Honey Bright Ltd; Healthinajiffy Ltd
 - PATEL, Rajive Shailesh
 - CHEUNG, Daniel Chun Ying

Veterinary prescriptions

- Mr Iqbal did his practice certificate in independent prescribing at [redacted], where one of the compulsory modules is entitled *Legal and Ethical Aspects of Prescribing*.
- In oral evidence, he “explained that he thought he was allowed to prescribe medication for animals, but he admitted that he had not done sufficient research into the relevant guidelines to be sure.”

Relevant legislation



Other cases involving PIPing in 2022

- BOATENG, Genevive (2212407)
- RASHED, Mohammed (2079936)

A parting gift

- <https://www.assuredpharmacy.co.uk/>