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IMO Submission to the Expert Taskforce on the Expansion of the Role of the Pharmacy

October 2023

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IMO Submission to the Expert Taskforce to Support the Expansion of the Role of the Pharmacy

The Irish Medical Organisation (IMO) is the representative body for all doctors in Ireland and welcomes the opportunity to make a submission to the Expert Taskforce to Support the Expansion of the Role of the Pharmacy.

Doctors and pharmacists have a long history of collaboration, working together in the community each in their different roles. The role of the doctor is to diagnose and advise patients with impartial information on the best course of treatment based on the symptoms presented and bearing in mind that resources for healthcare are limited. The role of the pharmacist is to dispense prescribed drugs, ensuring appropriate supply and counselling patients on the use of prescribed and non-prescribed drugs.

However, in response to the challenges facing healthcare systems today - of an ageing population, increased rates of chronic disease, economic constraints and a shortage of doctors -many jurisdictions have sought to expand the role of pharmacists into activities normally carried out by doctors. The IMO is concerned however that the transfer of tasks from Doctors to Pharmacists is unsupported by the evidence and has implications for patient safety, quality of care and healthcare sustainability. The IMO fears that pharmacy prescribing will increase medicalisation of self-limiting illness and lead to fragmentation of care with worse outcomes, especially in instances of delayed or incorrect initial diagnosis by community pharmacy.

Patient Safety

Doctors must undergo five - six years of undergraduate medical education, and following the intern year, a minimum of four years of post-graduate training before they qualify as a General Practitioner and can enter the Specialist Register . Only then are they are considered to be competent to diagnose and treat patients in their communities. Continuity of care and a holistic approach are the cornerstone of GP care.

Pharmacy education and training centres around understanding pharmacological and biochemical processes, which are essential to the medical treatment of patients, however this type of education should not be confused with medical education of the kind received by medical practitioners.

Diagnosing and prescribing skills acquired by doctors should not be conflated. Prescribing options for a patient must only be considered after appropriate diagnosis and with due regard for alternative diagnoses and alternative treatment options (including no treatment). There is a considerable risk where patients presenting with undifferentiated symptoms are assigned diagnostic labels without adequate clinical examination and/or treated based on a narrow range of therapeutic options, decided by a provider with limited medical knowledge thus increasing the risk of delayed diagnosis, mis-diagnosis or over-treatment of self-limiting conditions.

This is particularly the case in situations where a less common disease can present with a symptom ‘usual’ to a common minor illness. A good example is, vulval, vaginal or lower urinary tract carcinoma presenting with urinary symptoms such as frequency and/or dysuria (painful urination) . There is significant chance that a pharmacist first pathway will result in instances of delayed identification and delayed correct treatment with increased hazard to the patient in terms of ultimate outcomes. The assignment of a false diagnostic label is particularly hazardous in this context. Such disease presentations in patients, while infrequent, present side by side with common

presentations for uncomplicated urinary tract infections, the management of which has shifted considerably in recent years[1]

Differentiation, even for experienced providers is complex and often hinges on physical examination, interval re-examination, and knowledge of past specific presentations by the patient under consideration (longitudinal care). The same principle and hazard applies to many common presentations – eg epigastric pain / headache / conjunctivitis etc. where continuity of care and same provider review allow for the application of time interval as a diagnostic assistant.

Taken as a whole, when considering the cohort of patients with symptoms likely related to uncomplicated urinary tract infection we are likely to see with a pharmacist led intervention;

1) A small added number of significant mis-diagnoses / delayed detection / delayed treatments in relating to severe underlying illness. [2] We anticipate incorrect treatment with antibiotics in females with symptoms relating primarily to estrogen deficiency.
2) A significant number of cases of patients with minor self-limiting symptoms being over treated with unnecessary antibiotics – eg premature treatment in elderly patients or patients with high expectation of medicines use. In an era of rising anti-microbial resistance, over prescribing of antibiotics is a major concern.
3) A smaller number of patients with known past resistance patterns to antibiotics being treated in the first instance with an incorrect therapeutic agent based on a 'blind' first choice by the pharmacist.

Quality of Care - Access to Contraception

In some jurisdictions, some oral contraceptives, mainly the Progesterone only Pill, are available over the counter in pharmacies without the need for a prescription. While this measure has been introduced largely to support ease of access, the Progesterone Only Pill has been found to be less effective than other Long Acting Forms of Contraception at reducing unplanned pregnancies as they reduce patient error. Studies also show that women are more likely to choose this form of contraception if they receive comprehensive information from their healthcare provider. [3]
Risk of Unplanned Pregnancy

- 90 per 1000 women using Progesterone only pill in the first year of use compared to
- 8 per 1000 using copper coil
- 2 per 1000 with Mirena/Kyleena/Jaydess
- 0.5 per 1000 with Implanon. [4]

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[1] position-statements-dipstick-urinalysis-for-utis.pdf (hse.ie)

[2]Kmietowicz Z, 2019, Delaying antibiotics in over 65s with UTI may increase risk of sepsis *BMJ* 2019; 364:1922 doi: https://doi.org/10.1136/bmj.l922
Atwool J, 2022, AMAQ survey cites 'alarming' complications from pharmacy pilot, RACGP - AMAQ survey cites 'alarming' complications from pharmacy pilot

[3] 'What do women say? Reproductive health is a public health issue'. PHE. 2018 https://assets.publishing.service.gov.uk/media/5b64731940f0b668806ca8e1/What_do_women_say_reproductive_health_is_a_public_health_issue.pdf
Gibbs SE, Rocca CH, Bednarek P, Thompson KMJ, Darney PD, Harper CC. Long-Acting Reversible Contraception Counseling and Use for Older Adolescents and Nulliparous Women. J Adolesc Health. 2016 Dec;59(6):703-709. doi: 10.1016/j.jadohealth.2016.07.018.

[4]Faculty of Sexual and Reproductive Health (FRSH) Guidelines , amended July 2023 https://www.fsrh.org/standards-and-guidance/

Like all medicines, oral contraceptive are not without risk or potential side effects (mood change, loss of libido, intermenstrual spotting or missed periods, breast tenderness, headaches, migraine etc)

There are numerous forms of contraception available and needs and preferences are different for women at different stages in their life. Individuals and couples must be able to make an informed choice about contraception based on age, sex, individual medical history, family history the efficacy of the contraception, potential side effects, etc.

Issues such as informed consent, patient safety, coercive situations, young people – all require the privacy and the skills of a vocational trained doctor. Indeed the assessment and consultation with the GP provides an invaluable opportunity to check in on particularly vulnerable patients including:

- teenagers, (those underage and trying to be responsible)
- victims of domestic abuse, (the consultation provides an opportunity to ask how everything is going at home)
- asylum seekers (particularly where there are concerns relating to FGM).

Sexual health is not just about contraception and preventing unwanted pregnancies. Access to contraception should form part of a comprehensive women's sexual health programme in General Practice that includes:

- Advice on contraception
- Access to contraception including Long Acting Reversible Contraceptive (LARC) methods. –
- Advice on sexually transmitted infection (STI), screening and testing for STIs – (Since 2019, the STI notification rate in females aged 20-24 years increased by 34%; chlamydia notification rate increased by 35%; gonorrhoea notification rate increased by 75%) [5]
- Advice on fertility and pre-conception
- Advice on menopause
- Counselling on crisis pregnancy

Conflict of interest

Patients and the State have always been well served by the separation of the prescriber (the doctor) and the dispenser (the pharmacist) role as a clear conflict of interest can arise when a healthcare professional incurs a financial gain from the medicine they prescribe.

This conflict of interest is recognized in national legislation and the Medical Council codes of ethics.

For example

- The Pharmacy Act 2007 prevents a medical practitioner from having a beneficial interest in a pharmacy or a pharmacist having a beneficial interest in a medical practice. A retail pharmacy business and a medical practice are also prohibited from carrying out activities together.
- Inducements to both prescribers and dispensers including gifts and hospitality are restricted under the Medicinal Products (Control of Advertising) Regulations 2007.

[5] https://www.hpsc.ie/a-z/sexuallytransmittedinfections/publications/stireports/title-23089-en.html#:~:text=The%20increase%20in%20the%20total,trichomoniasis%20have%20remained%20relatively%20stable.

- The Medical Council has clear guidelines in place to support transparency between the medical profession and the pharmaceutical industry requiring doctors to declare any potential conflicts of interest and limiting the influence of the pharmaceutical on educational events and material.
- GMS rules only allow doctors to dispense in rare circumstances where there is no pharmacist available to a majority of their patients.

Legislators and regulators – must be compelled to recognise that a clear conflict of interest arises when a pharmacist takes on an expanded prescribing role, particularly given the growing number of retail pharmacy chains and the vertical integration of pharmaceutical wholesale distribution and pharmacy retail.

Since deregulation of the market in 2003 there has been a significant growth in retail pharmacy. There are approximately 1,900 pharmacies operating in Ireland[6], of which approximately 45% are owned by chains of 3 or more pharmacies of which almost half are non-pharmacist owned.[7] The largest chains are growing rapidly – Since acquiring the McCauley Pharmacy group in 2022, Pharmacy wholesaler Uniphar (who claim c50% of the wholesale market) now owns 140 pharmacies nationwide and has distribution relationships with a further 280 pharmacies.[8] US pharmaceuticals group McKesson Corp recently sold its Irish business , which includes the 90-outlet chain of Lloyds pharmacies and the United Drug wholesale group, to the Phoenix Group, with a growing wholesale and retail presence across Europe.[9] While the Boots Ireland, a member of the Boots Walgreen Alliance now owns 89 boots stores in Ireland. [10]

At the same time in response to falling turnover and rising costs , the pharmacy sector has sought to reposition itself in patient services.

While these services may not generate direct sales, pharmacists that have introduced patient care facilities and services have reported increases in shop sales and improved customer relationships.[11]

With the corporatisation of pharmacy and pharmaceutical distribution, the ethical obligations of community pharmacy staff can be submerged into contractual obligations. The pharmacy chains Lloyds and Boots both came under fire in 2016 for abusing Medicine Review Schemes. Lloyds pharmacy chain paid €12m in settlement fees to the HSE following investigation into additional drug dispensing fees it received from under its MyMed Scheme. It was reported that "an internal newsletter found Lloyds had set targets for its stores and highlighted how staff visited local day care centres to sign up patients."[12] Similarly a *Guardian* investigation alleged that Boots managers in the

[6] Pharmaceutical Society of Ireland 2023, PSI Data https://www.thepsi.ie/gns/Registration/public-registers/Statistics.aspx
[7] IPU, 2023 Annual report of the IPU Executive Committee https://ipu.ie/news-publications/annual-report/
[8] https://www.uniphar.ie/static/about-us/news/uniphar-to-buy-mccauley-pharmacy-for-about-50m/ https://www.independent.ie/business/irish/uniphar-consolidates-pharmacy-market-with-purchase-of-mccauley-chain/41999518.html
[9] https://lloydspharmacy.ie/pages/phoenix-acquisition
[10] https://www.boots.ie/editorial-/about-boots/about-company-information
[11] Fitzgerald Power, Retail Pharmacy benchmarking Study 2012
[12] https://www.independent.ie/irish-news/pharmacy-chain-forced-to-pay-hse-12m-after-probe-into-dispensing-fees/35050425.html , https://www.independent.ie/irish-news/lloyds-pharmacist-is-senior-member-of-standards-watchdog/35053159.html

UK were directing chemists to give medicine-use reviews to customers who didn't need them, for company profit. [13]

Other areas of concern are

- "Linked sales" policies which link the purchase of one pharmaceutical product to other pharmaceutical products which may or may not be necessary, again risking the over-medicalisation of minor illness.
- Pharmacists frequently stock and sell vitamin supplements, homeopathic remedies and other products of limited or no proven therapeutic value. Research has also highlighted that commercial factors can encourage pharmacists to recommend products which may not be supported by evidence.[14]
- Recently doctors have witnessed a considerable market drive to sell near patient testing kits, which present a considerable risk of incorrect diagnosis, over diagnosis and under diagnosis.[15] (examples include self-check 'bowel health' tests , gluten intolerance tests, 'thyroid health' tests, 'stomach ulcer' test and 'prostate health' tests. These lack both the sensitivity and specificity required for use in undifferentiated populations). Vulnerable patients may perceive these clinically invalid and unregulated tests to be relevant if sold in a pharmacy setting, with a consequent stream of referrals when abnormal results ensue.
- Pharmacists also offer services such as 24 hour ambulatory Blood pressure monitoring, ECGs, with no context in which to interpret the data nor expertise to treat it.

Interruption to Continuity of Care

The implication that an increased role for pharmacy in prescribing will help reduce demand on General Practice shows a profound misunderstanding of the importance of continuity of care in General Practice and risks further fragmentation of care.

International evidence shows that patient focused continuity of care in General Practice is key to improved patient outcomes, reduced inequalities in health, and long-term cost effectiveness. [16] For that reason GMS patients register with one GP but can receive their medication from any pharmacy.

Continuity of care is also an essential part of chronic disease management. The close relationship between GP and patient that develops over time allows GPs to better detect changes in health status, provide preventative care and support patient conformity to therapy suggestions from the GP

[13] https://www.theguardian.com/business/2016/apr/13/boots-staff-under-pressure-to-milk-the-nhs-says-pharmacists-union

[14] Rutter and E. Wadesango, 'Does evidence drive pharmacist over-the-counter product recommendations?', *Journal of Evaluation in Clinical Practice*, Vol. 20, Issue 4, August 2014, pp. 425–428.
P. P. C. Chiang, 'Do pharmacy staff recommend evidenced-based smoking cessation products? A pseudo patron study', *Journal of Clinical Pharmacy and Therapeutics*, Vol. 31, Issue 3, June 2006, pp. 205–209; P.

[15] Orth, Matthias, Vollebregt, Erik, Trenti, Tomaso, Shih, Patti, Tollanes, Mette and Sandberg, Sverre. "Direct-to-consumer laboratory testing (DTCT): challenges and implications for specialists in laboratory medicine" *Clinical Chemistry and Laboratory Medicine (CCLM)*, vol. 61, no. 4, 2023, pp. 696-702. https://doi.org/10.1515/cclm-2022-1227

[16] Starfield B, Shi l, Mackinko J, Contribution of Primary Care to Health Systems and health, The Milbank Quarterly Vol 83. No 3 2005 (pp457-502)
Sandvik H, Hetlevik O, Blinkenberg J and Hunskaar S,2022 Continuity in general practice as predictor of mortality, acute hospitalisation, and use of out-of-hours care: a registry-based observational study in Norway British Journal of General Practice 2022; 72 (715): e84-e90. DOI: https://doi.org/10.3399/BJGP.2021.0340
Barker I, Steventon A, Deeny SR. Association between continuity of care in general practice and hospital admissions for ambulatory care sensitive conditions: cross sectional study of routinely collected, person level data. BMJ2017;356:j84. doi:10.1136/bmj.j84 pmid:28148478

as well as reduce hospitalisations. In the interests of patient safety it is vital that patients with chronic conditions, continue to have both their conditions and treatments reviewed by a medical practitioner on a regular basis. Many conditions can deteriorate significantly over time and prescriptions are issued by a medical practitioner for a limited time to allow for review. In addition prescribed medicines may cause adverse reactions, interact with other pharmaceutical products or doses may need to be adjusted depending on the individual. All of these are issues which are addressed during the review. Any delay to or diversion of the review has implications for patient safety.

Brief visits for minor illness present an opportunity for to build GP-Patient relationships. It is often during these interactions that items of care such as opportunistic screening take place and afford opportunity to discuss lifestyle and disease prevention[17] Time intensive consultations for complex illness may not always afford the same opportunities.

Currently there is a capacity issue in General Practice and further supports are needed, however, the diversion of care from GPs to pharmacists risks further fragmentation of care, increased medicalisation and consequently workload for GPs.

Nonetheless the IMO recognises that there may be value to patients and the state in allowing pharmacists to extend prescriptions in certain emergency situations and in allowing GMS patients to access certain OTC drugs without prescription which are currently available to private patients.

Rather than supporting pharmacy prescribing, further consideration should be given to supporting the integration of non-commercial / non retail pharmacists, to enhance prescribing safety, either as part of the practice team or at the request of the GP.

Recommendations

Empowering Pharmacists to extend Prescriptions

- **The IMO is of the view that the separation of the prescriber/dispenser role serves both patients and the health service well and should remain in place.**
- **Extension of prescriptions for certain medicinal products beyond 6 months runs contrary to best practice and poses a significant risk to patient safety.**
- **Nonetheless, the IMO recognizes that there may a benefit to patients by allowing pharmacists to extend prescriptions in emergency circumstances – where dispensing the prescription is necessary to the on-going treatment of the patient and the patient is unable to get a GP appointment. - This would require an amendment to the Medicinal Products (Prescription and Control of Supply) Regulations.**
- **The extension period should be limited to one week for certain drugs.**

Empowering Pharmacists to prescribe within their scope of Practice

- **Again the IMO is of the view that the separation of the prescriber/dispenser role serves both patients and the health service well and should remain in place.**

[17] https://www.hse.ie/eng/about/who/healthwellbeing/making-every-contact-count/

- **To expand the role of pharmacists within their scope of practice, the Department of Health and the HSE could consider permitting pharmacists to dispense OTC drugs for minor ailments to GMS patients without the need for a prescription. - This would be limited to OTC items reimbursable to pharmacy contractors under the GMS - Eg Lyclear for scabies, Brufen / pool suppositories, Paracetamol & Brufen tabs, Fybogel, Nexium, etc**
- **OTC drugs that contain Codeine should be excluded – eg ibuprofen/codeine products - due to the potential for dependency and the risk of serious harm from pro-longed use - including renal tubular acidosis and severe hypokalaemia[18]**
- **The Pharmaceutical Society of Ireland should monitor community pharmacy to ensure strict compliance with dispensing guidance and protocols – The National Suicide Research Foundation have highlighted research that found that adherence to legislation on the sale of paracetamol products is poor.[19]**
- **Regulations should be enhanced to restrict linked selling and other sales incentives.**

- **Finally, the Department of Health and the HSE should give further consideration to supporting the integration of non-commercial / non retail pharmacists, to enhance prescribing safety, either as part of the practice team or at the request of the GP –As above, pilots have shown that pharmacists working as part of the General Practice team, have influenced the safety and quality of prescribing and have the potential to improve patient outcomes.[20] The 2019 Agreement between the IMO, the Department of Health and the HSE[21] provided for a pharmacy supported medicines usage review process to support GPs. This was identified as a priority, however to date no progress has been made from the HSE.**

[18] https://www.hpra.ie/docs/default-source/3rd-party-documents/mims-articles/hpra-mims-article---nurofen-plus-(codeine_ibuprofen)-march-2023.pdf?sfvrsn=4

[19] Daly C, Are tougher regulations on paracetamol availability justified? NSRF https://www.nsrf.ie/are-tougher-regulations-on-paracetamol-availability-justified/ Ni Mhaolain AM, Davoren M, Kelly BD, Breen E, Casey P. (2009) Paracetamol availability in pharmacy and non-pharmacy outlets in Dublin. Ireland. *Ir J Med Sci.* 178(1):79–82.

[20] Cardwell, K., Clyne, B., Moriarty, F. *et al.* Supporting prescribing in Irish primary care: protocol for a non-randomised pilot study of a general practice pharmacist (GPP) intervention to optimise prescribing in primary care. *Pilot Feasibility Stud* **4**, 122 (2018). https://doi.org/10.1186/s40814-018-0311-7

Tan ECK, Stewart K, Elliott RA, George J. Pharmacist services provided in general practice clinics: a systematic review and meta-analysis. Res Soc Adm Pharm. 2014;10:608–22.

[21] https://www.hse.ie/eng/about/who/gmscontracts/2019agreement/agreement-2019.pdf