End pharmacists' monopoly on selling certain drugs

Evidence is lacking that oversight by pharmacists has benefits, writes **Paul Rutter**, who thinks that the US dichotomy of prescription-only and non-prescription drugs is simpler

In January 2015, the UK Medicines and Healthcare Products Regulatory Agency announced that oral diclofenac would no longer be available as a non-prescription drug sold exclusively under the direction of a pharmacist (a "pharmacy medicine"). Instead, it would revert to being available only on prescription because of a small but notably increased risk of cardiovascular side effects.[1]

Despite oral diclofenac having previously been restricted to sale through pharmacies the UK regulator decided that risks could not be ruled out—even in short term use and at lower doses than those prescribed. This implies that, even with this system of restricted availability, doubt exists that pharmacists (and their staff) can supervise sales to consumers appropriately.

Given this decision, should any drugs still be restricted to sale only with a pharmacist's supervision? Globally, many governments have healthcare policies that advocate for less prescription-only control of drugs. The mechanism for deregulation varies, but consumers worldwide can access drugs more easily than ever before.[2] Use of non-prescription drugs is the most prevalent form of medical care in the world, with a global market worth an estimated €73bn (£52bn; $82bn), and their sales growth now exceeds that of prescription-only drugs.[3]

Many countries (including Australia, Canada, France, New Zealand, Sweden, and the United Kingdom) foster the declassification of drugs that are under prescription-only control by having a category of drugs that can be bought only at a pharmacy. These "pharmacy medicines" must be sold either by pharmacists or under their supervision. In the past 30 years this approach to reclassification has seen many therapeutic agents made available to consumers without a prescription, including proton pump inhibitors (in the United States and the European Union), orlistat (EU), triptans (UK and Germany), and β_2 agonists (Singapore and Australia).

Helping patients care for themselves

Some may argue that the pharmacy medicines category helps pharmacists in the community to help patients care for themselves[4] and that the more drugs become available this way, the more opportunity this gives pharmacists to reduce people's need to access general medical services, thereby reducing doctors' workloads.[5]

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These arguments have been used by government and pharmacy organisations to champion a bigger role for community pharmacists. This may seem sensible and appropriate; pharmacies manage large numbers of consumers who seek advice and help for many minor illnesses.[2 6] But does their four to six years of drug training mean that they should have a monopoly on selling some drugs? The evidence indicates not.

Firstly, community pharmacists may well act as a "screen," effectively triaging people away from doctors' surgeries by supplying these drugs, but doctors still have a high case load of minor illness. In part, this is because recent reclassifications from prescription-only control to pharmacy medicines have all come with extra conditions to their sale, compared with when they are dispensed under prescription. (For example, UK pharmacists cannot give 1% hydrocortisone to children under 10, and "cautions in use" for triptans when prescribed by doctors became contraindications for retail sale.) This often results in consumers having to seek the drug through prescription from their doctor.

Pharmacists have also questioned the value and use of some drugs that have been recently deregulated to pharmacy medicines,[7] and consumer demand for some of these drugs has been low: in the UK, for example, poor sales led to the withdrawal of simvastatin.

Secondly, and more importantly, if pharmacies are to hold a monopoly on selling some medicines they need to show value to consumers in terms of health outcomes, when compared with consumers purchasing these drugs without restriction. Evidence is lacking on this, but what is known is that community pharmacy practice has been criticised over its ability to sell pharmacy medicines appropriately all of the time.[8-10] More research is needed to establish whether and how pharmacists' intervention affects patient outcomes. Furthermore, questions have been raised about pharmacists' diagnostic ability, which tends to use rigid and established questioning strategies.[11 12]

Time for a two tier system

In the UK in the past four years just three drugs were switched from prescription-only control to pharmacy medicine status, but 12 pharmacy medicines were switched to general retail sale. The need for a pharmacy medicines category seems limited, especially as government policies seek to widen drugs' availability. The decision to switch diclofenac back to prescription-only control will surely make manufacturers more cautious in seeking pharmacy medicine status for their prescription-only drugs, especially as the deregulatory process is lengthy, complex, and costly.

In conclusion, without credible evidence to support the pharmacy medicines monopoly—namely, that pharmacy intervention improves patient outcomes—it is only a matter of time before a two tier system of prescription or non-prescription drugs becomes the standard model, as in the US.

This system is easy to understand: access to medicines is obtained either with a prescription or from any retail outlet. This is less confusing for consumers and increases accessibility, but it still allows pharmacies to sell drugs and gives them a chance to demonstrate their worth.

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References and competing interests are in the version on thebmj.com.

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NO HOLDS BARRED Margaret McCartney

Medicine is a bit of a giggle

Medicine is serious, pressurised, and stressful; it deals with death, life, ethics, human suffering, tragedy, hard statistics, and the Krebs cycle. It's also a bit of a giggle.

I can hardly tell of the truly funny things that have happened in the consulting room, what with confidentiality and all. But some things get repeated often enough to be at least partly, and probably totally, mythical.

Take, for example, the GP on a house call whose patient complained of her washing machine being broken. Bemused, the doctor fixed the leaky connection, only to find later that he had called at the wrong house and that the "patient" had assumed he was an engineer.

Or the one about the patient in hospital who developed blue discoloration above the waist. He had all manner of angiograms until it was discovered that his pyjama top was new and that the dye was gently leaching into his skin.

Here's a gem from my own catalogue of stupidity. I had finished extracting advice on the phone about a patient from a delightful but deeply conversational consultant. Hearing knocking at my door and with urgent messages flashing on the computer screen, I tried to close the chat by saying goodbye, but I also managed to gush, "Love you!"—I had never met him. Oh, the shame; but it has also been quite funny in the recounting.

Don't we all have a bank of similar anecdotes? We could respond to these silly situations with significant event analyses, concerned faces, and forms to fill in, to prevent such medical misadventures from ever happening again. Yet the hilarity itself means that we can't forget, and so we don't have to worry.

In fact, humour often gets people through the stoma problems, the tiresome ongoing need for injections, or the readmission to hospital.

As I closed the chat I also managed to gush, "Love you!"—I had never met him. Oh, the shame

There is subtle laughter as well as out-loud laughter, a silver lining to the storm cloud. And humour directed against oneself is often useful. Laughter is infectious, is more likely when we are in the company of others, and bonds us together.[1]

A few years ago I was on a crowded train. The people I sat next to, one of whom was terminally ill, were returning from a weekend away. We pooled our food, found some wine, and giggled all the way back to Glasgow. I missed my stop because of significant inebriation. We found this hilarious, and happy tears fill my eyes now as I recount it.

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BLOG Natika H Halil

Providing emergency contraception to under 16s

Recently the UK's press went into overdrive reporting on the recent change in emergency contraceptive pill ellaOne's product licence—now available to buy over the counter for women of "all reproductive ages," and therefore including under 16s.

Of course levonorgestrel was already available to under 16s in pharmacies in many areas through patient group directions. In these instances, it has been given outside of product licences, but in line with all guidelines relating to contraception and young people, and with pharmacists working within Gillick competency and Fraser guidelines.

Emergency contraception is also widely available to under 16s for free at young people's services, from GPs that provide contraceptive services, sexual health and contraception clinics, some GUM clinics, and most NHS walk-in centres (in England).

So it is certainly not new that under 16s are able to access emergency contraception.

With this in mind I fear all of this coverage, which could have been used to highlight the effectiveness of the different methods of emergency contraception to women of all ages, and the different health settings in which they can be provided, rather missed the point and was instead used to further fuel

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hysteria around the use of contraceptives by teenagers.

And that's not to mention headlines talking about the "morning after pill," betraying the choice of three methods, one of which is not a pill, and the fact that none of them have to be used "the morning after," or within as narrow a window of time as 12 or 24 hours.

Although teenage pregnancy rates are at a record low, the UK still lags woefully behind the rest of Western Europe—a study of 2012 statistics found that the UK had lower live birth rates than only Bulgaria, Romania, and Slovakia across the European Union.

But we don't expect the new availability of a £35 pill to substantially affect teenage pregnancy rates.

This month the government announced a £200 million cut to the public health budget for the year ahead. The All Party Parliamentary Group on Sexual and Reproductive Health, of which FPA is secretariat, has already heard evidence of overstretched services and cracks in contraceptive provision around the UK.

Adding more choice to women's reproductive health is to be welcomed, but making ellaOne available over the counter is in no way a substitute for making all methods of contraception widely and freely available and accessible.

We must not ignore the needs of women of all ages because the media chooses only to talk about under 16s, and we must ensure local authorities keep sexual health as a priority despite coming under increasing pressure to make savings.

There is a role for everyone involved in sexual and reproductive health, from charities and organisations who raise awareness and provide information and advice, through to health professionals who dispense medication and have the opportunity to discuss wider contraceptive needs, to ensure all women and girls are equipped with the knowledge they need to make informed choices that are best for them.

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