Oral contraception over the counter at last: a momentous occasion

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Some 27 years ago, in 1993, *The Lancet* published an editorial arguing the case for oral contraceptives over the counter (OTC).[1] It opened by saying that the oral contraceptive pill (OCP) had helped women 'escape from the confines of their own reproductive system' but that 'these ex-prisoners remain on probation' because they still needed to see a doctor regularly for a repeat prescriptions. This month, almost 60 years after approval in the UK, at last an oral contraceptive has been approved here for initiation and use without a doctor's prescription. Desogestrel 75 μg daily, a progestogen-only pill (POP) available in the UK for over 20 years, will be available as a pharmacy medicine for use by women of all ages wishing to prevent pregnancy. While a few countries, like the Netherlands and New Zealand,[2] have arrangements which allow women to obtain repeat supplies from pharmacies without a prescription, this will be the first time that women living in the industrialised world will be able to buy the pill without ever consulting a doctor.

It has taken a long time. The pill is arguably one of the most widely used drugs in the world and one of the most intensively researched. In the UK, where almost one in three women currently using contraception choose the OCP,[3] there must be very few women of reproductive age who have never taken it. Doctors have argued for years that oral contraception should be available without prescription. As early as 1968, Potts controversially wrote that the pill should be available from vending machines while cigarettes should be available only on prescription.[1] In 1976, the UK Department of Health and Social Security Working Group on Oral Contraceptives and Great Britain did not 'rule out the possibility of making oral contraceptives available over the counter' provided the lower dose pills proved to be safer than, but as effective as, pills containing 50 μg ethinylestradiol.[1] More than 30 years later, and with an abundance of evidence of the safety and efficacy of newer pill formulations, in 2007 at a seminar organised by the UK Medicines and Healthcare products Agency (MHRA) entitled 'Widening access to medicine – focus on women's health' it was said that the agency was 'opening the dialogue' to discussion.[4]

Obtaining approval for a drug to be available without prescription is not easy. In the UK, a medicine must remain prescription-only if a direct or indirect danger exists to human health, even when used correctly, if used without medical supervision; if there is frequently incorrect use which could lead to direct or indirect danger to human health; and/or if further investigation of activity and/or side effects is required.[5] These conditions patently do not apply to the POP. The concern of regulators is that making a drug available without expert assessment of medical eligibility and without medical supervision of use of the medicine may jeopardise its safety and effectiveness. With regard to medical eligibility[6] there is only one absolute contraindication to initiation of the POP (breast cancer diagnosed within the past 5 years) and only three relative contraindications (breast cancer >5 years, liver tumours and severe cirrhosis). There are only two relative contraindications for continuation (the onset of ischaemic heart disease or stroke while using a POP). These are all serious conditions of which women will be well aware, and for which they will be under close medical supervision. As to safe and effective use, the instructions for the POP could hardly be simpler: 'take one pill every day, at the same time every day, until you no longer need contraception'. It is hard to argue that only a highly qualified doctor can get this message across. Even in industrialised countries the risks of maternal mortality (9.8/100 000 women in 2016 in the UK[7]) must be considerably higher than any risk of death associated with use of a POP.

Some individuals have voiced concern that making a POP available OTC might undermine efforts to increase the use of long-acting reversible contraception (LARC) methods.[8] But it seems unlikely that in the UK, where all contraceptive methods are available free of charge from the National Health Service (NHS), there would be a wholesale switch to a contraceptive which has to be paid for. Not all women want an intrauterine device or contraceptive implant, and they are not that easy to get, even before COVID-19. Pharmacists, and the patient information leaflet, can signpost women to services which provide LARC; and while women wait, often a very long time, for an appointment, a POP would provide excellent interim contraception. The gains from improving access to an effective oral contraceptive could be substantial. Twice as many unintended pregnancies could be prevented by enabling couples who are not using contraception to use a modern method compared with persuading pill-users to change to a LARC.[9] And, anyway, the perfect should never be the enemy of the good.

But who is likely to buy a POP in pharmacies? A surprising number of women are choosing to buy oral contraceptive over the internet. They may be uncomfortable or embarrassed about seeing a doctor, or too busy, they may have run out of supplies or perhaps simply want to try something new. In a recent study in which women obtaining emergency contraception from pharmacies were offered a supply of desogestrel POP, many women chose to continue it after their initial supply had run out because they liked it.[10] An OTC POP is unlikely to result in major changes in patterns of contraceptive use in the UK, but it will increase choice and the ability of women to control their own fertility. It may act as a positive example for other countries where contraception – and the cost of seeing a doctor for repeat prescriptions – is high and it may pave the way eventually for an increasing choice of methods available from pharmacies. This is a momentous occasion that should be widely celebrated.

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Competing interests The author has worked for over 20 years with HRA Pharma, the French company that is launching the desogestrel progestogen-only pill (Hana). In 2007 at the Medicines and Healthcare products Regulatory Agency (MHRA) seminar the author was told that no agency/organisation could make an application for oral contraception over the counter, it could only come from a pharmaceutical company. The author is proud to have worked with a company that is at last willing to take the risk and make the effort to get approval.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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REFERENCES

1 OCs o-t-c? *Lancet* 1993;342:565–6.
2 Gauld N. New Zealand pharmacists will soon be able to dispense oral contraceptives. *The Pharmaceutical Journal* 2017;298.
3 French RS, Gibson L, Geary R, *et al*. Changes in the prevalence and profile of users of contraception in Britain 2000–2010: evidence from two National Surveys of Sexual Attitudes and Lifestyles. *BMJ Sex Reprod Health* 2020;46:200–9.
4 MHRA begins to consider OTC availability of contraceptive pill. *The Pharmaceutical Journal* 2007;278:153.
5 gov.UK. Guidance. Medicines: reclassify your product, 2020. Available: https://www.gov.uk/guidance/medicines-reclassify-your-product#prescription-only-medicine-pom-to-pharmacy-p-medicine
6 Faculty of Sexual and Reproductive Healthcare. UK medical eligibility criteria for contraceptive use, 2019. Available: https://www.fsrh.org/standards-and-guidance/documents/ukmec-2016/
7 MBRRACE-UK. Saving lives, improving mothers' care. Lessons learned to inform maternity care from the UK and Ireland Confidential Enquiries into Maternal Deaths and Morbidity 2014-16. Oxford National Perinatal Epidemiology Unit, University of Oxford; 2018. https://www.npeu.ox.ac.uk/downloads/files/mbrrace-uk/reports/MBRRACE-UK%20Maternal%20Report%202018%20-%20Web%20Version.pdf
8 Jarvis S. Head to head: should the contraceptive pill be available without prescription? No. *BMJ* 2009;338:090244.
9 Thomas A, Karpilow Q. The intensive and extensive margins of contraceptive use: comparing the effects of method choice and method initiation. *Contraception* 2016;94:160–7.
10 Cameron S, Glasier A, Norrie J, *et al*. A pragmatic cluster randomised crossover trial to determine use of effective contraception following provision of the progestogen-only pill to women presenting to community pharmacies for emergency contraception: the Bridge-It study. *Lancet* 2020.