Medicines & Healthcare products Regulatory Agency

MHRA

Via email, for attention of:
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Medical Director
National Unplanned Pregnancy Advisory Service (NUPAS)

Patricia Lohr
Medical Director and Responsible Officer
British Pregnancy Advisory Service (BPAS)

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Medicines & Healthcare products Regulatory Agency

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Dear Colleagues

Provision of medicines for Early Medical Abortion during the coronavirus pandemic

I am writing in light of concerns about the provision of medicines to support abortion care during the coronavirus (COVID-19) pandemic to set out regulatory flexibilities.

The Human Medicines Regulations 2012 currently provide exemptions from the need for manufacturing and product licences for certain healthcare professionals so that they can assemble and supply medicines to patients under their care. Splitting larger packs or 'packing down' and labelling is normally considered an assembly activity, which doctors and nurses can ordinarily do for patients under the own care and doctors for patients under the care of a doctor who is part of the same medical practice.

'Medical practice' is not defined for these purposes, but during the current COVID-19 situation, the MHRA is prepared to accept that BPAS, MSI and NUPAS, when acting as umbrella organisations for a number of clinics, or abortion services located within particular NHS Trusts, can be considered single medical practices for these purposes, provided that all the clinics in question are working within the same governance structure. This should allow the clinics to consolidate activity onto particular sites, if the circumstances require this.

This MHRA advice relates to care provided by hospitals and clinics that are acting in accordance with the Abortion Act 1967 and, for the purposes of providing the services permitted by the approval contained in "The Abortion Act 1967 - Approval of a Class of Places" dated 30 March 2020,[1] are packing down their own stocks of abortion management medicines for supplying directly to named patients for treatment. There is also an expectation of the following:

1 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/876740/30032020_The_Abortion_Act_1967_-_Approval_of_a_Class_of_Places.pdf

- The medicine should only be supplied following a consultation with the patient.

- The medicines supplied will be for a treatment regimen that is accordance Royal College of Gynaecologists guidance and, where appropriate, NICE guidelines. Normally it will be limited to 1 mifepristone (200mg) tablet; 4 misoprostol (200microgram) tablets; and up to 4 codeine (30mg) or co-codamol (30mg/500mg) tablets, but it is recognised that RCOG guidance allows for alternatives in some instances.

- Patients should be supplied with appropriate information leaflets and clear instructions on the order in which the medicines are to be used.

- If the supply requires the splitting of a licensed pack of medicine, a dispensing label will be applied.

- The assembly activity is conducted at a level commensurate with medication needs for the duration of the COVID-19 situation as defined in the Abortion Act 1967 - Approval of a Class of Places dated 30 March 2020 and is not carried out on a large scale or by an industrial process.

- The assembly activity is conducted by or under the direction of a doctor by appropriately trained healthcare professionals in their own practice;

- Appropriate medicines management policies are in place.

This advice does not apply where a practice has its own pharmacy or the medicines are being sourced from a pharmacy service. Pharmacies dispensing against prescriptions come under a different set of legal provisions relating to pharmacists, who are also able to prepare stock of medicines for dispensing or by someone working under their supervision. Clinics that normally outsource medicines supply to pharmacies by arranging for them to dispense against prescriptions may of course continue to do so.

Please contact me using the details below if you require further information or assistance.

Yours sincerely,

Sarah Branch

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