

Oireachtas Joint Committee on Health: 19th September, 2018

Opening Statement from the Health Products Regulatory Authority

Good morning Chairman, and Committee members. My name is Elaine Breslin, Clinical Assessment Manager, and I am joined by my colleague, John Lynch, Director of Compliance.

We are pleased to provide this opening statement in response to the Committee's request to consider the matter of the authorisation of medicines for the termination of pregnancy, in light of the impending introduction of abortion services in Ireland.

The HPRA, as the competent authority for the authorisation of health products in Ireland, seeks to fully inform the Committee in this regard by providing the following information:

At the outset, we will briefly outline the medicines for medical termination of pregnancy, and the system for the authorisation of medicines in Ireland and across the European network, in particular the 'mutual recognition' procedure which is relevant to these medicines.

We will then provide an update on our work to date to secure authorised medicines, while respecting the applicants' confidentiality. We will conclude with a description of the Exempt Medicines Scheme, which is relevant to facilitating the availability of a medicine where an authorised equivalent is not available.

By way of background, medical termination of pregnancy is achieved by the taking of two medicines, up to 48 hours apart, to induce a miscarriage. The use of these medicines, in combination, results in a safer and more effective procedure. In the EU, both of these medicines are subject to prescription, and can only be prescribed and administered in accordance with a country's national laws and regulations.

The first medicine, mifepristone, acts by blocking the effects of progesterone, a hormone which is needed for pregnancy to continue. It can also be used to soften and open the entrance or the cervix to the womb or uterus.

The second medicine, misoprostol, a prostaglandin, causes contraction of the womb and also softens the cervix. Gemeprost, an alternative prostaglandin may be used instead of misoprostol.

At present in Ireland, there are no medicines authorised for the termination of pregnancy. Medicines for this medical indication are authorised in many European Union (EU) Member States. It should be noted that, across the EU, only a small number of companies are involved in the supply of these medicines.

Apart from exceptional circumstances, to which I'll refer later, under European and Irish law, medicines must be authorised before being marketed in a member state. This is to ensure that they meet the required standards, and patients have access to information on the safe and appropriate use of medicines.

A medicine is authorised by the HPRA for sale and supply to the Irish market, following a detailed technical assessment of an application for a marketing authorisation. This application is submitted by a company seeking to market a medicine in Ireland, in the form of a dossier which contains data to support the medicine's quality, safety and efficacy. If, following assessment, the benefit/risk of the medicine is positive a marketing authorisation is granted. The company is then termed the 'Marketing Authorisation Holder'.

Medicines used in the termination of pregnancy are currently authorised in other European member states under a scheme of mutual recognition. Under this scheme a single EU member state is designated as the 'Reference Member State'. The Reference Member State is the EU-based competent authority which was responsible for assessment of the original application dossier and the on-going coordination of dossier updates on behalf of other named EU countries, known as Concerned Member States.

EU law requires that where a medicine is authorised in another Member State, a mutual recognition procedure must be used. Therefore, in order to market a medicine in Ireland for this indication, a Marketing Authorisation Holder must apply to the Reference Member State to extend their authorisation to the Irish market and, simultaneously, submit an application dossier to the HPRA to allow the national phase of this process to occur. This procedure is required to be completed within a maximum of 90 days of the HPRA's validation of the company's application dossier. The HPRA will grant an authorisation, having confirmed the medicine's benefit to risk balance based on an abridged review, which acknowledges the authorisation granted by the Reference Member State.

Following the outcome of the Referendum relating to the 8th Amendment to the Constitution in May 2018, the HPRA sought to identify medicines actively marketed in other EU member states which were indicated for use in the medical termination of pregnancy and to enquire of the Marketing Authorisation Holders as to their plans to apply for authorisation to market their medicines in Ireland. This was with a view to, if possible, ensuring authorised medicines would be available at the time of coming into force of the legislation on medical termination of pregnancy.

Whilst the HPRA cannot comment on specific applications for reasons of confidentiality, we can confirm that, to date, we have received applications, and these are currently being assessed under 90-day mutual recognition procedures. If the applications are considered acceptable, marketing authorisations can be issued in late 2018.

It should be noted that these applications are running in a common procedure with a number of other EU Concerned Member States, so whilst we do not foresee significant issues, we would insert this note of caution with respect to the impact of other member states' assessments on the timing of any final authorisation in Ireland.

If an authorisation is granted for a medicine for the termination of pregnancy, the HPRA has requested that the company would expedite the process for making supplies available in Ireland, in order to facilitate the timely implementation of services.

In the event that medicines for the medical termination of pregnancy are not authorised by the end of 2018, there is an exemption in law for the treatment of patients with medical conditions for which an authorised medicine is not available. This is known as the Exempt Medicines Scheme.

Specifically, an unauthorised medicine is considered 'exempt' from authorisation when it is supplied under prescription from a registered doctor for treatment of their individual patients in order to fulfil an unmet medical need (Medicinal Products (Control of Placing on the Market) Regulations, 2007, (SI No 540 of 2007) as amended).

The HPRA does not issue approvals for use of exempt medicines. Wholesalers and manufacturers based in Ireland are required to notify the HPRA when they have sourced exempt medicines for the purposes of supply in Ireland. The wholesaler or manufacturer is required to have processes in place to capture and record any adverse reaction notified in relation to an exempt medicine and to report this to the HPRA.

Over the coming weeks, the HPRA will assess the applications received to date, and maintain contact with prospective Marketing Authorisation Holders regarding the supply of their medicines in Ireland. The HPRA anticipates receipt of further applications in early 2019, and these will also be made through the mutual recognition procedure.

The HPRA is aware of the importance of ensuring supply of medicines for the medical termination of pregnancy, and we will continue to work with the Department of Health, relevant stakeholders and companies in order to put in place the services mandated by the forthcoming legislation.

Thank you Chairman, and we will be happy to address any questions.