CENTER for REPRODUCTIVE RIGHTS

IPPF European Network

Recommendations regarding the Directive on the Union Code relating to Medicinal Products for Human Use

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The revision of the EU's regulatory framework on medicinal products offers an important opportunity to modernise EU law on medicinal products to take account of significant legal reforms across EU member states to remove bans and restrictions on abortion and expand access to contraception as well as significant updates to international public health guidelines and clinical practice.

The current Directive 2001/83/EC contains an outdated and unnecessary exception for contraception and abortion medication in Article 4, paragraph 4, a version of which was first included in the Directive in 1965 and revised in 1993. This provision has been carried over in the Commission's proposal in Article 1, paragraph 10(a).

As further outlined below, the maintenance of this provision, which allows Member States to prohibit or restrict the sale, supply or use of medicines for contraception and abortion, is fundamentally contrary to the purpose of EU law on medicinal products and the principle of free movement, lacks any basis in Member States' laws and practice, and is contrary to international human rights standards as well as public health recommendations.

The European Parliament's negotiating mandate proposes the removal of the above mentioned outdated provision from the Directive.[1] The European Parliament has called for universal access to a range of high-quality and accessible modern contraceptive methods and supplies, including emergency contraception, and to abortion medication.[2]

In light of this, EU Member States should support the removal of the above mentioned provision from the Directive as part of the Council position. This is critical for ensuring that the EU's legal framework on medicines is evidence-based and provides equal protection for access to essential medicines for sexual and reproductive health.

<u>Recommendation: Removal of the Exception</u>

Article 1, paragraph 10(a)

This Directive shall not affect the application of national legislation prohibiting or restricting the following: **~~(a) the sale, supply or use of medicinal products as contraceptives or abortifacients;~~**

* Please note that the proposed change is highlighted in strikethrough and bold.

Six reasons why the exception for medicines for contraception and abortion should be removed?

In order for the Directive on medicinal products to meet its objectives and be evidence-based and effective it must treat medicines for contraception and abortion in the same manner as other medicinal products and ensure that these medicinal products are not subject to restrictions that contradict free movement principles and undermine, and potentially even jeopardise, sexual and reproductive health.

Ensure Consistency with the Aims and Purpose of the Directive: The essential aim of the Directive is to safeguard public health while harmonising the EU internal market for medicines. The Directive also seeks to guarantee that all patients across the EU have timely and equitable access to safe, effective, and affordable medicines. The provision in Article 1, paragraph 10(a) is wholly contrary to the aims and purposes of the Directive. It contravenes the principle of free movement as it is not necessary for the protection of public health and is not proportionate. On the contrary, the provision undermines public health and clearly contradicts public health recommendations, including the World Health Organization List of Essential Medicines. The provision also fails to respect principles of equality and non-discrimination and does not comply with the Charter of Fundamental Rights' provisions on the rights to health, life, private life, and non-discrimination. Removing the provision would only mean that medicines for contraception and abortion would be subject to the same rules set out in the Directive as for all other medicines regarding their authorisation, manufacturing, distribution, and monitoring.

Compliance with Public Health Recommendations: The WHO List of Essential Medicines presents a core set of minimum medicines that are critical to priority health care needs and meet efficacy and safety criteria. The WHO recommends that these medicines should be widely available. The WHO List includes a range of contraceptives, including oral hormonal contraception, emergency contraceptives, injectable hormonal contraceptives, intra-uterine devices, barrier methods (condoms and diaphragms), implantable contraceptives, intravaginal contraceptives, several of which would be covered as medicinal products by the Directive.[3] Access to emergency contraception is particularly critical for victims of sexual violence and is recognised as an integral part of the clinical management of rape. The WHO List also includes abortion medicines, such as mifepristone and misoprostol, where abortion is permitted under national law, which is the case across all EU member states. Further, the 2022 WHO abortion care guideline recognises the safety and efficacy of abortion medication and recommends that abortion care can be provided via this medication.[4] Access to abortion medication can be life-saving care during miscarriages and other life threatening obstetric emergencies.

Reflecting Member States' Laws: Under Article 168 of the Treaty on the Functioning of the European Union, Member States are responsible for the organisation and delivery of health services and medical care. In contrast to 1993, when the current Article 4, paragraph 4 was included in the current Directive, all EU Member States now allow abortion in some situations and no Member State prohibits it entirely any longer.[5] Moreover, no Member State prohibits emergency or hormonal contraception. For example, all EU Member States have authorised two of the main forms of hormonal emergency contraception.[6] Many Member States have also authorised the main medicines for abortion. To date it appears that no Member State has notified the Commission of national legislation prohibiting or restricting the sale, supply or use of medicinal products for contraception or abortion under the existing Directive. As such, the provision in Article 1, paragraph 10(a) has no basis in the laws and practice of Member States.

Consistency with other EU Legislation: The revised EU legislation on medical devices (Regulation (EU) 2017/745), which took effect in 2021, explicitly states that devices for the control of conception are medical devices (Article 2(1)). This provision clearly regulates certain forms of contraception such as intra uterine devices, condoms, femidoms, and diaphragms. The Regulation contains no

provision that allows Member States to prohibit or restrict the use of these contraceptive devices. As such, the provision in Article 1, paragraph 10(a) of the Directive on medicinal products not only wholly contradicts existing EU law on medical devices, but risks creating unnecessary and unjustified contradictions in the regulation of contraceptives and appears arbitrary and discriminatory in allowing restrictions on certain forms of contraceptives, while other forms of contraceptives are not subject to such restrictions.

Compliance with International Human Rights Obligations: International human rights law and standards require States to guarantee the right to sexual and reproductive health as an integral part of the right to the highest attainable standard of physical and mental health.[7] International human rights bodies have affirmed that this entails core minimum obligations to guarantee access to essential drugs as defined by WHO and that non-compliance with these obligations cannot be justified under any circumstances.[8] They have further held that legal restrictions that prevent equal access to health care, including sexual and reproductive health care, are not permissible and that restrictions on access to sexual and reproductive health services and goods that only women need must be removed. They have affirmed that banning or restricting access to sexual and reproductive health services and medicines and failures or refusals to incorporate technological advances and innovations in sexual and reproductive health care violate human rights and jeopardise the quality of care.[9]

Addressing Key Barriers and Harmful Impacts: Key barriers in access to contraception include cost and limited availability of a broad range of affordable methods of modern contraception. The removal of the provision in the Directive would contribute to addressing these barriers. When women and girls are unable to access affordable contraception methods of their choice, they are often unable to protect themselves from sexually transmitted infections and HIV and to control their fertility. Resulting unintended pregnancies expose women and girls to pregnancy-related health risks. Access to contraception plays a key role in reducing these risks, especially for adolescent girls.

[1] European Parliament legislative resolution of 10 April 2024 on the proposal for a directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (COM(2023)0192 – C9-0143/2023 – 2023/0132(COD)) (AM 85).
[2] European Parliament resolution of 24 June 2021 on the situation of sexual and reproductive health and rights in the EU, in the frame of women's health (2020/2215(INI)).
[3] Word Health Organization, Model List of Essential Medicines, 23rd List, 2023: see 22.1 and 22.3.
[4] Word Health Organization, Abortion care guideline, 2022.
[5] Center for Reproductive Rights, European Abortion Laws: A Comparative Overview, https://reproductiverights.org/european-abortion-laws-comparative-overview/.
[6] European Consortium for emergency contraception, An update on access to emergency contraception in Europe, February 2022, https://www.ec-ec.org/wp-content/uploads/2022/02/ECEC-Update-EC-access-Europe_FEB_2022_FINAL.pdf.
[7] Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 16 on The equal right of men and women to the enjoyment of all economic, social and cultural rights (art. 3 of the International Covenant on Economic, Social and Cultural Rights), UN Doc. E/C.12/2005/411, 2005; CESCR, General Comment No. 14 (2000) The right to the highest attainable standard of health (article 12 of the International Covenant on Economic, Social and Cultural Rights), UN Doc. E/C.12/2000/4, 2000; CESCR, General comment No. 22 (2016) on the right to sexual and reproductive health (article 12 of the International Covenant on Economic, Social and Cultural Rights), UN Doc. E/C.12/GC/22, 2016; CEDAW General Recommendation No. 24 (20th session, 1999) (article 12 : Women and health), para. 11.
[8] CESCR, General Comment No. 16 on The equal right of men and women to the enjoyment of all economic, social and cultural rights (art. 3 of the International Covenant on Economic, Social and Cultural Rights), UN Doc. E/C.12/2005/411, 2005.
[9] CESCR, General Comment No. 16 on The equal right of men and women to the enjoyment of all economic, social and cultural rights (art. 3 of the International Covenant on Economic, Social and Cultural Rights), UN Doc. E/C.12/2005/411, 2005; CESCR, General comment No. 22 (2016) on the right to sexual and reproductive health (article 12 of the International Covenant on Economic, Social and Cultural Rights), UN Doc. E/C.12/GC/22, 2016. See also Center for Reproductive Rights and UNFPA, Briefing Paper: The right to contraceptive information and services for women and adolescents, available at https://www.unfpa.org/sites/default/files/resource-pdf/Contraception.pdf.