

Brussels, 8 July 2021

Dear Commissioner Helena Dalli Dear Commissioner Stella Kyriakides

Last November, we welcomed the European Commission's "LGBTIQ Equality Strategy 2020-2025" as a cornerstone towards a Europe truly united in diversity. Unfortunately, despite equality and non-discrimination being core values of the EU, still today fundamental rights already recognized in the strategy are being seriously violated.

We have recently noticed with great concern that various civil society organizations are warning about oestrogen and hormone replacement therapy (HRT) shortages. LGTBI organizations have denounced that hormonal preparations used by trans people, and, in the case of Spain, covered by Public Healthcare, have been stocked-out, creating a serious problem of continuity of prescribed hormonal treatment with the risks for the health that this entails.

The mentioned medications refer to various oestrogen-containing medicines (essentially estradiol, estradiol hemihydrate and estradiol valerate) in which the recognized indications are: the treatment of the symptoms of natural or surgically caused menopause and the prevention of osteoporosis in menopausal women but, surprisingly and despite its *de facto* use, not the transitioning process of trans women.

Regardless of this pressing situation, the Spanish Agency of Medicine and Sanitary Products (AEMPS, for its acronym in Spanish), informed that they do not plan to open the access for foreign medicines since in the Spanish market there is availability of medicines containing the active ingredient. Nonetheless, these medications are not among those covered by the public healthcare system, raising concerns about affordability and clearly undermining equal access to chronic medication. According to the information provided also by the AEMPS, the shortage is due, in the case of medicines owned by BAYER HISPANIA SL, to capacity limitations in the BAYER plant of active ingredients in Germany, which is causing problems in the supply of various oral hormonal products globally.

Therefore, we are not in face of a problem that affects a single member state. In recent years, there have been also reports of testosterone shortages in Spain and Croatia. In fact, the European Commission publication "Legal gender recognition in the EU: The journeys of Trans people towards full equality" ¹

¹ <u>Legal gender recognition in the EU: The journeys of trans people towards full equality</u>
Directorate-General for Justice and Consumers (European Commission), ICF (June, 2020) (p.46)

acknowledged "that the ease of accessing hormone therapy varies by Member State" and some people interviewed for the study "mainly in Italy, were unable to access hormones due to country-specific shortages".

The same publication states "that in the EU-28 as a whole and in most Member States there was an increase between 2012 and 2019 in the share of trans people who have either gone abroad or considered going abroad for medical treatment to alter their physical appearance, including buying hormones over the internet from other countries". It, indeed, reflects the difficulties experienced by some people in accessing the hormones that may be part of their transitioning process or a prerequisite for accessing legal gender recognition, so long as such requirements are in force.

Unfortunately, the lack of information available to assess the exact range of the consequences of the supply problem at European level highlights another serious concern: the lack of awareness and knowledge about trans people's health rights in particular, and trans people's rights in general.

Furthermore, since we are discussing medicines aimed at women, and potentially those who are in the most vulnerable situations such as the older women or trans women, the gender aspect of this issue is undeniable. In this regard, the European Parliament has already recalled the shortages of hormones used for contraception and hormone replacement therapy (HRT)². It noted "with concern the threats posed by such shortages to women's and girls' sexual and reproductive health and rights"; stressing "the importance of enhancing the control and management of the manufacturing, stockpiling and marketing of those medicines to ensure continuity in supply chains, fair pricing and availability for women".

As a result, we face a multifaceted problem: the shortage of medicines, which has been highlighted as a critical challenge for Europe by the COVID19 pandemic; the specific threat to women's health rights; and, of course, the rights of transgender people.

Therefore, the dimension of the challenge requires an equally comprehensive approach:

- 1. In the short term, it is urgent to take measures to alleviate the recurrent shortages of hormone replacement therapy. Moreover, in order to tackle the potential legal uncertainty on hormone replacement treatments, it is crucial that the European Medicines Agency (EMA) updates the indication for these treatments to include the transition process.
- In the long term, it is imperative to address the lack of information about the trans experiences in health and their access to healthcare. We need an ambitious research about health and transgender persons which contributes to a broader European healthcare strategy fully inclusive of LGBTIQ+ health rights. We would not be able to tackle discrimination against LGBTIQ people; ensure LGBTIQ people's safety; build LGBTIQ inclusive societies; and lead the call for LGBTIQ equality around the world (four pillars of the Commission's strategy) unless we are capable of shedding light on sources of discrimination.

² European Parliament resolution of 17 September 2020 on the shortage of medicines – how to address an emerging problem (2020/2071(INI))

And the commitment should be comprehensive. At this point, we cannot imagine an EU4Health 2021-2027 program that does not take a gender perspective into account, or a Pharmaceutical Strategy for Europe that is not consistent with this gender sensitivity and the goal of making medicinal products, medical devices, and crisis-relevant products available and affordable. Europe must talk about transgender people's rights more and better so that knowledge becomes actions that lead to a full protection of their rights.

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