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**Input for the United Nations Office of the High Commissioner for Human Rights analytical study on key challenges in ensuring access to medicines, vaccines and other health products (HRC Resolution 50/13)** **on access to hormone replacement therapy for trans and gender-diverse people**

Introduction

This submission by Transgender Europe (TGEU) and the European Region of the International Lesbian, Gay, Bisexual, Trans and Intersex Association (ILGA-Europe) addresses the shortages of hormones in Europe and its impact on trans people. It draws on TGEU’s research on shortages as reported in the publication “[The State of Trans-Specific Healthcare in the EU: Looking Beyond the Trans Health Map 2022](https://tgeu.org/wp-content/uploads/2023/09/TGEU-Trans-Health-Map-Report.pdf)” and information from publicly available sources.

Specific barriers faced by trans people in accessing hormones

Feminising and masculinising hormones like oestrogen and testosterone – whether in the form of injections, gels, capsules, or patches – constitute essential medication in the medical transition process for many transgender and gender-diverse people (together “trans”).

Commercial shortages of medications for hormone replacement therapy (HRT) have long been a source of concern among the trans community. In 2021, a group of concerned members of the European Parliament addressed a letter to the European Commission’s Equality and Health Commissioners highlighting the growing hormone shortages and the impact on trans people in the European Union (EU).[[1]](#footnote-1) However there is little research or publicly available documentation on the issue and its impact on trans people. In most cases, trans people are not accounted for as active consumers of hormones and the impact of non-availability is not considered. Specifically, trans women have experienced an acute shortage of estradiol injections and gels.[[2]](#footnote-2) Estradiol injections – which are considered by many to be the most effective method of administering oestrogen for trans women and consequently are in high demand (see page 5) – are in extremely short supply due to the war in Ukraine.

In 2022, TGEU conducted a survey among trans activists in the EU on how they experience hormone shortages. Most of the respondents indicated that they have experienced a shortage at least once in the last year or at least once in the last three years. In Malta, Romania and the Netherlands, hormone shortages were reported to occur several times a year, while it was reported to occur at least once a year in Sweden, France, Poland, Italy, Belgium, and Greece.[[3]](#footnote-3) The situation has considerably worsened since the COVID-19 pandemic – a recent report from Denmark noted that during COVID-19 “the shortage of hormones is so drastic, that people have had to wait even weeks to continue their treatment”.[[4]](#footnote-4) A related challenge is that not all countries in the EU provide full cost coverage for hormones under public health funding; coverage gaps were reported in Bulgaria, Croatia (testosterone), Latvia, and Romania.[[5]](#footnote-5)

The most concerning news about hormone shortages comes from the United Kingdom where media reports have consistently highlighted the shortage of oestrogen.[[6]](#footnote-6) These reports have focused on the needs of women undergoing menopause and the impact it has on their health and wellbeing. However, the impact of the shortages of products such as Oestrogel, Ovestin cream, estradiol patches and Premique tablets on trans women has received very little attention, including in policy responses.[[7]](#footnote-7)

Lack of timely access to hormones necessary for transition can have severe implications for trans people. For trans women, the side effects of a break in use of hormones mirror those of menopause, can lead to a spike in cholesterol and blood pressure levels, and can lead to the risk of developing osteoporosis. Further, for trans men, the physical changes resulting from use of testosterone, such as changes to the quality of facial hair growth, changes to menstrual cycle, or changes in voice, can reverse on pausing or stopping hormone use, and for those transmasculine and non-binary people who have had their ovaries removed, menopause can also be induced – this can be highly harmful to the mental health and wellbeing and can also exacerbate experiences of gender dysphoria.[[8]](#footnote-8) For many trans people, switching to alternative methods of hormone administration (e.g. from injections to patches) may not be feasible because of prior medical history, employment, inability to afford alternatives, and/or the extent of physical changes an individual seeks.[[9]](#footnote-9)

The frequency of shortages can force trans people who wish to access care through formal and regulated channels to instead purchase hormones from the black and grey markets. This can have a two-fold consequence: (a) unregulated sources can result in adverse consequences on physical health and safety when the quality of the hormones is not optimal and (b) in many countries, such as Belgium, the Netherlands, and the United Kingdom, serious barriers exist to returning to supervised care after accessing hormones through unregulated sources.[[10]](#footnote-10)

Potential reasons for the shortages

This section is based on TGEU and ILGA-Europe’s analysis of the available reporting on shortages of hormonal medication used by trans people and feedback from our members. We note that there may be other reasons for the shortages that we have not considered or come across. Some reasons for the shortage include: (a) the war in Ukraine which led to shuttering of pharmacies, inaccessibility of drug stockpiles, and supply chain disruptions,[[11]](#footnote-11) and caused spillover shortages in neighbouring countries; (b) potential failure to account for trans people as consumers of hormones while estimating demand and supply, particularly estradiol injections of which trans people are the primary users; (c) current licensing regimes under which products need to be licensed individually in each country, making the procurement of alternative products in times of a shortage challenging;[[12]](#footnote-12) (d) national rules on prescription of medication which have failed to include alternative formulations containing the same active substance, under public health funding, such as in Spain and the United Kingdom;[[13]](#footnote-13) and (e) limited producers of estradiol injections, misaligned incentives of pharmaceutical companies for whom HRT for trans people constitutes a minor market, as well as differential and non-transparent pricing mechanisms in different countries.[[14]](#footnote-14)

Legal, regulatory, and other challenges that impact the accessibility and affordability of hormones

Some legal and regulatory obstacles to ensuring equitable access include: (a) barriers to switching or being prescribed alternative formulations[[15]](#footnote-15) or medications[[16]](#footnote-16) as a result of national regulations and coverage under public healthcare funding;[[17]](#footnote-17) (b) lack of transparency on shortages, existing stocks, and pricing mechanisms set for pharmaceutical companies; (c) high costs and variations in insurance coverage of alternative medications (e.g., compare Bayer’s Primoteston with Grünethal’s Nebido, both of which increase testosterone levels, where the latter costs 10 times as much as the former);[[18]](#footnote-18) (d) the introduction of anti-doping legislation that bans the use of hormone supplements without excluding therapeutic or medical uses from its scope, as in Romania;[[19]](#footnote-19) and (e) lack of attention paid to the impact on trans communities and specific measures targeted towards essential medications for trans people in national guidance documents on managing shortages.[[20]](#footnote-20)

In the EU, the European Commission has taken note of some of these issues under the Pharmaceutical Strategy for Europe, released in 2020. In response to a question raised by the European Parliament focusing on the concerning hormone shortages, the Health Commissioner responded that “*Under the strategy, the Commission is considering legislative measures to enhance security of supply [of medicines]. These include stronger obligations for supply, earlier notification of shortages, enhanced transparency of stocks and stronger EU coordination and mechanisms to monitor, manage and avoid shortages. The strategy also includes non-legislative actions on pricing, an area of national competence. National competent authorities will share knowledge and exchange best practices on pricing, payment and procurement policies, to improve the affordability and cost-effectiveness of medicines and health system’s sustainability.*” The Commission is in the process of reforming the EU’s pharmaceutical legislation, which is also expected to address the issue of shortages through regulations on stockpiling, advance notifications of expected shortages, and development of a list of critical medications.[[21]](#footnote-21)

Recommendations

Fundamentally, the issue of hormone shortages is tied to the biased belief that HRT is not essential medical care.[[22]](#footnote-22) This is evident from news reports of shortages that refer only to cis women, even though hormone shortages for trans people has been an issue for over 5 years. Greater mainstreaming of and increased investment in the production of hormones is needed, whereby production is not limited to only the few manufacturers or suppliers.

Rules around prescribing alternative formulations and swapping of medication on prescriptions in the event of extreme shortages should be relaxed. The experience of shortages in Ukraine revealed that many trans people do not wish to change the formulation or method of administering hormones (e.g., switching from injections to tablets) because of the impact it can have. Therefore, our recommendation is for doctors to prescribe alternative formulations and methods only in the event of an extreme and serious shortage, where the alternative would be complete lack of access, and only after thorough discussion with the trans person about the reasons for and potential physical and psychological consequences of changing medications.

Further, a central formulary of approved medications and formulations should be maintained and shared with medical professionals so that they can prescribe the medication that is available.[[23]](#footnote-23) This would also require greater transparency from states on the existing stockpiles of medication. Similar rules are in the process of being developed with respect to many essential medications in Germany, but for them to have an impact on hormone shortages, HRT medications would need to be categorised as essential.[[24]](#footnote-24)

Another way to manage supply issues before they grow out of control could be to put in place standard procedures that must be followed when the likelihood of impending shortages is detected, including effective communication with pharmacists and healthcare providers.[[25]](#footnote-25) Standard procedures should also involve providing appropriate guidance to communities affected by a shortage – in this case, trans people. One gender clinic in the UK published detailed guidance for trans people who were considering alternative formulations or methods of administration during the shortage.[[26]](#footnote-26)

Finally, rules regarding import of hormones can be relaxed, to permit the import of unlicensed drugs in the event of a shortage. This has been done in the United Kingdom, when HRT medication that was not licensed in the UK was imported from France and Poland.[[27]](#footnote-27)

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3. Noah Adams and Deekshitha Ganesan (2022). The State of Trans-Specific Healthcare in the EU: Looking Beyond the Trans Health Map 2022. TGEU. p. 15. [↑](#footnote-ref-3)
4. TransAktion (n.d.). TransAktion’s observations on the effect of the COVID-19 pandemic on the trans communities in Denmark, available at: [www.ohchr.org/Documents/Issues/SexualOrientation/IESOGI-COVID-19/CSOs/TransAktion-Denmark.docx](http://www.ohchr.org/Documents/Issues/SexualOrientation/IESOGI-COVID-19/CSOs/TransAktion-Denmark.docx). p.5. [↑](#footnote-ref-4)
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9. See for example Emilio De Benito (2016). Spain’s transgender men start menstruating due to drug shortage. El Pais. available at <https://english.elpais.com/elpais/2016/12/16/inenglish/1481878341_247391.html>. [↑](#footnote-ref-9)
10. Noah Adams and Deekshitha Ganesan (2022). The State of Trans-Specific Healthcare in the EU: Looking Beyond the Trans Health Map 2022. TGEU. p.11. [↑](#footnote-ref-10)
11. Natalie Vikhrov (2023). A year after Ukraine invasion, trans people struggle for hormones. Openly. available at <https://www.openlynews.com/i/?id=ea8bc511-5467-4485-a64c-f0676d7d743f>; Lucie Heath (2023). Why are there HRT shortages in the UK? How supplies can be improved as treatments falter. MSN. available at <https://msn.com/en-gb/money/other/why-are-there-hrt-shortages-in-the-uk-how-supplies-can-be-improved-as-treatments-falter/ar-AA17ejxB>. [↑](#footnote-ref-11)
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13. European Parliament. (2021) Shortage of medicines used in hormone replacement therapies. https://www.europarl.europa.eu/doceo/document/P-9-2021-002638\_EN.html. [↑](#footnote-ref-13)
14. See for example Dominic Coyle (2022). Pricing is major factor in Ireland’s HRT shortage, drug chief says. The Irish Times. available at <https://www.irishtimes.com/business/health-pharma/pricing-is-major-factor-in-ireland-s-hrt-shortage-drug-chief-says-1.4867738>. [↑](#footnote-ref-14)
15. By alternative formulations, we mean that while the active pharmaceutical ingredient (API) remains the same, the combination of ingredients varies. This combination of ingredients can be absorbed differently by different people and can also have different side effects depending on the individual. Further, depending on the compound, the optimal method of administering the resulting hormonal medication can vary. [↑](#footnote-ref-15)
16. Hormone therapy options generally vary based on the active pharmaceutical ingredient (API) of the hormone itself (e.g., testosterone cypionate versus testosterone undecanoate), which can have radically different absorption rates and side effects. As hormone therapy for trans people is generally closely linked with mental wellbeing as well as the physical consequences of hormone treatments, these variables can be particularly important; trans people may be unwilling or unable to change medications for clinically relevant reasons, and accounting for the variety of APIs in use is vital in addressing hormone shortages. [↑](#footnote-ref-16)
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19. Law no. 219/2021 for modification and completion of Law no. 104/2008 on preventing and combating the illicit production and trafficking of high-risk doping substances. available at: legislatie.just.ro/Public/DetaliiDocument/245003. [↑](#footnote-ref-19)
20. See for example Medicinal products for hormone replacement therapy. Prescribing guidance in response to product shortages (2020). HSE. available at. <https://www.hse.ie/eng/about/who/cspd/medicines-management/guidance-on-shortages/mmp-guidance-for-prescribers-on-hrt-shortages-september-2022.pdf>. [↑](#footnote-ref-20)
21. European Commission (2023). Reform of EU pharmaceutical legislation. available at <https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en>. For a preview of the expected changes see Carlo Martuscelli et al (2023). EU pharma reform: Winners and losers. available at <https://www.politico.eu/article/eu-pharma-reform-winners-and-losers/>. [↑](#footnote-ref-21)
22. The World Health Organisation, in its Universal Health Coverage Compendium, in fact clearly lists both gender-affirming surgeries and hormones. See <https://www.who.int/universal-health-coverage/compendium/database> in the section on Reproductive and sexual health. Further, the WHO has initiated a process to develop guidelines for trans-specific healthcare in 2023: <https://www.who.int/news/item/28-06-2023-who-announces-the-development-of-the-guideline-on-the-health-of-trans-and-gender-diverse-people>. [↑](#footnote-ref-22)
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24. Preventing supply bottlenecks for medicines (2023). available at <https://www.bundesregierung.de/breg-en/news/medicinal-products-supply-2183498>. [↑](#footnote-ref-24)
25. See for example Department of Health and Social Care (2023). Supply update: hormone replacement therapy medication Utrogestan. GOV.UK. available at <https://www.gov.uk/government/news/supply-update-hormone-replacement-therapy-medication-utrogestan#:~:text=Temporarily%20changing%20prescriptions%20of%20Utrogestan,intermittent%20supply%20until%20late%202023> [↑](#footnote-ref-25)
26. Alternatives when there are HRT shortages. Gender Identity Clinic. NHS Portman Trust. Available at <https://gic.nhs.uk/gp-support/updates-on-physical-interventions/>. [↑](#footnote-ref-26)
27. See Julia Kollewe (2022). HRT products could be sent to UK from mainland Europe next week. The Guardian. available at <https://www.theguardian.com/society/2022/may/13/hrt-products-could-be-shipped-to-uk-from-europe-next-week>; Furvah Shah (2022). HRT to be shipped from Poland to tackle UK shortage. The Independent. Available at <https://www.independent.co.uk/news/health/hrt-shortage-poland-uk-b2078336.html>. [↑](#footnote-ref-27)