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**INPUT OF THE SLOVAK NATIONAL CENTRE FOR HUMAN RIGHTS** **ON KEY CHALLENGES IN ENSURING ACCESS TO MEDICINES, VACCINES AND OTHER HEALTH PROCEDURES**

*About the Slovak National Centre for Human Rights:*

*The Slovak National Centre for Human Rights (hereinafter the “Centre”) is a national human rights institution established in the Slovak Republic, accredited with status B by the Global Alliance of National Human Rights Institutions (GANHRI). As an NHRI, the Centre is a member of the European Network of NHRIs (ENNHRI). The Centre was established by the Act of Slovak National Council No. 308/1993 Coll. on the Establishment of Slovak National Centre for Human Rights. Pursuant to the Act No. 365/2004 Coll. on Equal Treatment in Certain Areas and on Protection from Discrimination, as amended (the Anti-Discrimination Act), the Centre also acts as the only Slovak equality body. As an NHRI and equality body, the Centre performs a wide range of tasks in the field of protection and promotion of human rights and fundamental freedoms including the observance of the principle of equal treatment.*

*The Centre among other powers:*

*1) monitors and evaluates the observance of human rights and the observance of equal treatment principle;*

*2) gathers and, upon request, provides information on racism, xenophobia and antisemitism in the Slovak Republic;*

*3) conducts research and surveys to provide data in the field of human rights; gathers and distributes information in this area;*

*4) prepares educational activities and participates in information campaigns aimed at increasing tolerance of the society;*

*5) provides legal assistance to victims of discrimination and manifestations of intolerance;*

*6) issues expert opinions on matters concerning the observance of the equal treatment principle;*

*7) performs independent inquiries related to discrimination;*

*8) prepares and publishes reports and recommendations on issues related to discrimination; and provides library services and other services in the field of human rights.*

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**The Centre submits the following input to the Call for Contributions – OHCHR analytical study on key challenges in ensuring access to medicines, vaccines and other health procedures:**

1. According to the 2022 OECD publication, in 2020, 10.9 % of the GDP of the European Union was devoted to health care. Slovakia with a share of 7.2 % falls significantly behind the EU average.[[1]](#footnote-1) The publication indicates that with spending at EUR 1 480 per person, the Slovak Republic is also well under the EU average of EUR 3 159 per person, showing a decrease compared to the 2019 national level.[[2]](#footnote-2) Compared to the neighboring countries, there is a poor availability of innovative cancer treatment in Slovakia.[[3]](#footnote-3) The unmet medical need for innovative oncology drugs has been documented by analyses of the Association of Innovative Pharmaceutical Industry (AIFP), that show that as of 1 March 2023, most of the innovative cancer treatments with the highest medical benefit, recommended by European and world experts, were not reimbursed by health insurance in Slovakia.[[4]](#footnote-4) In the period 2011-2022, 299 indications for innovative cancer treatment have been registered by the European Medicines Agency (EMA). As of 1 March 2023, only 85 out of 299 indications were covered by health insurance in Slovakia[[5]](#footnote-5) and among the indications that have received the highest rating from European experts in cancer treatment, only 48 out of 173 such top indications were covered (27.7 %).[[6]](#footnote-6)
2. Slovakia has had a categorisation process in place since 2011, that sets whether a medicine will be reimbursed fully or partially by health insurance.[[7]](#footnote-7) The list of categorised medicines is an exhaustive list of what the patient is entitled to from the public health insurance.[[8]](#footnote-8) Alongside the categorisation process, a parallel “system of exceptions” have been created, where the reimbursement of so-called "exceptional medicines" is decided by health insurance companies under Act No. 363/2011 on the scope and conditions of reimbursement of medicines, medical devices and dietetic foods under public health insurance. In such cases, insurance companies may reimburse the requested therapy if it is the only available treatment left to the patient.[[9]](#footnote-9) Since a relatively high number of medicines do not get into the system of standard reimbursement (categorization) from public health insurance, the system of exceptions in Slovakia becomes essentially a parallel system of reimbursement of medicines from public funds.[[10]](#footnote-10) Therefore, there are significant differences in the access of insured persons to treatment with medicines from public health insurance funds.[[11]](#footnote-11) Attributes such as unsystematic, non-transparent, unfair, unpredictable, and lengthy are associated with the system of exceptions,[[12]](#footnote-12) thus creating room for violations of the principle of equal treatment. In June 2022, the National Council of the Slovak Republic adopted an Amendment to Act No. 363/2011,[[13]](#footnote-13) which objective was to support the entry of innovative medicines into the list of categorised medicines, i.e. to support their transfer from the exception regime to the categorisation regime,[[14]](#footnote-14) as well as to eliminate unjustified discrepancies in the decision-making of health insurance companies in the system of exceptions.[[15]](#footnote-15)
3. The shortcomings of the so-called system of exception were also evident in the case of the two-year-old Editka R., who has been diagnosed with spinal muscular atrophy SMA 2. Since Editka’s physician suggested as the most appropriate treatment a two-million-euro medicine (Zolgensma), which was not categorised in Slovakia, the hospital requested its reimbursement from the patient’s insurance company in the exception regime. The insurance company refused the request, even though it had reimbursed the medicine to several patients in the past.[[16]](#footnote-16) The Centre, as Editka’s legal representative assessed the insurance company’s decision as violating the prohibition of discrimination and in February 2023 applied to the court for an interim injunction, upon which the court ordered the insurance company to reimburse the medicine.[[17]](#footnote-17) The Ministry of Health of the Slovak Republic (hereinafter as the “Ministry of Health”) has recently adopted a decision,[[18]](#footnote-18) under which as of 1 January 2024 the medicine Zolgensma will be included in the list of categorised medicines, i.e. it will be reimbursed by public health insurance.[[19]](#footnote-19)
4. In 2021, the Centre has issued an expert opinion on discrimination against a marginalised group of drug addicted patients in access to treatment for chronic hepatitis C (CHC).[[20]](#footnote-20) The Ministry of Health has defined for a group of drug-addicted patients an indication restriction related to access to treatment of CHC disease with all direct-acting antivirals that are included in the list of categorised medicines. According to the indication limitation evidence of at least 1 year of abstinence documented by a psychiatrist’s report and the results of a toxicological examination (at three-month intervals during the course of treatment) is a prerequisite for reimbursed treatment for drug addicted patients. Drug addicted patients are thus forced to wait at least 12 months to access health care. At the same time, patients have no alternative to any other treatment. The Centre has assessed the case and reached a conclusion that the Ministry of Health had violated the constitutional norm of non-discrimination set out in Article 12(2) of the Constitution of the Slovak Republic in conjunction with Article 40 guaranteeing the right to health and to free health care on the basis of health insurance.[[21]](#footnote-21) After examining the case in cooperation with the Centre, the Public Defender of Rights also concluded that denying patients’ access to treatment for CHC disease solely on the basis of their addiction constituted discrimination.[[22]](#footnote-22) In 2023, the indication restriction was removed by a decision of the Minister of Health of the Slovak Republic in relation to one medicinal product as of 1 June 2023.[[23]](#footnote-23)
5. As part of the legislative attempts to limit access to abortion in 2021, the Ministry of Health has adopted an Amendment[[24]](#footnote-24) to the Abortion Decree[[25]](#footnote-25) that removed the item “*conception after the age of 40*” from the list of diseases, syndromes and conditions for abortion contained in the Annex to the Abortion Decree.[[26]](#footnote-26) From 1 March 2021, the age of women over 40 is thus not one of the medical reasons for which abortion is covered by public health insurance. As a part of the inter-ministerial commentary procedure on the Amendment to the Abortion Decree, the Centre raised a fundamental objection to the proposal as a whole. It called for maintaining the status quo and considering the preparation of new rules for the reimbursement of abortions from public health insurance for all women. The Centre drew attention to the amount of the fee which in several health facilities may exceed the maximum abortion fee set by the legislation. It further stated that the amount of the fee alone may be a barrier to safe access to abortions for many women.[[27]](#footnote-27) The Centre argued that the proposed legislation would be most restrictive for women from socially excluded backgrounds and Roma from excluded communities and women at risk of poverty or experiencing domestic violence.[[28]](#footnote-28) As regards the financial availability of services in relation to reproductive rights, the non-observance of the maximum fee for the performance of abortion set by the Regulation of the Ministry of Health is an issue.  Publicly available information shows that health facilities continue to publish price lists in such a way that the fee for abortion does not always include the ancillary costs associated with the abortion.[[29]](#footnote-29) The Centre has been addressing the issue of access to medical abortion, pointing out a legislative obstacle to place the medicines necessary for medical abortion on the market in the Slovak Republic.[[30]](#footnote-30) The Centre has recommended the Ministry of Health to prepare a proposal of relevant legislative changes that would enable medical abortion, including the classification of the relevant medicines in the list of categorised medicines and the list of medicines with an officially determined price.[[31]](#footnote-31) The Centres recommendations have not been accepted by the Ministry of Health and so Slovakia continues to lack access to one of the safe forms of abortion. Recently, the Minister of Health has stated that she is willing to approve the necessary legislative changes to enable medical abortion once standard procedures have been approved. However, she does not consider the issue a priority.[[32]](#footnote-32)
6. The results of a 2023 research[[33]](#footnote-33) show that as for the use of different types of contraceptives by Roma women from excluded communities, the barrier is not only financial accessibility, but also physical accessibility.[[34]](#footnote-34) Poverty and low financial literacy mean that even relatively small expenses related to travel to the city, additional payments for medicines or hygiene needs are not affordable for Roma living in excluded communities.[[35]](#footnote-35)
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2. Ibid., p. 128. [↑](#footnote-ref-2)
3. Pažitný & Kandilaki: Healthcare Consulting: Medicines policy in a wider budgetary context, version 11.4.2022, Bratislava, p. 50, available in Slovak at <https://healthcareconsulting.sk/novinky/studia-o-liekovej-politike-na-slovensku> [↑](#footnote-ref-3)
4. Association of Innovative Pharmaceutical Industry: Has the expected change in the availability of modern medicines begun? 2023, p. 1, available in Slovak at <https://aifp.sk/sk/media-a-verejnost/73/nastartovala-sa-ocakavana-zmena-v-dostupnosti-modernych-liekov/> [↑](#footnote-ref-4)
5. Ibid., p. 2. [↑](#footnote-ref-5)
6. Ibid., p. 3. [↑](#footnote-ref-6)
7. State Institute for Drug Control: What is categorisation of medicines? Available in Slovak at <https://www.sukl.sk/hlavna-stranka/slovenska-verzia/databazy-a-servis/faq/co-je-to-kategorizacia-liekov?page_id=509> [↑](#footnote-ref-7)
8. Pažitný & Kandilaki Healthcare Consulting: Medicines policy in a wider budgetary context, version 11.4.2022, Bratislava, p. 38, available in Slovak at <https://healthcareconsulting.sk/novinky/studia-o-liekovej-politike-na-slovensku> [↑](#footnote-ref-8)
9. Association of Innovative Pharmaceutical Industry: Country approaches to the pricing of medicines. Overview of key pricing instruments for medicines in selected European countries, p. 8, available in Slovak at <https://shorturl.at/jINW4> [↑](#footnote-ref-9)
10. Ibid. [↑](#footnote-ref-10)
11. Explanatory Memorandum to Act No. 266 amending Act No. 363/2011 Coll. on the scope and conditions of reimbursement of medicines, medical devices and dietetic foods under public health insurance and on amendments and supplements to certain acts, as amended and amending certain acts, p. 48, available in Slovak at <https://www.nrsr.sk/web/Dynamic/DocumentPreview.aspx?DocID=510049> [↑](#footnote-ref-11)
12. Pažitný & Kandilaki Healthcare Consulting: Medicines policy in a wider budgetary context, version 11.4.2022, Bratislava, p. 53, available in Slovak at <https://healthcareconsulting.sk/novinky/studia-o-liekovej-politike-na-slovensku> [↑](#footnote-ref-12)
13. Act No. 266 amending Act No. 363/2011 Coll. on the scope and conditions of reimbursement of medicines, medical devices and dietetic foods under public health insurance and on amendments and supplements to certain acts, as amended and amending certain acts, available in Slovak at <https://www.nrsr.sk/web/Dynamic/DocumentPreview.aspx?DocID=513885> [↑](#footnote-ref-13)
14. Explanatory Memorandum to Act No. 266 amending Act No. 363/2011 Coll. on the scope and conditions of reimbursement of medicines, medical devices and dietetic foods under public health insurance and on amendments and supplements to certain acts, as amended and amending certain acts, p. 48, available in Slovak at <https://www.nrsr.sk/web/Dynamic/DocumentPreview.aspx?DocID=510049> [↑](#footnote-ref-14)
15. Ibid., p. 142. [↑](#footnote-ref-15)
16. SME Blog: The case of Editka - when experts do not deal with the cause, but with the consequences. Decisions on the reimbursement of so-called exceptional medicines must be centralised. 4 April 2023, available in Slovak at <https://blog.sme.sk/preludskeprava/spolocnost/pripad-editka-ked-sa-odbornici-nezaoberaju-pricinou-ale-nasledkami> [↑](#footnote-ref-16)
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20. Slovak National Centre for Human Rights: Expert Opinion. Available in Slovak at <https://www.snslp.sk/wp-content/uploads/OS-Diskriminacia-drogovo-zavislych-pacientov-pri-vykone-prava-na-bezplatnu-zdravotnu-starostlivost.pdf> [↑](#footnote-ref-20)
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23. Ibid. [↑](#footnote-ref-23)
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25. Decree of the Ministry of Health of the Slovak Socialist Republic No. 74/1986 Coll. implementing Act of the Slovak National Council No. 73/1986 Coll. on Abortion, as amended [↑](#footnote-ref-25)
26. See: Slovak National Centre for Human Rights: Report on the Observance of Human Rights Including the Principle of Equal Treatment in the Slovak Republic for the Year 2021, Bratislava 2022, available at <https://www.snslp.sk/wp-content/uploads/Human-rights-report_-for-the-year-2021.pdf> [↑](#footnote-ref-26)
27. Ibid., p. 80. [↑](#footnote-ref-27)
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30. See: Slovak National Centre for Human Rights: Report on the Observance of Human Rights Including the Principle of Equal Treatment in the Slovak Republic for the Year 2019, Bratislava 2020, available in Slovak at <https://www.snslp.sk/wp-content/uploads/Sprava-o-LP-v-SR-za-rok-2019.pdf> [↑](#footnote-ref-30)
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