

 **Republic of Cyprus**

**CYPRUS INPUT REGARDING HRC-RESOLUTION 50/13**

**Subject: Call for contributions – OHCHR-analytical study on key challenges in ensuring access to medicines, vaccines and other health products (HRC-resolution 50/13)**

1. **What are the major obstacles at the national, regional and international levels to ensure equitable access to medicines, vaccines and other health products?**

*Cyprus as a small market, is not considered as attractive for medicine and vaccine producers (Marketing Authorization Holders) to place their products. As a consequence, the number of products registered and actually placed in the Cyprus market is significantly lower than in larger member states.*

1. **Please elaborate on the specific barriers, if any, that women and girls, older persons, children, persons living in poverty, or other persons or groups in situations of vulnerability or marginalization face in accessing medicines, vaccines and other health products.**

*The Cyprus healthcare system, including the provision of medicines, vaccines and other healthcare products, is designed to address any specific issues faced by vulnerable or marginalized groups. Cyprus has recently implemented the National Healthcare Scheme where all citizens are eligible for healthcare provision. The Scheme is administered by the Health Insurance Organization (HIO) who is the primary payer for health interventions including but not limited to, medicines.*

*In extraordinary situations and as mitigation measure relating the availability of medicines and vaccines, the Ministry of Health may also cover cases not or not yet covered by the HIO as a measure to address specific issues that may include patients in vulnerable or marginalized groups.*

1. **Are there any legal or regulatory challenges that impact the accessibility and affordability of medicines, vaccines and other health products?**

*Cyprus utilizes a Reference Pricing System to set the maximum wholesale and retail price of medicinal products, including vaccines, following the submission of a pricing application by Marketing Authorization Holders. This procedure must be followed after a marketing authorization has been granted in order to place a product on the market as per the provisions of the legislation.*

*It has been observed that for a significant number of products, no pricing application is been submitted or even if a price is set, the product is not launched in the market, or its launch is delayed. It is estimated that this is due to the small and unattractive market of Cyprus and the strategic planning of Marketing Authorization Holders on the marketing of their products in larger member states.*

*This phenomenon is considered as a significant obstacle to the accessibility to many medicinal products.*

*It should be noted however as stated above, that the Ministry if Health in order to address potential unmet medical needs, has procedures in place in order to procure medicines and vaccines that are otherwise not available, to cover the population for reasons pertaining to the protection of public health.*

1. **Please elaborate on the impact of research and development models for pharmaceuticals and other health technologies, including emerging digital technologies, on the access to medicines, vaccines and other health products?**

*Due to its small size as well as other factors, little clinical research is performed in Cyprus. Although this is currently rigorously addressed with an aim to attract more research and development activities that could include multicenter international trials, the number of clinical trials and other research activities remains relatively small.*

*Through clinical research and development, it is considered that many patients participating in trials may benefit by accessing innovative therapies to address their unmet medical and other needs. It is also safe to assume that successful research eventually provides patients with better options in terms of available treatments and quality of life.*

*In addition, the utilization of emerging digital technologies such as Big Data and Artificial Intelligence (AI), may have a significant positive impact on the design and conduct of clinical research on medicines, since they may bring together a better structured and efficient knowledge base for researchers across the world. Such technologies could be proactively and prudently pursued and integrated in clinical research as it is anticipated that this will better enable Cyprus to enter into a more rigorous research culture.*

1. **From your perspective, what are the main challenges in terms of international cooperation, partnerships and collaboration to ensure access to medicines, vaccines and other health products?**

*A prime example of international cooperation to ensure access to medicines, vaccines and other health products are schemes of common procurement. This could be done among countries with similar needs and offer better negotiating powers with the industry resulting in better and more affordable access to the products in question. As an illustration of this, the successful COVID-19 vaccine common procurement scheme during the pandemic crisis among the member states of the European Union should be noted.*

*Challenges to this could include the political willingness to participate, competing interests, cultural factors, as well as the perceived benefits and the sustainability of such cooperations.*

*Common procurement schemes could also take place among organizations within one country such as hospitals and other healthcare facilities with similar needs.*

*The option of common procurement should despite its challenges, be continuously pursued and optimized until concrete and measurable results are achieved.*

*Other options could include a continuous collaboration and discourse (both nationally and internationally) with stakeholders such as patient organizations, medical and pharmaceutical societies, the industry and the government in order to identify the needs and create mutual understanding and consensus whenever possible.*

1. **What impact, if any, does the existing intellectual property rights regime have on access to medicines, vaccines and other health products. How can global efforts better address intellectual property rights and technology transfer issues to enhance access to medicines, vaccines and other health products**

*Intellectual property rights as well as other protection mechanisms are designed to provide an incentive to innovators to develop their products by providing an adequate timeframe to generate revenue. Research and development of medicines and vaccines is very costly and may take many years to complete. Thus, the protection of the intellectual property generated for innovative medicines is understandable and acceptable. However, the temporal length of such protections and rights of their beneficiaries should be balanced against the fair needs of societies, such as the entry of generic products after the expiration of intellectual property rights. When generic and therefore, less costly options enter the market, overheads are created for payers such as insurance organizations and even patients themselves, enabling them to channel funds to new innovative products entering the market.*

*Although the current intellectual property rights scheme could be considered successful in providing fair incentives for innovation, caution should be observed in attempts by owners of such rights to abuse the system by attempting to lengthen the prescribed timeframes by other means (a phenomenon dubbed as “evergreening”) by exploiting legal uncertainties and other loopholes. This has been observed with innovators of medicinal products as well. Undue delays in generic products entry, is a significant barrier to the accessibility and affordability of medicines and vaccines.*

*Therefore, it is recommended that international efforts should be directed towards protecting the system of intellectual property rights from activities that may constitute or be perceived as abuse, by providing more legal certainty, thus making the system more robust, fair and resilient.*

1. **What are the main challenges to ensure the quality, safety and efficacy of medicines and vaccines?**

*Cyprus as a member state of the European Union, has transposed and is implementing all European legislation relevant to medicinal products and vaccines.*

*The European legislation has been in place since 1965 and is continuously evolving in order to adapt to technological and scientific progress as well as to address various issues that at times emerge. Therefore, it is considered robust, adaptable and resilient in ensuring the quality, safety and efficacy of medicines and vaccines as its detailed provisions encompass all relevant issues.*

1. **What obstacles do you see in ensuring the affordability of medicines, vaccines and other health products?**

*In terms of more often than not, costly innovative products, any undue delay in the entry of cheaper generics and biosimilar products is a barrier to affordability. In addition, there needs to be adequate generic and biosimilar products actually entering the market in order to create a healthy price competition.*

*Moreover, a culture of generic and biosimilar prescribing and interchangeability should be continuously promoted with an aim to curtail the costs of therapy without off course, compromising its quality.*

1. **What concrete recommendations would you make to enhance access to medicines, vaccines and other health products?**

*Ensure availability of essential medicines and vaccines in small markets (countries).*

*Introduce transparency in pricing and force a fair price setting mechanism especially for small countries where there is a weak negotiation power.*

*Some more concrete recommendations to enhance access to medicines, vaccines and other health products could include:*

* *A balanced policy on incentives and obligations for Marketing Authorization Holder to actually place their products on the markets of small countries.*
* *Measures to prevent the abuse of intellectual property rights while safeguarding the system.*
* *Collaboration among countries with similar needs for the common procurement of medicines and vaccines.*
* *Regulatory flexibility of government competent authorities on minor issues relating to the quality, safety and efficacy of products and a reduction of bureaucratic burden whenever possible.*
* *Scrutiny of shortages of medicines and vaccines that may occur, in order to provide or recommend alternatives.*
* *Provision of incentives for the research and development of innovative medicinal products including vaccines. The governments as well as the academia could be involved to generate knowledge in the public domain without any restrictions on its access and utilization.*
* *A robust Health Technology Assessment system that will effectively enable the efficient reimbursement of innovative products.*
* *A continuous discourse among all stakeholders and the general public.*
* *Adequate and continuous education and training of prescribers and dispensers.*

*The urgent need for supply of treatments, vaccine and tests during the Covid-19 pandemic brings to the fore once more the need under special circumstances to balance the development of pharmaceuticals through Intellectual property rights protection and to ensure that treatments are delivered quickly and fairly to the people who need them urgently. Global efforts can better address Intellectual Property Rights and technology transfer issues by*

*(i) relaxing and widening the compulsory licences systems provided for in European legislation and Global Agreements e.g TRIPS Agreements so as to apply compulsory licences not only locally according to the degree of urgency and the size of the pandemic.*

*(ii) providing Intellectual Property Rights holders adequate legal safeguards, such as information barriers and limitations, to monitor the way information revealed through global use of their Intellectual Property has been used.*

*(iii) providing some sort of legal concessions Intellectual Property Right holders for the use of their property*

1. **Please add any other information or data you would like to share that have not been covered above?**

*No further information is considered necessary at this time.*