Warsaw, 16 September 2024

Memorandum of the Union of Entrepreneurs and Employers on Poland's proposed activities during its presidency of the Council of the European Union in the field of healthcare.

1. Synthesis.

- **The Polish presidency should actively promote the implementation of strategic directions in the area of healthcare, ensuring the stability and predictability of regulations and supporting innovation and development in the pharmaceutical sector.**
- **Improving the promotion of healthy lifestyles and preventing key risk factors could reduce the incidence of non-communicable diseases by up to 70%, which should be a priority for health policy in Europe.**
- **Digitalisation is a key element in rebuilding health systems after a pandemic and strengthening Europe's resilience. Despite overall progress, the digitalisation of healthcare in the EU has been slower due to stringent regulations and health data risks.**
- **The EU should support cooperation between Member States in the digitalisation of health, harmonising technology standards, promoting e-prescriptions and countering misinformation, which will improve healthcare accessibility and quality.**
- **The number of people aged 65 or over in the EU is expected to increase by 41% by 2050 and the number of people aged 80 or over by 88%, increasing the old-age dependency ratio.**
- **It is necessary to develop adaptation strategies for health systems, including long-term care for the elderly, which can be supported by the EU.**
- **The whole of Europe, including Poland, is struggling with shortages of raw materials, rising production costs, logistical problems and competition with Asian markets. There is a need to update pharmaceutical regulations to bring them in line with modern reality and make the European market more attractive to producers.**
- **The return of API and finished medicines production to Europe comes at a high cost, so financial support from Member States and the EU is essential. This can be achieved through a friendly legal and tax system, subsidies, grants and preferences. Particular emphasis should be placed on regulations that support the operation of pharmaceutical companies, especially those producing generic medicines, thus increasing the availability and reducing the cost of pharmacotherapy.**

2. Preventive Healthcare.

Non-communicable diseases account for almost 90 per cent of all deaths in the World Health Organisation (WHO) European Region. Much of this disease burden is preventable and largely depends on risk factors such as tobacco use, harmful alcohol consumption, unhealthy diet, physical inactivity, air pollution and exposure to carcinogens and radiation. Improving the promotion of healthy lifestyles in combination with preventive measures against key risk factors

for non-communicable diseases has the potential to reduce their incidence by up to 70%[1]. Therefore, action to eliminate these risk factors through prevention and health promotion, as well as addressing the underlying socio-economic determinants of these diseases, should continue to be a priority for health policy in Europe.

Not only do non-communicable diseases place a heavy burden on the overall health and well-being of the population, but they also negatively impact our economies, put a strain on our medical workforce and place an unequal burden on health systems that are significantly understaffed and lack sufficient investment in many European countries. In addition, as we saw during the *SARS-Cov-2 coronavirus* pandemic*, COVID-19*, people with concomitant conditions are also more affected during public health crises. They are more susceptible to contracting infectious diseases and experience an impaired immune response, including a greater risk of severe disease associated with infectious diseases such as COVID-19. Therefore, the rationale for investing in the elimination of non-communicable diseases risk factors is clear: they generate high healthcare and pharmaceutical costs in all countries, and lead to significant social expenditures such as lost productivity.

In addition, with ageing populations in Europe, healthcare costs tend to rise. The return on investment in prevention is well known; however, the share of investment in prevention as a proportion of overall health expenditure remains significantly low, accounting for only 3% of overall health expenditure in the EU[2].

In contrast, the perceived focus of the health system in the Member States on remedial action, i.e. action taken in the event of illness, results in healthcare being seen mainly as a cost, whereas well-functioning healthcare - and not just health recovery - is essential for a country's socio-economic development, including GDP growth. One way to do this is through health education and prevention. These are actions that reduce future costs, increase productivity, prosperity and quality of life for society.

The aim of healthcare measures should be to ensure the mental and physical well-being of citizens, which is directly reflected in their professional activity level and healthy life expectancy. Above all, therefore, multidimensional promotion of health-seeking attitudes is needed.

An area that has been neglected over the years has been psychological and psychiatric care, with an estimated one in six people having a mental health problem in 2019, both in the EU and in the wider WHO European region. This number has increased by around 25% as a result of the COVID-19 pandemic. In contrast, access to psychiatric care is a key problem in many Member States. Although most countries have policies to improve the mental health of the population, there are challenges in implementing them. These challenges include a growing shortage of health and care professionals and the need for stronger and more numerous programmes to prevent mental health problems and promote well-being. In addition, people

[1] Pan American Health Organization (PAHO) Healthy Aging and Non-Communicable Diseases, n.d. https://www3.paho.org/hq/index.php?option=com_ content&view=article&id=9979:healthy-aging-noncommunicable-diseases&Itemid=0&lang=en#gsc. tab=0

[2] Eurostat. Preventive health care expenditure statistics. Database. 2023. https://ec.europa.eu/eurostat/statistics-explained/index. php?title=Preventive_health_care_expenditure_statistics#:~:text=Highlights&text=EU%20 Member%20States%20spent%20,of%20the%20COVID%2D19%20crisis.&text=Preventive%20 health%20care%20expenditure%20in,0.37%20%25%20of%20GDP%20in%202020

with experience of mental health problems need to be more involved in the creation of these programmes, to ensure that countries develop them in line with their needs.

The lack of adequate education and access to support not only generates high costs for the health system, but also has a significant impact on the costs for businesses, the financial condition of social security systems and the economy as a whole. Figures for 2022 clearly show that the number of sick leave issued due to mental and behavioural disorders amounted to 1.29 million in Poland alone, which translates into as many as 23.8 million days of sickness absence for employees. The increasing trend in this area is worrying, and the lack of access to mental health advice and long waits for help only add to the problem.

3. Digital Transformation.

EU citizens today take digital technologies for granted, allowing them to communicate with their peers anytime, anywhere, as well as manage their transport bookings, accommodation and other activities via their smartphone. Digital development has been strongly supported by the European Union over the past decade: EU policy makers have made digital transformation a political priority and created a whole package of legislation to support this transition. However, digitalisation in healthcare has been slower than in other sectors, which can be attributed to the rigorous regulatory environment underlying healthcare delivery, the nature of the risks associated with technology failure and the sensitivity associated with handling personal health data[i]. For all these reasons, it was not fully anticipated how dynamic the changes in healthcare digitalisation were during the COVID-19 pandemic.

COVID-19 has forced patients, medical professionals and institutions to reorganise almost all existing care pathways to manage the pandemic. As medical practices and hospitals were limiting face-to-face visits to essential consultations, teleconsultation and telemedicine became the new standard of care in many European countries, even though for up to 84% of patients this represented their first experience of virtual care[3]. The pandemic also revealed weaknesses in both the health and digital sectors in Europe: reliance on products and technology from outside Europe led to supply bottlenecks and shortages of medicines and equipment.

Today, this new impetus for digitalisation can play a key role in accelerating the recovery of health systems after the COVID-19 pandemic and strengthening Europe's resilience to avoid future crises. EIT Health, in its report 'Unlocking Innovation to Build More Resilient and Sustainable Healthcare Systems in Europe'[4] identified digitalisation as a pillar of this recovery and highlighted ways in which EU funds, policies and regulations can be used to remove barriers to innovation in health. Looking beyond the pandemic and its consequences, the current moment could be a historic opportunity to finally make digital technologies an integral part of public health services, which could thus simultaneously become more equitable and accessible to all European citizens and offer greater personalisation and value to the individual patient.

However, there are still significant differences in access to services within the European Union, and funding for healthcare by Member States, measured as a percentage of GDP, also varies.

[3] European Parliamentary Research Service, 2021
[4] EIT Health (2022) Unlocking Innovation to Build More Resilient and Sustainable Healthcare Systems in Europe

This indicates the need for a local approach when implementing digital solutions in the health sector, as levels of digital readiness are uneven across EU countries. The expanded use of mobile healthcare (mHealth) beyond pilot programmes and its integration into clinical and public health initiatives will be challenging, especially in countries with limited economic resources.

From a technological point of view, it is crucial to create a reliable public infrastructure in the Member States that will enable the seamless integration of mobile healthcare with routine health activities. These innovative digital solutions should be part of 'integrated health services', which are defined as 'health services managed and delivered in such a way that people receive a continuum of health promotion, disease prevention, diagnosis, treatment, disease management, rehabilitation and palliative care, coordinated across levels and settings of care, both within and outside the health sector, according to their needs throughout their lives'.

The European Union should support Member States in the digital transformation of health in particular by promoting cooperation with other EU countries on the digitalisation of health. This should include the exchange of best practice, joint research projects and, in particular, the harmonisation of technological standards, allowing, for example, the cross-state implementation of e-prescriptions in all Member States. It is also necessary to put in place appropriate information programmes to counteract health misinformation and increase transparency in public health communication, thus engaging a larger proportion of the population to enjoy the benefits of digitising parts of health processes.

Digital technologies can improve people's access to healthcare and bring advances in health issues, especially as healthcare becomes more personalised. While modern technology cannot fully solve all healthcare challenges, it can add significant value when effective and accessible solutions are scarce. However, there are many obstacles to the digitalisation of the healthcare system, including resistance from healthcare professionals and patients[5]. The most important thing is to understand what is required to accelerate the digitalisation of healthcare, beyond the basic need to develop an information society.

4. Healthcare in the context of demographic change.

The European population is ageing. The increase in life expectancy, combined with low birth rates, will increase the size of the older population groups in the EU. The number of people aged 65 or over is expected to increase by 41% over the next 30 years (from 92.1 million in 2020 to 130.2 million in 2050), while the number of people aged 80 or over is expected to increase even more, by 88% (from 26.6 million in 2020 to 49.9 million in 2050)[6]. As a result, the old-age dependency ratio is expected to increase significantly, from 32 in 2020 to 52 in 2050 - which represents an increase of more than 62%.

These demographic changes are significantly increasing the European population's demand for health services, while at the same time the phenomenon of ever-decreasing resources for

[5] Hashemi G, Wickenden M, Bright T, Kuper H. Barriers to accessing primary healthcare services for people with disabilities in low and middle-income countries, a Meta-synthesis of qualitative studies. Disabil Rehabil 2022;44(8):1207–20.
[6] Eurostat, data base

healthcare is continuing. Between 2000 and 2017, employment in health and social services in OECD countries increased by 48%[18] . As the population ages and changes, the demand for health services will also grow and change: it is estimated that the global demand for health employees will almost double by 2030[7].

The key to ensuring continued economic growth opportunities will in future reside in better use of healthcare funds. Ageing populations, living longer, generate increasing health and social care costs, which could be less if people age in good health. Economic productivity and prosperity depend on a healthy population, and healthy life expectancy is an important factor in economic growth. OECD studies show that each additional year of population life expectancy translates into a 4% increase in EU GDP[8]. Work absenteeism of between 3 and 6% of working time represents an annual social cost of around 2.5% of GDP[9]. The health of citizens is fundamental to economic prosperity, and investment in the healthcare system is a key investment in the economy.

A consequence of the changing demographic and epidemiological profile of the populations of European Union Member States will be the need to reorganise healthcare. This will mainly be due to the population's increased susceptibility to certain age-related diseases, such as cancer, cardiovascular disease or musculoskeletal conditions. The volume of consumption and costs of healthcare, especially long-term care, are influenced not only by demographic factors, but also by socio-cultural factors such as the institutionalisation of chronic care and the medicalisation of social life[10]. Projections to 2050, ordered by the European Commission as part of a study in four Western European countries, show a further increase in the number of people needing this type of care, its services and the associated expenditures[11].

Above all, the priority of the Polish presidency should be to develop appropriate strategies to adapt healthcare systems to new reality. Particularly relevant here is the issue of long-term care for the elderly, and while this remains the responsibility of the Member States, the EU is in a position to support its development through various measures such as dedicated funding, data collection and the design of appropriate long-term goals in this area. Long-term care policies must be considered in the context of other policies that have a direct impact on long-term care, in particular policies on pensions, healthcare and healthy and active ageing. Adequate pensions, which are the main source of income for older people, are a key element in ensuring that long-term care is financially accessible. The European Commission's 2021 Pension Adequacy Report, jointly prepared by the European Commission and the Social Protection Committee (SPC), outlines the state of pension adequacy in the EU, including in relation to the availability and cost of long-term care services. One of the key messages of the

[7] Liu, J.X., Goryakin, Y., Maeda, A., Bruckner, T., Scheffler, R., Global Health Workforce Labor Market Projections for 2030
[8] The WHO 2010 Global Report on Non-Communicable Diseases, World Health Organization 2011 Reprinted 2011. Available on: http://whq libdoc.who.int/ publications/2011/9789240686458_eng.pdf.
[9] EUROFOUND (2010), Absence from work report, European Foundation for the Improvement of Living and Working Conditions, 2010. Available on: http://www.eurofound.europa.eu/ewco/studies/tn0911039s/tn0911039s_5.htm.
[10] Iga Rudawska, Epidemiological and demographic trends as a challenge for European healthcare systems, Management Issues (*Oryg*. Trendy epidemiologiczno-demograficzne jako wyzwanie dla europejskich systemów ochrony zdrowia, Problemy Zarządzania) vol. 11, no. 1 (41), vol. 2.
[11] European Commission, European study on long-term care expenditure.

report is that accessible and high quality long-term care services are important for maintaining an adequate standard of living and activity in retirement[12].

5. EU pharmaceutical law reform.

The limited availability of medicines affects not only Poland, but the whole of Europe. EU countries are facing shortages of raw materials, rising production costs, logistical problems and competition with Asian markets. There is a need to adapt pharmaceutical regulations, which have not been substantially changed for 20 years, to modern reality. It is crucial to increase the attractiveness of the European market to encourage producers to relocate to the EU.

The Commission's proposals set out in April 2023, while well-founded, appear insufficient, focusing on changes to registration and market exclusivity periods, shifting responsibilities to producers. Incentives are virtual, offering no real investment support. At the same time, the planned legislation ignores issues that the industry has been facing for years, which would need to be communitarised at European level (e.g. the problem of early access to therapy, implementation of a modern distribution chain, delivery of medicines to the patient's home, price pressure from the public payer).

In the context of these regulations, there have also been claims that their introduction will reduce Europe's innovativeness in relation to other regions of the world. We believe that the decline in the global competitiveness of the European pharmaceutical sector is not due to the erosion of intellectual property, as the EU has systematically increased regulatory incentives and monopolies in this area since the 1990s. New forms of intellectual property protection introduced since then have aimed to make Europe a leader in R&D innovation.

However, the rise of monopoly protections has contributed to a relative decline in R&D in Europe compared to China and the US, undermining the thesis that larger monopolies lead to greater innovation. Moreover, these measures have contributed to the relocation of medicines production outside Europe, even though the EU is now trying to correct the situation.

In turn, measures to promote generic medicines competition have had positive effects, increasing access to medicines in Europe and reducing pressure on healthcare budgets. The biosimilars legislation has made Europe a leader in this technology, which has encouraged investment in the production of biologic medicines in the EU. Therefore, the Polish presidency should strive to ensure that the final shape of the pharmaceutical strategy for Europe continues to provide support for the generic medicines and biosimilars sector, which is crucial for Europe's medicine security.

A necessity for the Polish presidency will be a detailed analysis of the proposed regulations in the further course of the legislative work of the Council, with significant consideration for the needs of patients and industry, and ensuring dialogue with regulators at the local and European levels.

[12] European Commission Directorate-General for Employment, Social Affairs and Inclusion Social Protection Committee 2021 Long-Term Care Report Trends, challenges and opportunities in an ageing society Volume I

6. Rebuilding medicines safety in Europe and Member States, including restoring production of APIs and finished medicines in Europe.

The events of recent years related to the COVID-19 pandemic and Russia's military aggression against Ukraine have shown how critical security of medicines is, especially in the face of crisis, and highlighted the need for Europe to be independent from API production in countries in the Far East. Continued production dependence could pose a threat to the health and safety of European and Polish patients. The need to bring back the production of APIs and finished medicines to Europe is a strategic objective of all European institutions expressed in guidance documents such as:

- the opinion of the European Economic and Social Committee of December 2023
- the Versailles Declaration of the Council dated 11 March 2022.
- the European Parliament Resolution of 17 September 2020 on the shortage of medicines
- the European Commission Pharmaceutical Strategy of 25 November 2020.

It is worth emphasising that locating the entire medicine production process in the country, including the production of the API, involves significant costs (construction of new infrastructure, training of personnel, environmental protection, etc.), so financial support from the Member State and the EU is essential. This can be done indirectly, by building a business development-friendly legal and tax system, or directly, through subsidies, grants or preferences. It is worth noting that in the case of Polish entrepreneurs, they are mainly focused on the production of generic medicines, which translates into increased availability and reduced costs of pharmacotherapy. Particular emphasis should therefore be placed on creating regulations that enable companies to operate smoothly, guaranteeing stability, predictability and return on investment. Some of the solutions currently being introduced will need to be further deepened in the future. The following are examples of proposals in the area of registration refunds:

- Complete exemption from statutory payback for a medicine produced in Poland and/or from a substance produced in Poland.
- Priority in the establishment of lists, in particular of free medicines for a medicine produced in Poland and/or from a substance produced in Poland.
- Ensuring that comparable reimbursement conditions can be obtained for medicines produced in Poland and/or from a substance produced in Poland.
- Shortening the period of data exclusivity/market exclusivity of original medicines.
- Elimination of regulatory gaps favouring abuse of the right to exclusivity and negative patent links delaying the marketing of equivalents.

It is necessary to take the lead on the above subject in order to guarantee the strategic autonomy of the European Union based on the production capacities of the individual Member States. There is a need for a dedicated European legislative act with financial and regulatory incentives to maintain and move production of APIs and finished medicines to Europe. The Polish presidency could turn the declared strategic directions of all European institutions into reality.

[i] Schuller, 2020; EIT Health, 2020