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MEDICINES SUPPLY SECURITY

FOR POLAND'S AND EUROPE'S MILITARY SECURITY

SGH Think Tank dla ochrony zdrowia

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INTRODUCTION

Amidst increasing geopolitical tensions and changes in the European security environment, medicines supply security is beginning to be considered not only as an element of health policy, but also as a key constituent of military security and state resilience. This report is inspired by the conclusions of the Sauli Niinistö report, which emphasises the need for an integrated approach to building the European Union's civilian and military preparedness, covering all areas of critical infrastructure.

The aim of this report is to identify and analyse medicines supply security as a distinct sub-area of Poland's military security, taking into account the wider European context. Particular emphasis is placed on the availability of medicines needed both in battlefield medicine and for population treatment during armed conflicts and crises. The report was produced in cooperation with the Ministry of National Defence.

The analysis carried out in the report focuses, in particular, on:

- lessons learned from the experience of the war in Ukraine in maintaining the continuity of the supply of medicines and the functioning of the health infrastructure,
- challenges of pharmaceutical security for the armed forces in peacetime and in crisis situations,
- risks posed by the concentration of API and medicines production in Southeast Asia,
- the need to integrate the pharmaceutical sector into the critical infrastructure system and to build strategic reserves.

Traditionally seen as the domain of health policy, medicines supply security must today be recognised as an important element of the state's defence system - on a par with energy, transport or communications. Adequate preparation at the national and European level, involving short-, medium- and long-term actions, is essential to maintain the state's ability to defend itself, protect public health and ensure the continuity of social and economic services under conditions of crisis or war.

EUROPE'S MILITARY SECURITY AND POLAND'S CURRENT ROLE

SECURITY OF CRITICAL INFRASTRUCTURE

Since the beginning of the 21st century, Russia has consistently enhanced its military capabilities and pursued an aggressive policy towards its neighbouring countries, posing one of the greatest threats to European security since the end of the Second World War [1]. Beginning in 2008 when Russia invaded Georgia while demonstrating its ability to intervene militarily at short notice, the Russian Federation has continued the strategy announced in 2007 at the Munich Security Conference by President Putin of regaining the sphere of influence it lost after the collapse of the USSR.

Another manifestation of this strategy was the violation of Ukraine's territorial integrity and the annexation of Crimea in 2014. Continuing this policy direction, Russia launched a full-scale military invasion of Ukraine in February 2022 with the aim of fully subjugating the Ukrainian state. Another demonstration of Russia's aggressive plans towards European states is the consistent militarisation of the Königsberg region, the deployment of Iskander-M missile systems there and the organisation of military exercises under the code name 'Zapad' (meaning 'West'), the scenario of which included war with NATO states, including the use of tactical nuclear weapons. The exercises were another demonstration of Russia's readiness to use force against the Alliance, but also a demonstration of the high degree of interoperability between the armed forces of Russia and Belarus [2].

Of special importance in Russia's military plans is the so-called Suwałki Gap, a direct land connection between the Königsberg region and Belarus, which openly supports Russia in the war against Ukraine by making its territory and military infrastructure available to it. Also important in assessing the military threat to the countries on the European Union's eastern border is the potential and geographical location of Belarus, which also pursues a hostile policy towards these countries and supports Russia in many areas.

The North Atlantic Alliance also identifies Russia as the most serious threat in its strategic documents, and this assessment is being followed up by an adaptation of the Allied deterrence and defence posture on the eastern flank, including by gradually increasing the presence of advanced military forces in Poland and other countries in the region [3].

The characteristics of today's conflicts, whether between states or organisations (e.g. religious, ideological, cultural, ethnic), are far from the standards adopted back in the 20th century to define war. We are increasingly dealing with what is referred to as hybrid warfare, which is defined, inter alia, as "war combining simultaneously various possible means and methods of violence, in particular including regular and occasional military actions, operations in cyberspace, as well as economic and psychological tactics, information campaigns (propaganda), etc." [4] .

Hybrid warfare is characterised by two key features. Firstly, it is waged below the threshold of military action and, consequently, the boundary between peace and war is blurred. In the current geopolitical situation in Central and Eastern Europe, it does not take the form of regular (kinetic) actions due to its multi-domain nature, both in the real world and in cyberspace. The second characteristic feature of hybrid warfare is its ambiguity and the question of attribution of responsibility, which makes it significantly more difficult to identify the aggressor.

In the case of the threat to the eastern borders of the European Union, including Poland, we have been dealing with hybrid warfare since 2021, and its primary means are operations involving the organisation of illegal migration. In 2024 alone, more than 30,000 attempts to illegally cross the Polish-Belarusian border were recorded. Foreigners who attempted to force the border in the Podlasie region came from 52 different countries. Most were citizens of Ethiopia, Eritrea and Somalia. Illegal migrants also included people from countries such as Comoros, Guinea, Sudan, Nepal, Iran, Iraq, India and Benin [5].

The activities of migration hybrid warfare are also visible in the information domain, where the problem of illegal migration is presented as a humanitarian crisis at the border. Disinformation disseminated mainly on the Internet gives rise to social conflicts regarding the humanitarian policy, the concept of the struggle between good and evil is blurred, and an internally divided society does not fully accept the actions of national security services.

The report authored by Sauli Niinistö, former President of Finland, and commissioned by the President of the European Commission, presents a comprehensive strategy for strengthening the European Union's civilian and military preparedness [6]. It responds to growing security threats - from war and cyber attacks to climate disasters - by proposing an integrated approach to building resilience across the Union. The document provides a starting point for the next European Commission (2024-2029) and includes specific recommendations for EU institutions and Member States.

State resilience is presented as a condition for the stability and security of the Union's economic and democratic systems. The report defines it as the ability to anticipate, survive, adapt and recover from crises of a complex nature - from military aggression to pandemics and climate disasters. It is proposed to move away from treating preparedness as a separate field to integrating it into mainstream public management. Central to this is the introduction of the principle of 'preparedness by design' - i.e. taking preparedness into account from the stage of designing legislation, funding instruments or institutional systems. The report promotes a 'whole-of-society' approach in which citizens, administrations, business and community organisations participate together in building resilience [7].

The report identifies critical infrastructure as one of the main security challenges and a priority for EU preparatory action. The high level of interconnectedness between energy, transport, health, food and communications systems means that a failure in one area can quickly have a knock-on effect on other sectors and countries [8]. Critical infrastructure includes key sectors such as energy, transport, telecommunications, the financial sector and military infrastructure. Currently, the pharmaceutical sector (industry, wholesalers, pharmacies) is not covered by critical infrastructure, which means production disruptions when electricity supply is interrupted.

The most important groups of threats to critical infrastructure include:

- hybrid activities,
- cyber threats,
- physical threats to critical infrastructure,
- disinformation and information warfare.

The Niinistö report emphasises the need to identify at EU level the societal and governmental functions whose continuity must absolutely be maintained - with appropriate preparedness standards and testing procedures. A special role is assigned to cooperation with the private sector, which is responsible for a large part of critical infrastructure. It recommends formalising cooperation mechanisms, sharing information, joint emergency planning and organising cross-sector exercises. The report also proposes extending the scope of the NIS2 and CER directives to further include industries critical to keeping the state functioning, such as the defence industry. In addition, it points to the need to coordinate the storage of strategic reserves and the monitoring of supply chains.

PILLARS OF POLAND'S MILITARY SECURITY

The Armed Forces of the Republic of Poland (Polish Armed Forces) play a key role in ensuring national security and territorial defence. In recent years, they have been undergoing a dynamic transformation, adapting to new threats such as aggressive Russian policy and cyber attacks. The main objective of the transformation of the Polish Armed Forces is to achieve readiness to perform tasks in the area of deterrence and defence.

The Chief of the General Staff of the Polish Armed Forces set out the priorities for the development of the Polish Armed Forces for the period 2025-2039, and identified the following key directions for the modernisation of the armed forces, commonly referred to as the 'Great Seven', which include modern technologies and organisational changes to ensure Poland's ability to effectively defend itself and deter potential adversaries:

01. intelligent mass - combining quantity with quality
02. multi-domain operations - war in physical, informational and cognitive space
03. air dominance and precision strike - the key to deterrence through punishment
04. aircraft, missile, counter-drone defence – protection of troops and infrastructure
05. next-generation personnel reserves - training system adapted to demographic challenges
06. dronisation and robotisation - efficiency, reduction of costs and personal losses
07. artificial intelligence - acceleration data analysis and real-time decisions.

Transformation involving technical modernisation requires vast and stable funding. In recent years, Poland has significantly increased its defence spending, becoming one of the leaders among NATO countries in terms of the GDP percentage spent on defence. In 2024, Poland allocated around PLN 135 billion to defence, which accounted for nearly 4% of its GDP. This was a record sum in the history of the Third Republic of Poland, with more than 40% of the amount spent on new armaments and infrastructure investments for the Polish Army.

In 2024 alone, contracts were concluded for the purchase of new equipment for the army worth more than PLN 161 billion, of which around PLN 110 billion went to foreign industry, with the remainder going to the Polish arms industry. The planned expenditure on defence is to amount to PLN 186.6 billion, which will account for 4.7% of the GDP. A significant part of the funds has been earmarked for the modernisation and purchase of modern armaments, including tanks, air defence systems and the development of military infrastructure. In addition, Poland plans to increase domestic production of munitions to strengthen its defence capabilities in the face of potential threats.

According to the definition worked out by both NATO and the European Commission, the term 'state resilience' includes the ability of societies to survive in the face of major crises and to quickly return to normal functioning [9]. In the Polish legislative framework, references to resilience are already found in the National Security Strategy of the Republic of Poland 2020. In addition, some elements related to resilience are included in both the National Crisis Management Plan [10] and the National Programme for the Protection of Critical Infrastructure [11]. All of the documents referenced above agree that achievement of state resilience and civil preparedness depends on ensuring synergies in three domains:

01. in the public sector, including through civil-military interaction;

02. in the private sector, through possible public-private partnerships; and

03. among the society, as the third domain, by building awareness of potential threats, the ability to respond adequately and a committed attitude in countering dangerous phenomena or trends.

Building resilience based on the above three domains, i.e. involving the public sector, the private sector and society, means to eliminate the weaknesses and vulnerabilities that can be exploited by a potential adversary or can become a target for an attack [12]. In this way, a forearmed country gains:

- **military resilience,** which includes the ability of the armed forces to undertake effective defence operations (including against hybrid attacks), as well as support mechanisms such as the strategic reserve system and logistics facilities, also in partnership with the private sector,

- **infrastructural resilience,** which involves the protection and restoration of key critical infrastructure, including energy, transport and telecommunications networks,

- **economic resilience,** which consists in ensuring the country's financial and economic stability, including mechanisms to protect against financial crises and cyber attacks (Ministry of State Assets, 2023); it also requires maintenance of the productive and economic capacity necessary to conduct long-term military operations,

- **societal resilience,** with civil society involved in defence processes, raising the awareness of threats and boosting patriotism,

- **information resilience,** consisting of countering disinformation and media manipulation and protecting the information sovereignty of the state.

The military security of Poland, as a border country of the European Union, primarily depends on its own military and economic potential and the country's preparedness to defend itself. Additional factors which strengthen their military security are membership of NATO and the European Union, the strategic partnership with the USA and regional cooperation

NATO membership remains the main external pillar of their military security. By pursuing an active policy of strengthening its military potential, increasing its defence spending well above the 2% of GDP until now considered to be the gold standard, and planning to expand its Armed Forces to 300,000 troops and engaging in NATO's 360-degree strategy [13], Poland is becoming one of the leaders of this defence bloc.

Poland's membership of the European Union is a factor promoting social and economic development and determining their position and international importance. The attitude of the European Union towards Russia's aggression against Ukraine shows that the Union, in difficult situations, is able to react uniformly to the threats posed by Russia's policy. A manifestation of this response is the successive packages of sanctions against Russia, as well as the direct military and financial aid given to Ukraine. It is noteworthy, however, that such an unequivocally negative assessment of Russia's actions was only expressed after Russia's direct attack on Ukraine in 2022. Until then, some EU countries, especially those outside Central and Eastern Europe, did not perceive the threat posed by Russia's actions in such a categorical way, continuing to cooperate economically with Russia, especially in the area of energy [14]. The underestimation of Russia as a threat contributed to a drastic decline in defence spending by European states and the loss of the ability of the European defence industry to produce military equipment, especially munitions. It was not until the March 2025 summit of EU leaders in Paris that a change in the vectors of European security policy was confirmed [15].

The strategic partnership with the US, alongside NATO membership, is the second pillar of Poland's military security [16]. A manifestation of this partnership is the permanent presence of the US military in Poland, including the deployment of an American missile base in Redzikowo. Cooperation with the United States is not only military, but also commercial in the area of energy (e.g. gas imports, nuclear energy technologies) and defence industry (e.g. purchase of the PATRIOT system, F-35 aircraft, Apache AH-64 helicopters). Despite some tensions between European countries and President Trump's new administration related to defence policy, it seems that the relationship and guarantees of the United States regarding Poland's security will remain stable.

The scale and type of threats emanating from Russia's aggressive and revisionist policy in the region has forced an increase in the importance of **regional cooperation.** The cooperation of the Baltic Sea states, the Bucharest Nine, the Weimar Triangle and the Trilateral Initiative is gaining particular importance. The importance of cooperation between the Visegrad Group countries is declining due to the differences in approach to the war in Ukraine presented by Hungary and Slovakia.

THE ESSENCE OF DRUG SUPPLY SECURITY

Access to medicines is one of the foundations for ensuring that the right to health can be fully exercised [17]. It depends on several fundamental elements, the balance of which provides the best possible access for citizens. These are availability and accessibility, affordability and innovation (innovation) [18]. Recent years, and especially the Covid-19 pandemic period, have exposed the problems of ensuring access to medicines, especially with regard to availability and affordability. This has been particularly true for critical medicines, i.e. medicines for which there is no adequate alternative and the insufficient supply of which could result in serious consequences for patients [19-22].

The causes of shortages are varied and may be due to [23]:

- unforeseen increases in demand,
- disruptions to logistic processes,
- supply restrictions due to quality problems, and finally
- a limited number of suppliers.

There have been several events in recent years that fall into one of these categories. Contaminants in active substances imported from India and China, the lockdown of China's industrial regions, delays in maritime transport and container ship availability, export restrictions and the priority of production for own domestic markets, the blockade of the Suez Canal - these are events that occurred in the last 10 years, raising questions about Europe's over-dependence on supplies from South-East Asia. The current geopolitical situation calls for a close analysis and caution with regard to goods delivered from the United States.

The problem of shortages is so serious that it has gained priority in the EU arena and has been raised by recent Council Presidencies, including the ongoing Polish Presidency in the first half of 2025. The European Parliament has adopted several resolutions on addressing shortages and improving access to medicines. A strategic document outlining the causes of the issue and strategies to counter them is the draft Critical Medicines Act. As it points out, shortages of medicines are due to the disruption of existing vulnerable value chains, high dependence on suppliers from outside the European Union and tensions in the geopolitical arena [24].

In particular, as highlighted by the Critical Medicines Alliance Strategic Report, this applies to critical and shortage-prone medicines [25]. This category refers to medicines with medium to high therapeutic significance and medium to high risk due to the limited availability of market alternatives, as well as those for which one of these criteria is significant and, also, for which supply chain resilience tests show high vulnerability to disruption.

Given the impact of globalised and concentrated (single-source) supply chains on the risk of medicine shortages, one of the solutions addressing the issue of shortages in the long term is the reshoring of pharmaceutical production – both for finished goods and active ingredients. Steps identified in the March 2025 version of the draft Critical Medicines Act include [24]:

- creating investment incentives - categorisation of selected investments as strategic, simplification of administrative and authorisation procedures, direct financial incentives for strengthening production of critical medicines and APIs,
- demand-side measures - promotion of favourable procurement practices, greater focus on joint procurement, promotion of a level playing field in terms of standards (e.g. environmental and social), defining procedures for the creation and restoration of emergency stocks,
- coordination of activities - at intra-EU level for critical and shortage-prone medicines, and at international level.

The steps outlined are in line with recommendations in other reports and documents emerging at EU level. The European Economic and Social Committee (EESC), in its exploratory opinion on the development of the Critical Medicines Act, also pointed to the need for [26]:

- establishment of a Fund dedicated to the financing of API and essential medicines reshoring projects,
- creation of a European funding instrument for a commercial market for APIs and essential medicines manufactured in Europe,
- introduction of tender preferences for European APIs and essential medicines,
- emergency purchases in justified cases,

- ensuring preferential, fast-track entry into reimbursement list for such medicines,

- imposing an obligation on market participants to purchase or stock European APIs and essential medicines.

The EESC also draws attention to the already visible consolidation of European API production sites in Italy, Germany, Spain and France. It points to the importance of diversifying future reshoring investments, both geographically and in relation to external threats such as armed conflicts taking place close to the EU's borders.

THE IMPORTANCE OF API AND MEDICINE AVAILABILITY IN A SITUATION OF INCREASING INTERNATIONAL TENSIONS

ENSURING ACCESS TO MEDICINES IN SITUATIONS OF ARMED CONFLICT - BASED ON THE EXPERIENCE OF THE WAR IN UKRAINE

Russia's full-scale attack on Ukraine began on 24 February 2022, and the first reports of shortages of life-saving medicines began to appear in the media within a week of the attack.

The causes of the first shortages were due to **the destruction of medical infrastructure,** including production facilities for medicines and medical devices [27]. The destruction of infrastructure ranged from direct damage (production lines or warehouses of production materials and medicines) to power outages that prevented continuity of manufacturing operations.

Disruptions in supply chains were a problem, causing difficulties in getting medicines and equipment to medical facilities in need. Road blockages and domestic and air transport disruptions caused delays in importing APIs and getting them to domestic manufacturers. The problem was exacerbated by the fact that Ukraine is heavily **dependent on international suppliers for API production.** Logistic problems resulted in significant delays in production.

The failure of supply lines to pharmaceutical factories was also a consequence of **fuel shortages, the diversion of transport vehicles and introduction of a curfew.** To limit the impact of these factors on the production continuity of the pharmaceutical sector, the government took steps to exempt pharmaceutical logistics chains from traffic restrictions and to ensure that fuel is available as much as possible [28].

In addition, **staff shortages** became an issue as personnel volunteered to join the Ukrainian Armed Forces (although the government exempted medical personnel from compulsory service) or were displaced [29]. Internal regulations were issued allowing also medical and pharmacy students to be engaged to work in pharmacies. There is no information on the steps taken in respect of employees of pharmaceutical and medical device manufacturing facilities.

The pharmaceutical market in Ukraine has grown rapidly in recent years (i.e. 2015-2022), with domestic production of finished medicines securing around 70% of all medicines sold in pharmacies. In 2020, 115 manufacturers and 400 pharmaceutical distributors were registered in Ukraine [30]. Despite this, during the first phase of the full-scale war, stocks of critical medicines in many cases fell to levels sufficient for less than 10 days, and shortages were reported at the local level in many cases [31]. A particular problem was the shortage of medicines and equipment causing immediate danger to the lives of patients, such as oxygen in healthcare institutions [32], cardiovascular medicines [33] and chemotherapeutics. Waiting times for medicines in pharmacies also increased significantly.

The shortages of medicines and equipment were experienced most acutely in the areas subjected to indiscriminate attacks and prolonged occupation - up to a third of the population had difficulty accessing medicines in those areas [34]. An example is Mariupol in the Donetsk region, where medicine shortages affected patients with a range of conditions, including oncological diseases, diabetes, tuberculosis and thyroid diseases [35]. In other regions, shortages of antibiotics and medicines for cardiovascular diseases and stroke treatment were reported [36]. In order to secure the supply of such medicines, the Ministry of Health and the Public Health Centre of Ukraine have established close cooperation with humanitarian organisations operating in Ukraine and internationally. External supplies of medicines and medical equipment provided support due to the lack of capacity of the domestic sector to satisfy the needs.

In Ukraine, measures were taken in response to shortages of medicines and raw materials. These included simplified regulations for the import and marketing of medicines, simplified or even suspended registration requirements for the import of medicines and APIs, and authorisations for direct contractual negotiations between healthcare institutions and manufacturers bypassing the tender process [37-38]. Such administrative measures facilitated access to medicines and raw materials in the early phases of the conflict, but gave rise to risks primarily related to the introduction of medicines of inferior quality or without information leaflets and labels in Ukrainian, as well as an increase in the price of medicines as a result of direct contract negotiations.

STABILITY AND SECURITY OF THE NORTH ATLANTIC ALLIANCE. NATO BASELINE REQUIREMENTS: RESILIENCE

Rooted in Article 3 of the North Atlantic Treaty, national and collective resilience is the basis for credible deterrence and defence and the effective fulfilment of the Alliance's core tasks.

Resilience is the ability to prevent, protect against, respond to and resist incidents, as well as to mitigate and absorb their consequences. It is both a national responsibility and a collective commitment. Each ally must be sufficiently prepared and ready to adapt to deal with the entire spectrum of crises such as a natural disaster, failure of critical infrastructure and hybrid or armed attack. At the same time, each ally's individual commitment to maintaining and strengthening its resilience reduces the vulnerability of NATO as a whole.

Events such as Russia's annexation of Crimea (2014) or the rise of the power of ISIS/Daesh (2013-2014) heralded changes within the strategic environment, prompting the Alliance to strengthen its deterrence and defence posture. Also, the Covid-19 pandemic and the full-scale armed conflict in Ukraine increased our understanding of the need to rewrite security scenarios. There is now an effort by Alliance members that complements NATO's military modernisation with a comprehensive deterrence and defence posture.

In 2016, at the Warsaw Summit, Alliance leaders pledged to strengthen resilience by pursuing the seven baseline requirements of civilian preparedness, the most relevant of which, in the context of the topic at hand, is the ability to deal with mass casualties. There are many stakeholders involved in the task of building resilience: the government, various civilian ministries, the armed forces, as well as the private sector and non-governmental organisations. All these stakeholders have a great role to play in the building of national resilience.

The issue of resilience has become - as confirmed by the 2023 findings of the NATO Summit in Vilnius - one of the key aspects of the organisation's work. It was included in the 90-point Summit Communiqué. Resilience is to be achieved not only by implementing and monitoring the commitments already made under the seven areas of resilience, but also by strengthening critical infrastructure, key industries or diversifying supply chains.

Military action taken to defend NATO's territory and population must be complemented by robust civilian preparedness to reduce potential threats and risks of attack in times of peace, crisis and conflict. Linking civilian preparedness and military capabilities is critical to NATO's efforts to protect its societies, populations and shared values. The resilience of civilian structures, assets and services is the first line of defence for today's modern societies [39-41]. As part of ensuring national preparedness, it is important to assess the extent to which our understanding of resilience is realistic and/or needs to be modified, and decide who should be involved in the process.

The development of sector-specific guidelines and tools to support national governments in their efforts to maintain their capacity to deal with mass casualties must include, among other things, the provision of medical supplies.

One of the most acute indicators of the healthcare system's failure in the course of hybrid war, terrorist acts or armed conflicts is the limited availability of medicines.

An obvious consequence of the scarcity of medicinal products is suboptimal pharmacotherapy. In addition, the need to use alternative substances necessitates increased patient monitoring, leads to delays in treatment, longer hospital stays, increased risk of hospital readmission and the occurrence of complications, relapse or even death. Furthermore, healthcare professionals are faced with many logistical, professional and moral dilemmas while trying to optimally distribute limited medicine resources [42].

The events surrounding the COVID-19 pandemic have demonstrated that global supply chains are key components of the economy, and any disruption to them has significant consequences [43]. Concentrating production in non-European countries entails a number of risks, (including long delivery times or insufficient product quality) and disruptions resulting from local armed conflicts, diplomatic crises, terrorist acts and natural disasters. These circumstances, as well as unforeseen increases in demand, pose a threat to the stability of the supply of medicinal products, APIs and raw materials for their manufacture. In turn, ensuring sufficient production of medicines in the EU can contribute to reducing the vulnerability of the distribution process and enhancing medicine supply security in the region [44].

MEDICINE SUPPLY SECURITY FROM THE PERSPECTIVE OF THE ARMED FORCES OF THE REPUBLIC OF POLAND. COMBAT MEDICAL SUPPORT SYSTEM.

The combat medical support system is an integral element of combat readiness. The purpose of medical support activities is to ensure a state of health that will enable the soldiers to perform tasks related to national defence. This is achieved by preventing diseases and injuries, providing first aid on the battlefield, evacuating and treating the injured and sick, and restoring as many soldiers as possible to duty. Providing effective medical cover is not possible without an efficient system of supplying troops with medicinal products and medical devices adequate to the nature of combat as well as non-combat injuries incurred during operational activities.

Healthcare services in the Ministry of National Defence are provided by a system based on independent healthcare institutions, military treatment and rehabilitation centres and military research institutes with patient facilities, for which the Minister of National Defence acts as the founder, as well as military clinics and institutions. Medical coverage of combat operations is carried out by mobile structures adapted to perform tasks primarily in wartime. Regardless of the conditions under which medical support is provided, its mission is to preserve the combat power of the army and its morale, to protect life and to minimise damage to health[1].

Poland, as a NATO member state, bears the main responsibility for the logistic security of its own troops in operations conducted under the national, allied or coalition schemes. Acquisition, storage, transport and distribution of medical products are executed within the functional logistics system of the Polish Armed Forces, taking into account the potential and resources of the Polish Armed Forces and the non-military area - mobilisation of the economy and strategic reserves.

The overriding effort of the logistics system is to provide immediate security and uninterrupted supply of materials. The scale and scope of the organisation of the medical logistics system depends on the nature of military operations, but it must be self-sufficient at every stage of the conducted operations. The organisation of the medical logistics system should be simple and ensure rapid delivery of medical supplies to the entire area of military operations. At the same time, the system should be guided by the principles of economy without limiting medical capabilities [45-46]. As the Armed Forces are consumers of the commercial pharmaceutical market, the stability and resilience of the military medical supply chain is highly dependent on market factors.

The response to temporary disruptions in the supply of medicines for mobilisation needs is the collection and maintenance of medical supplies and the use of resources of the national economy within the framework of the Government's Strategic Reserve Programme (RPRS) [47] and the Plan for Securing the Needs of the Armed Forces implemented by entrepreneurs [48-49].

Determining the qualitative and quantitative structure of maintained stocks starts with the identification of medicinal products considered critical and essential for routine treatment taking into account the therapeutic indications and the vulnerability of supply chains [50]. As a general rule, stocks held for emergencies or war are slow-moving stocks [51]. The products are consumed with a low frequency while occupying warehousing space and generating costs. However, due to the strict expiry dates of medicinal products, the stocks of medicines must be regularly replaced.

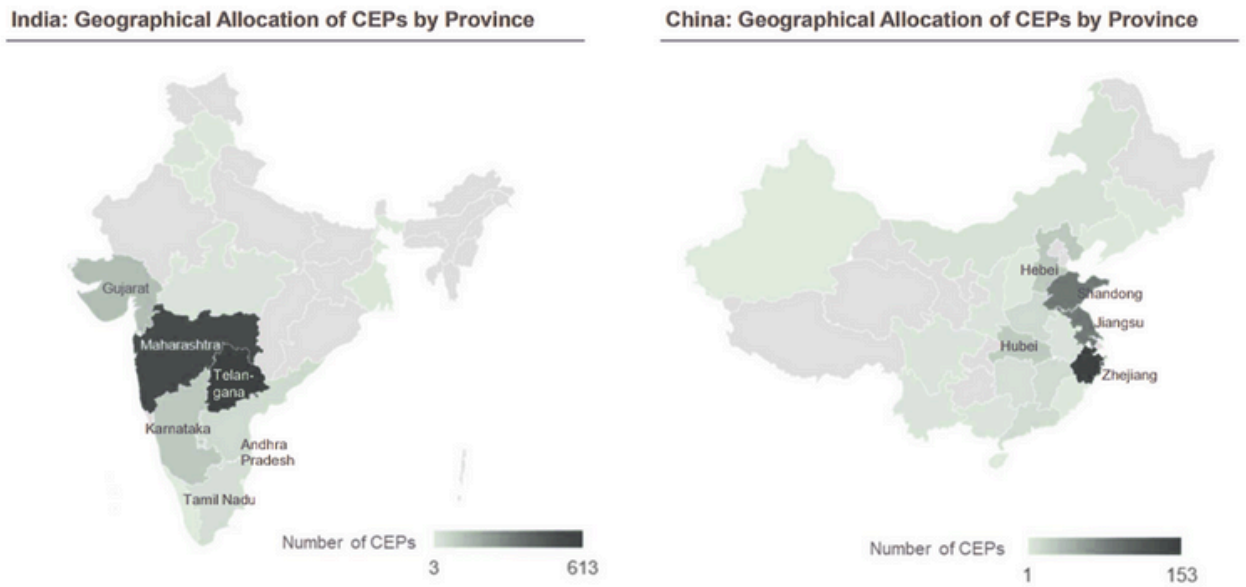
In times of war or the occurrence of emergency situations, the pace of stock rotation changes dramatically and its rate depends on the course of military operations or emergency response. This enforces the need for efficient and timely replenishment of stocks held.

Military medical logistics must track the changes that are taking place on the modern battlefield. Increasing the economic sustainability of pharmaceutical production and expanding the product portfolio of domestic pharmaceutical companies will contribute to maintaining defence capabilities and mitigate threats not only to public health but also to national security. The challenges of the modern world, such as pandemics, armed conflicts and economic crises, call for redefining of the approach to medicine supply security by, inter alia, eliminating or reducing the threats mentioned herein, while enhancing the potential of domestic and allied pharmaceutical industry.

THE LEVEL OF EUROPEAN UNION'S DEPENDENCE ON ASIAN MANUFACTURERS OF MEDICINES AND ACTIVE SUBSTANCES

The process of concentration in the production of APIs and finished medicines has accelerated significantly over the last 20-30 years. As recently as 25 years ago, the European Union accounted for more than half of global API production; today it accounts for about ¼ [52]. Production was gradually shifted to South-East Asia, primarily to China and India, due to lower manufacturing costs, reduced regulatory burdens and active policies of the governments of both countries to support the development of the chemical and pharmaceutical industries [53] and the development of technological competencies in Asia. The development of these competences followed a model referred to as Schumpeter's 'inverted triad', in which development starts with imitation of solutions used in Western countries, followed by innovations that improve them, until finally self-invention develops and new domestic inventions emerge.

Figure. Geographical distribution of API production in India and China



Source: [54]

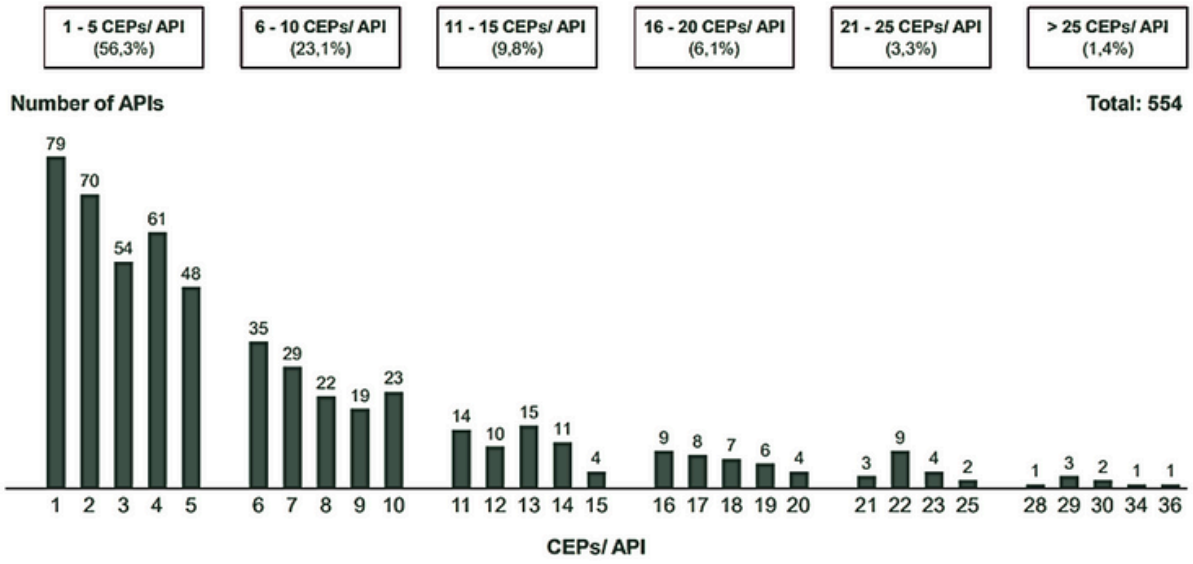
Since 2015. China has been implementing a strategic 'Made in China' initiative to develop domestic production of high-tech goods and services. One of the developed sectors is biomedical production. The Chinese government has supported foreign investment by promoting partnership agreements and joint ventures with local companies [55]. In parallel, direct financing, low-interest loans, tax breaks and subsidies were provided to support the pharmaceutical sector [56].

Innovation centres, including those focused on biotechnology development, were being established within China. Intensive human resource development and the simplification of regulation of innovative medicines were intended to encourage multinational companies to locate the process of developing and implementing innovations (including clinical trials) in China [57].

The development of the industry in India is primarily based on generic medicines. This has been an outcome of India's specific patent law in effect between 1970 and 2005, which allowed foreign medicines to be lawfully reproduced [58]. Such a situation, coupled with high-quality technical education institutions, resulted in the development of national research institutions to support the development of medicines manufacturing processes and new drug formulations. Additional government actions to support the export of generic medicines, including through simplified regulations and tax breaks, has resulted in the growth of domestic companies that have gained the status of global tycoons [59].

Currently, China and India account for approx. 60-70% of global API production. Of the 565 APIs produced worldwide, 93 are not available in Europe (and 78 have never historically been available). In the case of 365 APIs manufactured both in Asia and in Europe, the share of Asian manufacturers exceeds 40% for more than 270 of them. The total number of API manufacturers in Asia is almost 2 times higher than in Europe. European producers manufacture more types of APIs but their production volumes are lower. In the Asian market, the situation is reverse.

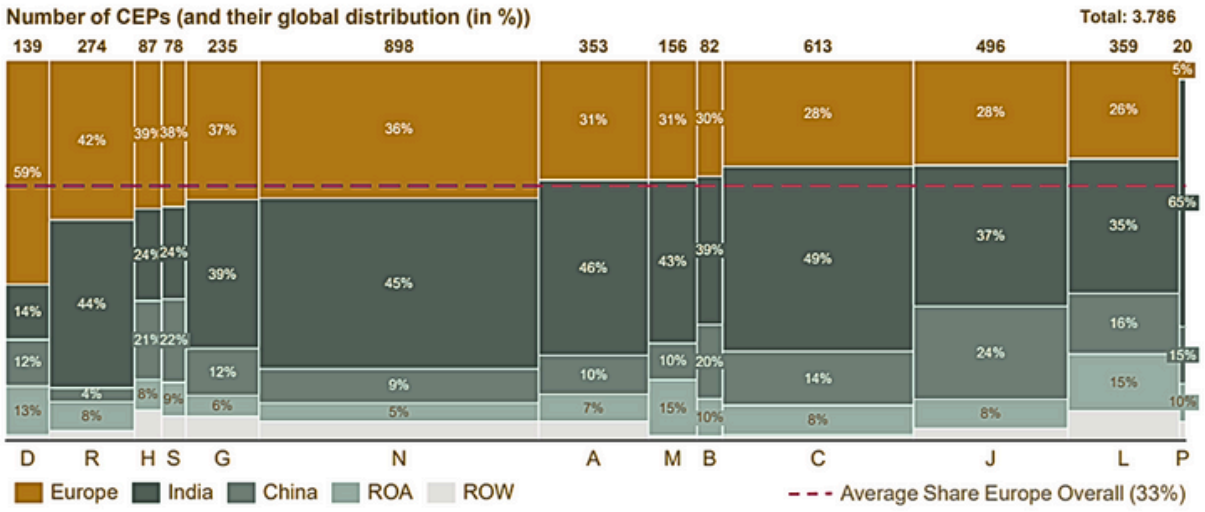
Figure. Distribution of the number of manufacturers for a single API



Source: [54].

For more than half of the APIs, less than five manufacturers are registered worldwide. A detailed analysis of APIs by ATC groups shows significant differences - the risk of loss of know-how is particularly evident for medicines from groups C (cardiovascular), J (anti-infectives for systemic use) and L (anticancer and immunomodulatory medicines). The share of CEPs in Asia for these medicine groups is around 70%.

Figure. Distribution of the number of Certificates of Suitability (CEPs)



Source: [54].

The distribution of the production of finished medicines is slightly more favourable. Both the European Union and the United States have a larger share of their production. Ireland, France, Germany and Belgium have the largest share of European pharmaceutical production [60]. The globally strong position of European manufacturers relates mainly to biologics, speciality and innovative medicines. Several of the global companies originate from the European Union. In addition, a number of important generic manufacturers are present in the European market. Globally, India plays a dominant role in the production of generic medicines.

The concentration of the production of APIs, as well as of some finished medicines, in Asia poses a challenge to Europe's medicine supply security. The Covid-19 pandemic and the associated disruption of supply chains highlighted the problems arising from the concentration of production, related mainly to the availability of essential medicines in European Union countries. This was particularly true for medicines used in intensive care, anaesthesia and the treatment of infections [61-62]. Effective health and industrial policy tools as well as recommendations at the microeconomic level have been the subject of analyses and studies [63-66].

RECOMMENDATIONS FOR ENHANCING EUROPEAN DRUG SUPPLY SECURITY: ACTIONS IN POLAND

01. Considering regional aspects in the context of establishing and allocating funds to support capabilities and improve medicines supply security.

02. Identifying in the final CMA document sources of funding for strategic projects under the next multi-annual financial framework.

03. Supporting security of supply of critical medicines in public procurement procedures by promoting joint purchases of North Atlantic Alliance member states and the European Union.

04. Increasing the capacity of the domestic pharma industry and ensuring that medicinal products on the national list of critical medicines are manufactured in Poland.

05. Preparing the medical logistics system to supply medicines and medical supplies to allied troops in the exercise of Host Nation Support (HNS) role.

06. Coordinating the continuity of medicines and medical materials supply at the level of the Council of Ministers (through the Government Security Centre).

07. Extending the list of entities exempted from electricity supply restrictions to include pharmaceutical companies, pharmaceutical warehouses and wholesalers

08. Expanding the catalogue of needs reported to the Plan for securing the needs of the Armed Forces implemented by entrepreneurs [67] to include the manufacture of medical supplies and maintenance of manufacturing capacity during peacetime and the resulting exemptions of key pharmaceutical personnel from the obligation to perform active military service in the event of mobilisation and in wartime.

09. Regional mapping of existing chemical and pharmaceutical industry resources in the context of optimising opportunities to enhance medicines supply security.

10. Improving the practical competences of employees of pharmaceutical companies, warehouses and wholesalers in procedures to be followed during military crises.

11. Incorporating the subject of medicines supplies in the scope of the national defence and civil defence system exercises.

12. Adapting the inventory structure of medicines and medical supplies stored for security purposes during armed conflicts to the specific characteristics of potential patients (mainly trauma patients).

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