STRATEGIC PLAN OF THE STATE INSTITUTE FOR DRUG CONTROL FOR 2021-2025

For internal purposes of the State Institute for Drug Control

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1. Foreword

The document “Strategic Plan of the State Institute for Drug Control for 2021-2025" (hereinafter referred to as the “Strategy”) summarises the direction to be taken by the State Institute for Drug Control (hereinafter referred to as “SÚKL”') in the period of 2021-2025.

The State Institute for Drug Control is an administrative authority executing its powers implied by its position in the legal order and acts as a regulatory authority recognised both nationally and internationally. It consistently fulfils specifically defined strategic objectives, based on the need to fulfil its mission and vision, availing of the opportunities, strengths, and eliminating threats and weaknesses identified by SÚKL's SWOT analysis.

Opening remarks

“SÚKL’s strategic plan for 2021-2025 determines ways to avail of key opportunities and challenges with emphasis upon measures against emerging health threats of the globalized world. I am aware that with regard to the increasing complexity of the regulatory environment, particularly with a view to the rapid development in the area of pharmaceuticals, advanced technologies, electronic health care (eHealth), principal revisions of the European legislation and associated implementing processes on the national level, the coming period will pose high demands upon SÚKL's operation and further development. It has turned out that achieving a higher degree of process effectiveness and availability of personnel and financial resources is the necessary precondition for SÚKL's continuous development and prosperity. The current health issues and challenges have been reflected in the defined strategic objectives and I am committed to ensure that SÚKL will accomplish these demanding tasks with flying colours.

I expect that in the coming years, the role of a regulator will be influenced by new perspectives of healthcare systems viewed through the prism of personalised medicine and its operation in the interest of the patient as an individual. The principle of complex risk/benefit assessment of pharmaceuticals, including the involvement of Health Technology Assessment (HTA) in the regulatory practice will continue to be accounted for with much care. The development of the recent years has clearly indicated that it will be necessary to enhance the capacity and effectiveness of regulatory processes within the lifecycle of pharmaceuticals, human tissues and cells, and the performance and safety of medical devices through close cooperation with both the stakeholders in the Czech Republic and the EU regulatory networks.

I am committed to support innovations and as quick a provision of scientific knowledge to patients, although I am fully aware how demanding this approach will be in terms of maximum capitalisation of results from clinical trials and Real World Evidence data and the subsequent surveillance over the entire lifecycle of pharmaceuticals in terms of their quality, efficacy, and safety for the patient. For SÚKL to be able to keep its competitive position amongst other EU regulatory authorities, it has to proactively enter strategic negotiations about a balanced distribution of centralised procedures and hence also funds administered by the European Medicines Agency (EMA).

The dynamics of the development not only in applied biomedical research but also in the area of information and communication technologies has been substantially increasing. SÚKL must be ready to respond to these new challenges so as to be able to continue to fulfil its mission, making maximum use of all professional resources and knowledge available thereto. This points out to the need of quality electronic technologies intended for the analysis and sharing of information and data, and contributing to a reduced administrative burden. In this context, the critical information system (ePrescription) administered and developed by SÚKL in compliance with legal regulations should be noted. Ensuring information security and data protection of the highest standard continues to form an integral part of SÚKL's strategic direction in this period.

Each professional output and completed task has to be perceived as the work of an individual employee who is a member of a broader team. SÚKL will continue to fulfil its personnel policy knowing that quality, educated, and loyal staff are the key factor for stability, prosperity, and performance growth of the organisation. I will continue to emphasise the importance of the development of managerial skills to safeguard a competent and sustainable team management. Modern management methods ensuring business continuity, adequate risk management with sufficient flexibility and foresight are the essential principles to maintain the integrity and high professional expertise of SÚKL.

The need to protect our citizens from threats associated with drug outages or shortages due to the failure of global supply chains and manufacturing processes must not be omitted from SÚKL's strategic target. SÚKL will support activities resulting in the development of a strategic pharmaceutical reserve of critical drugs within the EU, including professional cooperation necessary for the transfer of manufacture of active substances to Europe, releasing the links to third countries, and increasing the robustness of supply chains. This period covered by the strategic plan will doubtlessly require further cooperation within the area of drug regulation in the EU, which will not do without cooperation among European drug agencies, professional scientists, representatives of the pharmaceutical industry, payers, clinical practitioners, and, last but not least, patient representatives.

In this strategic period, SÚKL, as a progressive medicines agency, intends to continue to be active in EU and EMA working groups and committees. Being part of the pan-European initiatives for the establishment of a leading global drug regulation system for the 21st century and keeping pace with global players such as the U.S. and Japan, continues to be a high priority for SÚKL. SÚKL's Strategy for 2021-2025 correlates with the strategy of EMA/HMA and the pharmaceutical strategy of the EC and has been drafted in a manner allowing SÚKL to implement any and all necessary measures to safeguard public health in cooperation with all domestic as well as European institutions concerned.

Let me conclude by emphasising that SÚKL has always focused and shall always focus upon the safety of Czech patients, not only in the sphere of medicinal products for human use, but also medical devices and human tissues and cells. With the growing interest in information about public health protection, SÚKL strives to continue to stand up to its high reputation of an institution providing quality and objective information about pharmaceuticals and medical devices that the citizens can confidently rely on at any time."

Mgr. Irena Storová, MHA, Director of SÚKL

Position in the system of administrative authorities of the Czech Republic

SÚKL is a nationally acting organisational unit of the state.

SÚKL, as the administrative authority with surveillance and decision-making powers, was established by Act No 79/1997 Coll., on Pharmaceuticals and on Amendments to Some Related Acts, and it is subordinated to the Ministry of Health of the Czech Republic.

2. Legal framework of SÚKL's operation

At present, the scope of SÚKL's activities and powers is defined by the following legal regulations:

1. Act No 378/2007 Coll., on Pharmaceuticals, as amended
2. Act No 296/2008. Coll., on Human Tissues and Cells, as amended
3. Act No 167/1998 Coll., on Dependency-Producing Substances, as amended
4. Act No 40/1995.Coll., on Advertising Regulation, as amended
5. Act No 265/1991 Coll., on the Powers of Czech Authorities in the Sphere of Prices, and Act No 526/1990 Coll., on Prices, as amended
6. Act No 526/1990 Coll., on Prices, as amended
7. Act No 268/2014 Coll., on Medical Devices and Amendment to Act No 634/2004 Coll., on Administrative Fees, as amended
8. Act No 102/2001 Coll., on General Product Safety, as amended
9. Act No 634/1992 Coll., on Consumer Protection, as amended
10. Act No 477/2001 Coll., on Packaging, as amended
11. Act No 372/2011 Coll., on Healthcare Services, as amended
12. Act No 78/2004 Coll., on Handling of Genetically Modified Organisms and Genetic Products, as amended
13. Act No 48/1997 Coll., on Public Health Insurance, as amended
14. Act No 272/2013 Coll., on Drug Precursors, as amended
15. Act No 255/2012 Coll., the Control Code, as amended
16. Act No 500/2004 Coll., the Code of Administrative Procedure, as amended

SÚKL's activities in the sphere of medicinal products and medical devices are also governed by relevant regulations of the European Union and directly applicable decisions.

SÚKL manages state assets as an organisational unit of the state on the basis of legal regulations governing this area. To fulfil the purpose, to safeguard the activities for which it has been established, and to ensure its adequate position amongst EU medicines agencies, a functional and effective model of funding has been set up, which also provides a motivation for increasing the effectiveness of work and fulfilling the strategic goals of SÚKL.

3. Mission, vision

Mission

Public health protection and support on the basis of effective regulation governing areas within the powers of SÚKL, based on state-of-the-art scientific and research knowledge. SÚKL fulfils its mission within the scope of powers stipulated by legal regulations, through the regulation of medicinal products and medical devices, in order to safeguard their quality, efficacy, and safety in clinical practice.

Vision
SÚKL as an independent competent, professionally sound, economically stable regulatory authority respected both nationally and internationally, with a high degree of transparency, flexibility, predictability of decision-making practice, and independence, governed by high standards of quality of work.

SÚKL undertakes to continue to abide by and increase the quality of procedures entrusted thereto by legal regulations. It shall be an institution that:

1. avails of a broad range of objective information about medicinal products and medical devices, available both to professionals and to the general public;
2. through its surveillance activities, enforces compliance with legal regulations in the sphere of medicinal products and medical devices, tissues, cells, blood, and cannabis for medical use;
3. avails of qualified, motivated, and impartial internal as well as external professionals;
4. employs an active approach to process automation, centralisation of shared data and electronisation of input data;
5. uses functional and secure information systems with a high degree of agenda electronisation, effectively increasing the effectiveness and productivity of work;
6. is an active partner of the Ministry of Health of the Czech Republic in the area of drafting legal regulations, taking part in discussions concerning legislation and standards, not only within the scope of its powers, but also in areas associated therewith;
7. openly communicates with other state administration bodies, professional organisations, and other external entities and provides professional and scientific consultations in the area covered by its powers;
8. actively communicates and provides information to the general public;
9. is a respected regulatory authority both in the Czech Republic and within the EU;
10. takes an active part in international activities relevant to its powers.

4. Strategic objectives of SÚKL

SÚKL's primary strategic objectives are based on the need to fulfil the mission and achieve the vision, availing of opportunities and strengths and eliminating threats and weaknesses identified through SÚKL's SWOT analysis.

The vision will be achieved through the fulfilment of the following strategic objectives:

Objective 1. SÚKL as a competitive and prestigious agency within the EU, with scientific and regulatory history for public health support and protection

Typically, each proprietary medicinal product is subject to marketing authorisation prior to the placement onto the market in the Czech Republic. In the process of marketing authorisation of pharmaceuticals, SÚKL assesses documentation, in which the future marketing authorisation holder evidences the safety, efficacy, and quality of the medicinal product. The dynamic development in the area of drug development has resulted in a situation, which is characterised by the ever-growing importance of empirical data from clinical practice – Real World Evidence and its use as an additional source of information about the medicinal product for regulatory decision-making. The addition of such data to the "golden standard" of data from randomised, controlled clinical trials contributes, with a view to patient interests, to a more effective regulatory decision-making based upon more complex evidence. In the sphere of assessment of applications for clinical trial authorisation or notification and surveillance over their course, SÚKL's strategic objective is to ensure compliance with regulatory requirements (taking into account the fact that the EU Clinical Trials Regulation is to become effective by 2025), so that the Czech Republic was a reliable partner for other Member States in the drafting of assessment reports. It is desirable for SÚKL to keep enhancing its competitiveness,

attractiveness and prestige for clinical trial sponsors, through which it could contribute to a quicker provision of patient access to advanced therapies with to-date non-authorised medicinal products. In support of this objective, it is necessary to communicate with the Ministry of Health and healthcare service providers to safeguard a quicker conclusion of contracts with clinical trial sponsors.

In this strategic period, SÚKL shall approach the fulfilment of the legislative obligation to safeguard the operation of ethics committees as SÚKL's body with great responsibility. Concurrently, it shall adopt measures necessary for the inclusion of an ethics committee into SÚKL's organisational structure, including the safeguarding of conditions for its operation and the issuance of the ethics committee Statutes and Rules of Operation. SÚKL will be actively involved in an effective clinical trial management with the objective to reduce their administrative burden. Attention will continue to be paid to compliance with the timelines for clinical trial authorisation, ensuring the rights, dignity, and safety of clinical trial participants, protection of vulnerable groups, and catering for the informed consent of participants. SÚKL is getting ready for the roll-out of the uniform EU clinical trials portal, through which source documents for clinical trial authorisations accessible to all Member States are to be submitted. SÚKL will continue to cooperate in support of academic research, which will require a dialogue with the Ministry of Health and possibly with the Czech Health Research Council.

The fulfilment of this strategic objective is represented by an increased interest of regulated entities in choosing the Czech Republic as the Reference Member State (RMS) for new marketing authorisation applications (MRPs/DCPs), and hence by a more competitive position among European regulatory agencies. SÚKL shall take a proactive approach in communication with important applicants for marketing authorisation, with whom it has already established cooperation and gained experience with effective conduct of MRPs/DCPs. SÚKL is interested in extending cooperation with EMA and its committees, i.e. the Committee for Human Medicinal Products (CHMP) and the Pharmacovigilance Risk Assessment Committee (PRAC), in its involvement in centralised marketing authorisation procedures and other activities as a rapporteur/co-rapporteur. In the concerned strategic period, SÚKL intends to maintain the degree of its involvement in marketing authorisation procedures as the Reference Member State in decentralised marketing authorisation procedures or as the rapporteur/co-rapporteur in centralised marketing authorisation procedures and Periodic Safety Update Report (PSUR) single assessment (PSUSA) procedures. In the period by 2025, SÚKL shall strive to obtain a position in the Scientific Advice Working Party (SAWP), where it has not had any representative to date. In this strategic period, an increase in post-authorisation variations to centralised marketing authorisations in association with procedures taken over from Great Britain after “Brexit” may be expected. On the basis of conducted analyses, SÚKL will prepare implementation of the “SPOR” project and will be involved in the ePI (electronic product information) project in compliance with EU requirements.

In order to safeguard the safety of medicinal products for patients, SÚKL has established effective pharmacovigilance processes and monitoring regimens to assess the benefits and risks of medicinal product use in clinical practice, as required by legal regulations. SÚKL collects data on possible risks of pharmaceuticals and implements regulatory measures that can minimise treatment-associated risks. SÚKL's objective is to increase the detection of experienced adverse drug reactions, to improve the quality and complexity of reports through enhancement of a web form developed for these purposes in the effort to make the form more user friendly and intuitive. In this strategic period, SÚKL will work towards increasing public awareness of the need for adverse drug reaction reporting. A new database of adverse drug reaction reports for the Czech Republic has been in place since November 2017; this database is compatible with the European database and complies with existing legislative requirements. The database will continue to maintained and amended on an ongoing basis as required by potential changes announced by EMA or The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

The necessary precondition for effective and consistent work of SÚKL is also quality scientific and regulatory history. SÚKL's objective is to create such information repository that would be able to capture the entire drug lifecycle and facilitate and streamline the provision of general information on active substances and medicinal products authorised in the Czech Republic. For SÚKL to present itself as a prestigious professional institute, closer cooperation with professional societies, professional chambers (the Czech Medical Chamber and the Czech Chamber of Pharmacists) and healthcare professionals will be necessary.

Objective 2. To enhance processes ensuring availability and sufficient amounts of pharmaceuticals for public health protection

SÚKL's strategic objective is to enhance and consistently fulfil all processes associated with the safeguarding of availability and sufficient amounts of medicinal products, with emphasis upon the analysis of processes that may cause unavailability or lack of pharmaceuticals. In this respect, it is necessary to pay special attention to the assessment of shortcomings arising due to commercial reasons (business strategies of pharmaceutical companies), with a view to the specific needs of the Czech market. In the current situation, SÚKL is prepared to support suggestions concerning the restoration of pharmaceutical manufacture in the EU, preferring the manufacture of essential and strategic pharmaceuticals and promotion of the development of a European emergency reserve of pharmaceuticals of this importance. SÚKL shall strive to enhance measures and procedures focused upon increasing the transparency of manufacturing and distribution chains within the scope permissible by effective legal regulations.

The established market report administration and subsequent assessment of medicinal product replacement with actual verification of the stock available on the market help SÚKL develop and effectively use associated processes for timely solution of critical situations (allowing for the import of foreign-language batches, individual import of non-authorised medicinal products, drafting of opinions on specific therapeutic programmes, utilisation of preventative tools to restrict re-export of medicinal products). SÚKL will continue to cooperate with stakeholders in formulating a generally valid definition of essential medicinal products, in the developing of more and more effective mechanisms mapping supplies and consumption of pharmaceuticals as well as in the automation of processes concerning data processing and its hand-over for use by other entities and systems. SÚKL will make use of any effective tools and measures to ensure that pharmaceuticals addressing emergency needs implied by clinical practice be available to patients within the necessary time scope. SÚKL will enforce the inclusion of parameters of medicinal product availability to projects associated with the strategic objectives of telemedicine development.

It is SÚKL's strategic interest to continue addressing this issue on a pan-European level within HMA/EMA working groups (Task Force on Availability of Medicinal Products) and as part of specific issues adopted in the EMA/HMA strategy and the EC pharmaceutical strategy. SÚKL's vision as an active partner in international cooperation among EU countries is closely associated with the vision of EMA's strategic goals to safeguard the necessary pharmaceuticals for all EU patients. The fulfilment of this vision requires strong joint and coordinated measures. Enhanced cooperation within the EU is a potential key to resolving the lack of pharmaceuticals, as unavailability typically affects more than one market. The effective functioning of such cooperation is preconditioned by the establishment of a harmonic and balanced relationships, respecting the national competencies of individual EU Member States. SÚKL will be actively involved in and will support the establishment of a European process aimed at the sharing of data on consumption, on distribution, and on the stock available in the EU as an instrument to prevent shortages of medicinal products (the “SPOC” project).

Objective 3. Well-defined personnel policy and employee education not only in purely expert areas but also in the area of health protection, that is stable in the long term and comprehensible for the employees, resulting in personnel stability

SÚKL's strategic objective is to continue the established direction of the organisation as a perspective and

valuable employer, with emphasis upon sustaining the necessary number of current expert staff. A well-elaborated personnel plan (employee recruitment system, employee development and education) and an optimally established personnel budget have a major impact upon the operation of the organisation and its perception by the employees. SÚKL will make use of any available forms of employee recruitment, such as advertising, including commercial advertisements, advertisements on websites of specialised university faculties, job fairs, cooperation with secondary schools and universities, cooperation with the Czech Employment Office, and cooperation with human resource agencies.

In the area of occupational health and safety promotion, during the effective period of the strategic plan, SÚKL will focus upon enhancement of employee responsibility for their own health by means of organising educational events including e.g. lectures about healthy nutrition and healthy lifestyle, stress and burn-out syndrome prevention, mental hygiene issues, and occupational ergonomics.

Within the scope of continuous quality improvement, employee surveys will be conducted at regular intervals, as they represent an important tool providing feed-back for a better focused personnel strategy, including human resource management. This tool, concentrating upon the opinions and positions of employees, will continue to be developed and utilised with emphasis upon overall evaluation and formulation of specific subsequent measures. In this strategic period, SÚKL intends to create an effective and sustainable employee remuneration system compliant with relevant legal regulations (Act No 262/2006 Coll., the Labour Code, and Act No 234/2014 Coll., the Act on Civil Service). SÚKL's strategic goal of improving and increasing the effectiveness of employee environment will be fulfilled through the newly prepared personnel information system ("PIS"), which will better reflect the specifics of state administration and the necessity of internal process automation.

The successful operation of the organisation depends also on effective management and communication that should respond to current needs and other strategic objectives of SÚKL; for this purpose, the process of centralisation of selected SÚKL units in Prague will continue.

Objective 4. High transparency of decision-making processes in the sphere of pharmaceuticals and medical devices based upon state-of-the-art scientific and expert knowledge and data from clinical practice

SÚKL's strategic goal is to continue to ensure maximum transparency and formal procedure of conducted administrative proceedings or other procedures of an administrative authority, process compliance with legal regulations, and compliance with defined administrative timelines, so as to safeguard a stable and foreseeable decision-making practice. SÚKL intends to continue to develop established rules of the administrative penal strategy, with emphasis upon its regularity, adequacy, and consistency. For SÚKL's stability and development, it is essential to identify and implement the necessary process changes within the organisation of work of individual units and revisions of the expediency of SÚKL's internal capacity utilisation. Effective maintenance, control, and evaluation of outputs, including reviews and compliance with internal procedures in operating, process as well as regulatory areas with the objective to identify reserves and improvements significantly influence the success of SÚKL's operation.

In this strategic period, SÚKL will focus upon such set-up of internal processes that will – with the application of relevant guidance – support a high professional standard of drug efficacy, safety, and quality evaluation as well as the evaluation of expediency of public health insurance resource utilisation during drug use in clinical practice, taking into account also state-of-the-art knowledge in the area of drug policy and Health Technology Assessment (HTA). SÚKL will support conceptual legislative changes in these areas in order to provide access to innovative medicinal products that may significantly extend survival and improve the quality of the patient's life.

Within the scope permissible by effective legal regulations, implementation of a modern information system

and modification of SÚKL's website will be prepared in order to safeguard transparent and uniform access of the public to information about conducted administrative procedures. SÚKL's strategic goal is to continue to establish a communication environment allowing for a balanced, open, and fair relationship with regulated entities, professional societies, professionals and the general public, and other state administration institutions. In this strategic period, SÚKL will also strive to further improve the standard of quality and clarity of information provided to the public in respect of its requirements and outputs within the scope of individual regulatory actions. SÚKL will continue to support processes targeted at obtaining feed-back for its own operation. Valuable information from regulated entities will be evaluated and subsequently, SÚKL will adopt appropriate measures.

Objective 5. Creation of conditions resulting in electronisation of processes associated with the safeguarding of information about the lifecycle of pharmaceuticals for human use, medical devices, and other activities of SÚKL and increasing information security and protection from cybernetic threats

SÚKL's strategic objective is to support pivotal, auxiliary, communication as well as management processes in SÚKL via electronic tools and systems, ensuring their quicker conduct, including a higher degree of robustness of the processed data. This strategic goal emphasises compatibility and interlinking of SÚKL's electronic systems, including the maximum utilisation of the developed state infrastructure within the scope of eGovernment and eHealth (e.g. basic registries, health registries, NIA – National Identity Authority, etc.). The primary effect of input data electronisation and internal process automation is a significant improvement of the efficiency of input resource utilisation, greater degree of data validity, and enhanced work productivity. A substantial strategic objective is the current enhancement of measures aimed at securing personal data during their processing. The implementation of these strategic goals is based particularly upon the needs of individual SÚKL units, taking into account the currently used and available technologies and obligations stipulated by binding legal regulations, with a view to the development of emerging technologies as well as implementation goals in the area of eGovernment of the Czech Republic and EU or EMA goals.

It hence includes making use of the supportive effect of information technology systems for the development of processes, strategic decision-making, and resource planning in compliance with legal regulations and technical and organisational capacities of individual regulatory agendas of SÚKL. This way the strategic objective responds to the current need for integration of individual existing or developed electronic systems, both on the national (eGovernment, eHealth) and international level (EMA, EU). Integrated electronic systems may then yield quality and objective data, standardised outputs, summary reports, and predictive analyses that are essential for strategic decision-making of SÚKL's management.

The development of agenda electronisation will proceed in compliance with the requirements stipulated by legal regulations and “best-practice” methodological recommendations aiming at increasing cyber-security. To increase resistance to the growing jeopardy of cyber-attacks, SÚKL also defines a strategy of active cooperation with official state security and surveillance institutions and organisations.

Communication between SÚKL and external entities takes place via web services or through specialised portals containing published forms. The fulfilment of this strategic plan will be the establishment of a single access to all agendas, for external entities and also for SÚKL employees, including the interlinking of shared information. A better accessible databases and information presented via modern web portals are the basic pillars of the strategic goal aimed at an increased comfort in access to information for professionals, the general public, and regulated entities. SÚKL intends to continue to support and extend maximum data availability for further use via open data (published statistics, overviews, databases, etc.).

Objective 6. Increased quality and effectiveness of SÚKL's surveillance activities

SÚKL is a national competent authority fulfilling its legislative obligations in the area of surveillance over the market with pharmaceuticals, products from human tissues and cells, and medical devices. For the

accomplishment of this mission, it has developed a consistent and transparent system and established a team of professionally qualified experts and inspectors capable to carry out ad hoc interventions anywhere in the Czech Republic.

SÚKL will concentrate on the conduct of efficient controls in the entire segment of entities handling pharmaceuticals and medical devices as well as controls of tissue centres also in this strategic period. The large scope of control activities will continue to require a complex and interrelated approach with focus upon the specialisation of individual inspection teams. The strategic goal of SÚKL for this period is focus upon improvement of quality of conducted surveillance activities, with emphasis on improvement of established control procedures, their professional conduct, synchronisation of individual actions and optimisation or adequacy of duration of controls. In this strategic period, SÚKL will follow up on the current trend of extending consultation and educational activities targeted, in particular, upon professionals, and enhanced efficiency of controls in the area of pricing regulation and surveillance in the sphere of regulation of advertising for medicinal products and medical devices.

SÚKL will pay special attention to arranging a greater scope of good clinical practice inspections at entities involved in clinical trials in third countries with regard to Regulation EU no. 536/2014. With respect to “Brexit", SÚKL is prepared to extend its involvement in foreign inspections, being fully aware of their more demanding nature and increased staffing intensity. SÚKL’s laboratories are ready to enhance their activities in the Official Medicines Control Laboratories (OMCL) international network and to increase the number of released batches or issued OCABR certificates.

Counterfeit and illegal pharmaceuticals still remain a global problem that, along with illegal offers of medicinal products, significantly affect the sphere of public health protection. The current topic that SÚKL will focus on within the scope of its legislatively defined powers in this strategic period, is a continuous improvement of detectability and enforcement in combatting counterfeit products, protecting the market from illegal offers, and protection from inadequate-quality pharmaceuticals.

In the sphere of human tissue and cell regulation, SÚKL will increase its focus upon cooperation with other EU Member States in the harmonisation of systems for the conduct of tissue centre inspections, including the currently developed system of international audits of competent authorities for human tissues and cells.

Objective 7. SÚKL as the primary source of professional, clear, and verified information about authorised medicinal products, notified medical devices, and reimbursements of these products or devices

One of the essential tasks of SÚKL is to safeguard an expedient communication covering the issues concerning pharmaceuticals and medical devices both with professionals and the general public, with regulated entities and media. With regard to its position, SÚKL, as a unique expert institution, avails of exclusively expert information. Its clear, straightforward, and objective presentation is the basis of citizens’ trust in quality, safe, and efficacious medicinal products and safe medical devices. SÚKL's strategic goals continue to include the provision of verified and clear information from the area of pharmaceuticals and medical devices, intended to safeguard a higher standard of public health protection. SÚKL will continue to offer seminars, presentations, and meetings as part of the operation of its various sections, and to organise regular meetings with patient organisations.

To provide for clear communication with the public, it is essential to choose optimal communication channels, with the objective for SÚKL to publish only factually accurate and objective opinions within the scope in which such opinions may be published externally pursuant to legal regulations. SÚKL's strategic objective is to ensure that long-term and planned communication towards the general lay public be implemented through information campaigns based upon a media plan for the respective year, approved in advance. SÚKL will

continue to develop websites both for the general public and for professionals, for patients, regulated entities, and media and to prepare and publish expert information via its publications: SÚKL's Annual Report; SÚKL Bulletin; the Adverse Drug Reactions Newsletter; Pharmacotherapeutic Information; and infoLISTY. For this strategic period, SÚKL intends to implement a new website project; this website is to become a modern platform for the presentation of information corresponding to current trends and demands for information availability, clarity, layout, and search options.

Objective 8. Achievement of sustained stability in the asset management and funding of SÚKL's activities and safeguarding of resources for the implementation and fulfilment of SÚKL's strategic objectives

The strategic objective in the sphere of SÚKL's financial resource management is to support expedient, economical and effective asset management and funding of activities and competencies stipulated by legal regulations, for which SÚKL has been established. To financially secure the fulfilment of strategic objectives, particularly in the area of information support for existing SÚKL's agenda systems, their development and building of new information systems, including solutions and enhancement of cyber-security, emphasis will be placed upon long-term planning and complex strategic decision-making in this sphere with established priorities. Within the scope of planned multiple-source funding, SÚKL will expediently utilise available resources arising from reimbursement of costs to safeguard its operation, avail of foreign programme funding options and, in cooperation with the founder, plan the funding of strategic activities, particularly in the investment sphere, from the state budget.

SÚKL will responsibly approach the evaluation of expenditures for the previous period and on the basis of economic analyses, it will identify opportunities for savings, particularly those that represent a significant and long-term effect on its asset management and on sustainability of the determined budget stability. Investments into the construction of a new administrative building form part of SÚKL's strategic development which represents a desirable enhancement of its autonomy in terms of capacities and the creation of space ensuring quality working conditions and fulfilment of standards of work environment appropriate for the 21st century. Outlook economic prognoses and investment plans will also include income analysis in relation to the safeguarding of necessary funds for the compilation of budget for the coming period.

Centrally managed planning, project development and implementation, including management of associated secondary activities via qualified project teams, with adequate involvement of regulatory units, continue to form part of SÚKL's strategic target for this period. Focus upon sustaining the principle of project management as the basic status for successful leadership of projects implemented across SÚKL's units corresponds to SÚKL's progressive approach to expedient resource utilisation and cost planning. Focus upon transparent and professional organisation of public contract preparation and awarding, including professional surveillance, control, review, and corrective actions, as applicable, forms an integral part of SÚKL's strategic plan for this period.

Objective 9. Strengthening of SÚKL's cooperation in European organisations and their task forces, preparation for the 2022 Czech Presidency

In light of new health threats, the need for mutual international cooperation is becoming more and more relevant. SÚKL will continue to be involved in the activities of the European Medicines Regulation Network (EMRN) and other bodies and institutions covering activities within the powers of SÚKL (regulation of medical devices or human tissues and cells). It will continue its active involvement in and cooperation with EU institutions (EC), the network of European medicines agencies (HMA/EMA), and international organisations acting in the sphere of pharmaceuticals and medical devices (EDQM etc.). Via its experts, SÚKL cooperates on the creation and fulfilment of strategic conceptual goals in the area of pharmaceuticals, drug policy, medical devices, dependency-producing substances and drug precursors, and contributes to the fulfilment of

liabilities implied by international treaties, including participation in their creation. It is SÚKL's strategic objective to strive to achieve a more pronounced position both in the European and global regulatory field, and hence to fulfil the strategic interests of the state in the regulatory policy covering the entrusted areas, and do so in a cost-effective manner, on a highly professional basis, and availing of state-of-the-art scientific knowledge for public health protection.

With the growing importance of SÚKL's involvement in international institutions and their task forces, the need for expedient sharing and broader utilisation of gained information and data among SÚKL employees has been also increasing. It is SÚKL's strategic objective to create a single platform that would fulfil this functionality and that would create, via a secured internal repository, a user-friendly electronic environment for the retrieval and sharing of data from international negotiations. The development of such platform will result in a greater comfort and security in the work with such information in compliance with SÚKL's internal communication principles.

In 2022, the Czech Republic will assume its second presidency of the European Council, which is one of the most important rights and demanding tasks implied by EU membership. Via its experts, SÚKL will be significantly involved in the execution of this task in the area of medicinal product and medical device regulation. SÚKL will organise and professionally cover numerous international negotiations and events, informal meetings and seminars, and it will also prepare source materials for and manage discussions on legislative drafts on the working level of the European Council. This involvement and the need for adoption of strategic decisions will be especially demanding in terms of organisation and preparation of these events and subsequent coordination of outputs. This offers the Czech Republic a special opportunity to avail of the current situation and available tools managed by relevant European institutions to influence the long-term direction to be taken by the EU in the sphere of pharmaceuticals and medical devices. SÚKL aspires to accomplish its tasks and obligations as best as possible in terms of their organisation and professional coverage, particularly with a view to the special importance and impact of this activity on the strengthening of its international prestige.

5. Implementation of SÚKL's strategy

To fulfil SÚKL's strategy, individual units of SÚKL develop specific strategic objectives within their specific powers and responsibilities.