STRATEGIC PLAN OF THE STATE INSTITUTE FOR DRUG CONTROL FOR 2016-2020

Public Section

1. FOREWORD

The document "SÚKL – Strategic Plan for 2016-2020" (hereinafter referred to as the "Strategy") summarises the direction of the State Institute for Drug Control (hereinafter referred to as "SÚKL") in the period of 2016-2020.

The State Institute for Drug Control is a stable institution that executes its powers implied by its position within the scope of the legal order; it is a regulatory authority respected both on the national and international level. It fulfils its clearly and specifically defined objectives which are based upon the need to fulfil its mission and visions, availing of its opportunities and strengths and eliminating threats and weaknesses identified through SÚKL's SWOT analysis.

In accordance with the development of science, research, new technologies and statutory obligations, SÚKL has directed its focus more intensively upon the regulation of the complete lifecycle of pharmaceuticals and medical devices through running assessment of their quality, adequate risk/benefit ratio, and surveillance over correct use and application of the regulated products. SÚKL also incorporates the State Agency for Medical Cannabis.

SÚKL has – and always will – focus its attention upon the safety of Czech patients, both in the sphere of human medicinal products and in the sphere of medical devices.

2. POSITION WITHIN THE SYSTEM OF ADMINISTRATIVE AUTHORITIES OF THE CZECH REPUBLIC

SÚKL is an organisational unit of the state with nation-wide powers.
SÚKL, as an administrative authority with supervisory and decision-making powers, has been established by Act No 79/1997 Coll., on Pharmaceuticals and on Amendments to Some Related Acts.

3. LEGAL FRAMEWORK FOR SÚKL'S ACTIVITIES

At present, the powers and authorities of SÚKL are 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 268/2014 Coll., on Medical Devices and on Amendment to Act No 634/2004 Coll., on Administrative Fees, as amended
7. Act No 102/2001 Coll., on General Product Safety, as amended
8. Act No 634/1992 Coll., on Consumer Protection, as amended
9. Act No 477/2001 Coll., on Packaging, as amended
10. Act No 372/2011 Coll., on Healthcare Services
11. Act No 78/2004 Coll., on Handling of Genetically Modified Organisms and Genetic Products
12. Act No 48/1997 Coll., on Public Health Insurance, as amended
13. Act No 272/2013 Coll., on Drug Precursors.

The operation of SÚKL in the area of medicinal products is, moreover, governed by the relevant regulations of the European Union and directly applicable decisions.

With a view to the growing demands within the regulatory environment, particularly with regard to the quick development in the sphere of pharmaceuticals, advanced technologies, the ever new updates to the European legislation, and the processes of gradual harmonisation of procedures on the national and European level both in the area of regulation of human medicinal products (e.g. also in the sphere of pharmacovigilance, clinical trials, combatting counterfeit products) and medical devices, associated therewith, the coming period will pose high demands upon the organisation of SÚKL's operation and further development, also in terms of available personnel and financial resources. Modern management methods safeguarding the continuity of operation, adequate risk management, and sufficient flexibility and foresight are clearly necessary to achieve the fulfilment of the Strategy in the period to come. Communication with partners and feed-back are of key importance for the maintenance and increase of effectiveness of the operation of the entire organisation.

In the monitored period, it is necessary to enhance the capacity and effectiveness of expert processes in the sphere of regulation of the lifecycle of pharmaceuticals and the performance and safety of medical devices, through close cooperation both within the country and within the EU regulatory networks. The major challenges are: safeguarding quality, effective and safe pharmaceuticals for patients, the inclusion of Health Technology Assessment (HTA) into the existing regulatory framework, and safeguarding cost-effectiveness of SÚKL's operation. For SÚKL to be able to stay competitive among other EU competent authorities, it has to become actively involved also in strategic negotiations on a balanced distribution of powers corresponding to the financial resources provided by national competent authorities and the European Medicines Agency (EMA).

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 activities for which it has been established, and to ensure its adequate position among the EU medicines agencies, a functional and effective model of available funds which is also motivating for increasing the effectiveness of work and the fulfilment of SÚKL's strategic goals has been established.

4. MISSION, VISION

Mission

Protection of public health based upon efficient regulation of the areas falling within SÚKL's powers, taking into account current scientific and research findings, within the scope of fulfilment of the obligations SÚKL has been subjected to and entrusted with by legal regulations of the Czech Republic

SÚKL fulfils its mission as part of the competences set forth by legal regulations through the regulation of medicinal products, medical devices, and medical cannabis, in order to safeguard their quality, efficacy, and safety in the clinical practice.

Vision

SÚKL as a free-standing, competent, professionally sound, economically and financially independent regulatory authority, respected both on the national and international level, with a high degree of transparency, flexibility, foresight in the decision-making practice, and independence, observes high standards of the quality of work.

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

a) Disposes of a broad range of objective information on medicinal products and medical devices, available both to professionals and to the general public;
b) Through its surveillance activities enforces compliance with legal regulations in the area of medicinal products, medical devices, tissues, cells and blood, and medical cannabis;

c) Avails of qualified, motivated and unbiased internal as well as external experts;
d) Uses functional and secure information systems with a high degree of electronisation of agendas effectively increasing work efficiency and productivity;
e) Acts as an active partner of the Ministry of Health of the Czech Republic in the sphere of drafting of legal regulations and debating legislation and standards not only within the scope of its powers, but also in areas associated therewith;
f) Openly communicates with other state administration authorities, professional organisations, and other entities, and provides expert and scientific consultations within the scope of its powers;
g) Actively communicates and provides information to the general non-professional public;
h) Is a respected regulatory authority both within the Czech Republic and the EU;
i) Is actively involved in international activities associated with SÚKL's operation.

5. SÚKL'S STRATEGIC OBJECTIVES

The primary strategic objectives of SÚKL are based upon the need to fulfil the mission and achieve the vision, availing of the opportunities and strengths and eliminating the threats and weaknesses identified by SÚKL's SWOT analysis.
The vision is to be achieved through the implementation of the following strategic objectives:

1. Through a suitable set-up of processes in the application of good practice guidance, support the innovation and scientific level of the evaluation of product efficacy, safety, and quality throughout their practical application.
2. Transparency of decision-making processes based upon state-of-the-art professional and scientific findings and clinical practice.
3. Creation of conditions resulting in the implementation of electronisation of processes associated with the securing of the lifecycle of human pharmaceuticals, medical devices, and other activities of SÚKL, in order to protect public health, at a high standard, to increase the efficiency of administrative processes and continue to increase the assurance of safety and data reliability.
4. Increased activities in the sphere of SÚKL's surveillance competences.
5. SÚKL as a primary source of professional, straightforward, and validated information about authorised medicinal products and notified medical devices both for professionals and for the general public.
6. The set-up of process, expert, and control procedures and conditions in a manner allowing for a quality, secure, and effective fulfilment of the goals and requirements of legal regulations.
7. A long-term economic stability and independence of external economic factors.

6. IMPLEMENTATION OF SÚKL'S STRATEGY

For the purposes of fulfilment of SÚKL's Strategy, individual SÚKL units elaborate on the visions, missions and strategies, and specific strategic objectives within the scope of their specific powers and responsibilities.

7. INFORMATION SECURITY AND QUALITY MANAGEMENT, INTERNAL AUDIT AND CONTROL

SÚKL's management wishes to continue to develop previously certified quality management and information security management systems and, concurrently, enhance their integration.

Through their use and constant updating reflecting legislative requirements and actual processes and the needs of SÚKL, SÚKL's management strives to safeguard as accurate a fulfilment of legislative obligations as possible, particularly in the sphere of cybernetic security, as well as a set-up of IT operation and development.
The task for quality management will continue to be the support and monitoring of adequate implementation of key processes within SÚKL and its units, their topicality and efficiency allowing, through their use, to safeguard the transparency, evaluability, and correctness of the procedures employed by SÚKL in the fulfilment of the obligations imposed thereupon.

For the purposes of control of the proper functional operation of both management systems, internal audit and control will be employed. The task of internal audit and control in SÚKL is to carry out internal audit and control particularly in compliance with the Act on Financial Control, or, as applicable, to perform internal audits, checks and controls where invited by the Director to do so. Unlike in other units within SÚKL, this hence does not involve executive activities.

The management, moreover, strives to constantly raise the awareness of SÚKL's employees about the importance of both management control systems.