



Environment, Social and Governance (ESG) Policy

The Supervisory Board of Krka, tovarna zdravil, d. d., Novo mesto at their 15th regular meeting of 16 November 2022 and the Management Board of Krka, tovarna zdravil, d. d., Novo mesto at their 11th regular meeting of 30 September 2022 adopted as follows:

ENVIRONMENTAL, SOCIAL AND GOVERNANCE (ESG) POLICY OF KRKA, D. D., NOVO MESTO

The *Environmental, Social and Governance (ESG) Policy* (hereafter the *ESG Policy*) applies to the parent company Krka, tovarna zdravil, d. d., Novo mesto (hereafter Krka) and its subsidiaries that together with the parent company compose the Krka Group (hereafter the Krka Group). The *ESG Policy* pursues the commitment to apply sustainability principles and encourage their use in business throughout the entire value creation chain.

1. THE KRKA GROUP

The Krka Group consists of the parent company, Krka, d. d., Novo mesto, a subsidiary in Slovenia (Terme Krka, d. o. o., Novo mesto), and subsidiaries outside Slovenia. The composition of the Krka Group is published in annual reports. The Krka Group develops, produces, markets, and sells human health products (prescription pharmaceuticals and non-prescription products), animal health products, and health resort and tourist services. Production takes place in the parent company in Slovenia and in subsidiaries in the Russian Federation, Poland, Croatia, and Germany. In addition to production, these subsidiaries, except Krka-Rus in the Russian Federation, also deal with marketing and sales. In China, production takes place in production facilities taken out on a long-term lease by the joint venture. Other subsidiaries outside Slovenia carry out marketing and/or sales of Krka products, but do not have production capacities. Terme Krka, d. o. o., Novo mesto is our subsidiary that deals with health resorts and tourist services. This industry is not our core business, and accounts for under 3% of total revenue of the Krka Group.

Sustainable development addresses environmental, social and corporate governance issues and is material for Krka's potential for long term value creation and successful implementation of the business strategy. We are aware that Krka's stakeholders find sustainability issues, achieving the related goals, and transparent sustainability reporting increasingly important. We therefore integrate sustainability in our strategy and everyday business operations. We encourage application of sustainability principles throughout the entire value creation chain, constantly upgrade sustainability governance, and build sustainability culture. We carefully plan the production and all processes that impact living in the environment where we operate. We earn trust of our patients and partners through knowledge, professional and ethical approaches, and high quality at all levels of our operations. We endeavour for constant improvement in protection of nature, health and safety, and participate in development of our social environment in line with sustainable development principles. We endeavour to respect human rights and freedoms, exercise labour rights, prevent discrimination, encourage diversity and equal opportunities.

Our core business rests on principles of ensuring innovative, high-quality, effective, safe, and affordable generic medicines that we supply on average to over 50 million of patients a day in nearly 70 countries across the world. We are aware of our great social responsibility, economic impact on wider environment,



and stakeholders' great expectations, which we satisfy with exemplary corporate governance, responsible management, and investing in sustainable activities. We endeavour to increase our positive economic and social impact, create value for our stakeholders, and at the same time reduce natural and social environment burdens in exchange for the approval referred to as the 'social licence to operate' (SLO).

Since the foundation of our company, sustainability has been thoroughly integrated in our operations and it facilitates our competitive edge, success and development. It enables us to achieve stable business results and at the same time protect healthy and clean environment for present and future generations. We endeavour for integral and transparent reporting in compliance with legislation and international sustainability reporting standards. We accomplish this in particular by publishing interim and annual business reports.

Our business operations, products and services have material impact on our internal and external stakeholders. Their present and planned activities impact, or even significantly impact, our potential to successfully pursue our strategy and achieve the strategic business goals. Identification and engagement of key stakeholders are therefore essential for sustainable long-term business operations of the Krka Group. This process is hence strategic, planned, and ongoing. We maintain a constant and proactive dialogue in order to understand the needs of and our impact on stakeholders and social environment. We regularly assess materiality of sustainability topics (hereafter the ESG topics), update reviews of key stakeholders, and engage them in identification of the material ESG topics of the Krka Group and definition of their boundaries.

Integrated, strategic and efficient sustainability governance of the Krka Group is essential for managing sustainability risks, identification of sustainability impacts, and detection of sustainability trends and opportunities for responsible management of natural and social environments and compliant and transparent corporate governance. This dictates strategic assessment of suitability of the Krka Group business model, and provides for long-term sustainable business operations, growth, and development.

We at the Krka Group are committed to high standards of ethics and integrity. The *Krka Group Code of Conduct* is a collection of principles and rules of ethical conduct, good business practices, and standards of conduct in the Krka Group, which are binding for all Krka employees. The *Code* is also the basis for all other internal rules. The basic principle is acting in accordance with the highest moral standards, principles governing integrity, loyalty, and professionalism, and consistent compliance with regulations and guidelines provided by international organisations for the pharmaceutical industry, and with Krka's internal rules. The *Code* is made public on our website. All our business partners are informed on the *Code*, and we expect them to comply with it when conducting business with us.

Another fundamental document is *Quality Manual*. It regards various aspects of operations, e.g. quality, the environment, health and safety at work, food safety, information security and business continuity, in an integrated management system owing to similarity of principles. The established quality system demonstrates to the interested public that we manage and regularly improve all said areas.

The main purpose of the *Quality Manual* is to:

- Describe the describe the management and quality control system of processes and products;
- Set up, document, implement and maintain the integrated management systems and constantly improve them in accordance with the requirements of ISO 9001, ISO 14001, FAO/WHO Food Standards (*Codex Alimentarius*), CAC/RCP 1-1969 (hereafter HACCP), ISO 45001, ISO/IEC 27001

(hereafter ISO 27001), ISO 22301 and Regulation (EU) 2017/745 (*Medical Device Regulation, MDR*);

- Consider the requirements of all the prescribed good pharmaceutical practices (GxPs);
- Fulfil the customers' requirements;
- Consider all legal and other responsibilities;
- Describe processes and their mutual impacts;
- Ensure the continuity of implementation of the quality policy, environmental policy, food safety policy, health and safety at work policy, business continuity management policy and information protection policy;
- Inform and train the employees so that they understand their role and responsibilities at the Krka Group, and their duties in the integrated management system;
- Inform business partners (i.e. buyers, suppliers, service providers), supervisory bodies, and other stakeholders about the policy principles and the quality system at the Krka Group.

Key Stakeholder Groups and Stakeholder Engagement

Stakeholder group	Engagement modality
Patients	<ul style="list-style-type: none"> • Responsible, professional communication about products through various media, including social networks and digital channels
Health professionals, healthcare providers and direct customers	<ul style="list-style-type: none"> • Long-term partnerships • Annual online survey on satisfaction with core aspects of business operations (general satisfaction, satisfaction with products, sales personnel, order processing and fulfilment, and complaint procedures) • Suggestions for improvement • Regular information on products provided in print and electronic forms • Direct contacts through medical representatives in 40 countries • Organisation and support for professional and educational meetings • Advanced digital content for the professional community • Feedback and opinion obtained through daily contact and market research
Employees and prospective employees; trade union organisations	<ul style="list-style-type: none"> • International conferences for employees (various topics) • Measuring organisational climate • Works Council • Worker assemblies
Regulatory agencies/bodies and government organisations	<ul style="list-style-type: none"> • Long-term cooperation and provision of reliable documents
Educational and scientific research institutions	<ul style="list-style-type: none"> • Cooperation with secondary schools, universities and scientific institutes • Cooperation under the Krka Prizes Fund for young researchers
Shareholders, financial institutions and other capital market stakeholders	<ul style="list-style-type: none"> • Meetings with investors at the Krka headquarters • Participation in investor conferences • Roadshows in financial centres around the world • Conference calls with investors following the release of business results • Regular annual general meetings • Communication with financial media
Strategic partners and suppliers	<ul style="list-style-type: none"> • Participation in tenders and competitions • Working meetings • Auditing
Local communities and non-governmental organisations	<ul style="list-style-type: none"> • Identification of needs of local and social environments through various activities related to donations and sponsorships, annual meetings for clubs and associations, and Krka's Week of Charity and Volunteering • Open dialogue and exchange of views with residents (inclusion of environmental goal planning and sustainable environmental protection) • Cooperation with environmental organisations

Media	<ul style="list-style-type: none"> • Transparent information on business operations and events in press releases and responses to media inquiries • Press conferences and meetings with media representatives • Information on websites
Professional associations and interest groups	<ul style="list-style-type: none"> • Work with specialised development institutions and companies • Involvement in the development of professional, scientific and regulatory environments by participating in various professional and industry associations in Slovenia, the European Union, and other countries

We also identify major sustainable development goals (SDG) of the United Nations specified in the *2030 Agenda* that the Krka Group actively contributes to. The number 3 ('Good health and well-being') is the most important goal and we can help attain it with our core business and through our mission 'Living a healthy life'. Our strategy also considers goals set by the United Nations and main sustainable development goals.

Main SDGs from the Perspective of the Krka Group



2. VISION, MISSION, AND VALUES

MISSION

Living a healthy life.

VISION

We are continually consolidating our position as one of the leading generic pharmaceutical companies in the world.

We base our achievements on sustainable development, remaining independent and strengthening long-term business connections and partnerships in development, product supply, and marketing.

VALUES

- *Speed and flexibility*
- *Partnership and trust*
- *Creativity and efficiency*

Krka's mission is to enable healthy and high quality living. We can achieve this only through long-term balanced sustainable development while keeping the environment clean and healthy for present and future generations. In achieving our mission, we focus on central ESG topics, most of all product quality and patient safety, as well as accessible healthcare. Our mission, vision and values serve as the foundation of our governance processes and business decisions and allow us to implement our business strategy, achieve our long-term strategic goals and value creation for stakeholders.

3. SUSTAINABILITY IN THE KRKA GROUP

The Krka Group respects all three sustainability pillars, i.e. the natural and social environments and corporate governance, in all its operations and includes sustainability principles in its strategic directions.

We are aware that our economic responsibility and impact matter. We strategically and systematically identify and manage sustainability risks and opportunities.

An interdisciplinary sustainability project team outlined key ESG topics, assessing them in a wide and open process that involved all business functions. Relevant departments analyse our stakeholders’ interests with direct and indirect communication (e.g. interpersonal relationships, questionnaires, publishing). We hold in-depth interviews with representatives of major stakeholder groups in connection with the ESG to check their understanding and prioritization of the ESG topics and the extent of expected disclosures.

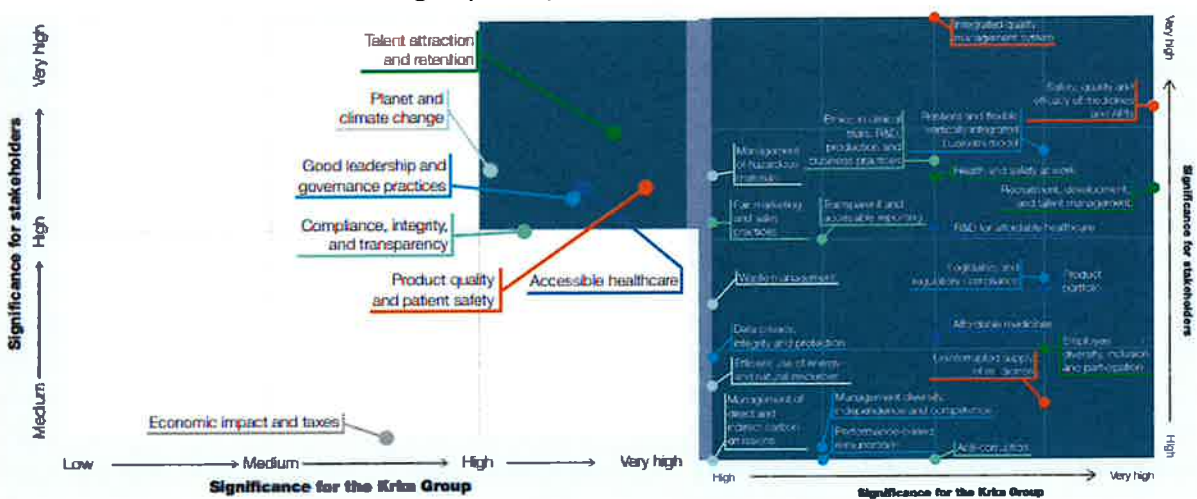
In addition to determining key stakeholders, we identified 36 material ESG topics of the Krka Group and broke them into seven groups. Material ESG topics and their management are detailed in the annexes to the *ESG Policy*. The Management Board of Krka considered and confirmed all the above-mentioned aspects.

The concept of double materiality applies in identification of materiality or relevance. We apply the double materiality principle to specify central ESG topics with reference to: (i) The impact of the Krka Group operations on stakeholders (the impact on the environment, society and economy is ‘impact materiality’), and (ii) The impact of the natural and social environments on the value of the Krka Group (the impact on corporate operations and position is ‘financial materiality’), which agrees with the specification given by the European Commission in 2019. The business strategy of the Krka Group, which includes the integral sustainability strategy, specifies sustainability goals for each ESG topic, relevant KPIs for monitoring their implementation, and the schedule for achieving them. The boundaries between business and sustainability strategy is blurred, because both are in equal relationship and mutual dependence.

The process of stakeholders engagement and continued interaction with them form a constant and important base for adequate identification of material ESG topics and any respective upcoming changes. Any potential changes to ESG topics will be subject to confirmation by the Management Board of Krka.

Materiality Matrix of the Krka Group

Material groups of Krka Group’s ESG topics are on the left hand side of the graphic. Detailed presentations of individual topics are stated in order of importance from high to very high on the right hand side. Colours indicate which of the relevant seven groups a topic belongs to.



The annexes to the *ESG Policy* include specification of material ESG topics and description of relevant management approaches.

4. PURPOSE, OBJECTIVES AND AREA OF IMPLEMENTATION OF *ESG POLICY*

The basic objective of integrating sustainability principles and sustainability governance of the Krka Group in management processes and business decisions is to increase recognition of sustainability risks and opportunities that could in the long term help to improve their management and increase the success of our business operations. We at the same time optimise long-term value creation for all stakeholders and achieve sustainable growth. We know that all material ESG topics can result in financial consequences for Krka's business operations.

Sustainability is the long-term driver of company's growth and development and the basis for achieving the competitive edge, business objectives and implementation of strategic guidelines.

Sustainability governance will allow the Krka Group to:

- Use natural resources and materials more effectively → Increase productivity and cost effectiveness;
- Increase innovation → Increase productivity, cost effectiveness, competitiveness, and accessibility of medicines;
- Increase reputation, recognition and quality of our products and services → Grow and strengthen the competitive position;
- Make new investments in research and development → Reduce our impact on the environment, add new forms of treatment, new products and grow;
- Keep the Krka Group attractive for employees and potential recruits → Facilitate long-term success;
- Reduce business operation, regulatory, and other risks → Improve risk management;
- Manage the vertically integrated business process and supply chain effectively → Ensure a flexible business model, high quality products, and improved market supplies;
- Increase attractiveness of the Krka Group for current and new shareholders → Increase the value of the Krka Group;
- Decrease the environmental impact → Increase the environmental responsibility and reduce the environmental burden.

The *ESG Policy* is the basic building block of sustainability governance and outlines the fundamental principles and efforts that the entire Krka Group follows throughout its business operations. It also forms the base for our business strategy, above all for determining explicit management approaches to material sustainability areas and setting the related sustainability objectives and relevant key performance indicators (KPIs) for monitoring goal achievements. We pursue a business strategy in consideration of sustainable development in order to increase our contribution to attaining sustainable development goals and targets of the *2030 Agenda* of the United Nations.

We aim for transparent and open communication about sustainability with internal and external stakeholders and wider public. We undertake to report on milestones, achievements, activities and indicators related to sustainable development in the Krka Group public releases. We intend to disclose in our annual reports detailed sustainability indicators, activities, and processes related to sustainability governance, considering in the process the *Global Reporting Initiative Standards (GRI)* and the future



legislative framework related to the international sustainability reporting standards. We also undertake to comply with the EU legislation, in particular *Corporate Sustainability Reporting Directive (CSRD)*; *European Sustainability Reporting Standards (ESRS)*; Regulation (EU) 2020/852 on the establishment of a framework to facilitate sustainable investment (*EU Taxonomy Regulation*); and other legal frameworks, for example *Non-financial Reporting Directive 2014/95/EU (NFRD)* and the established sustainability reporting best practices. We plan to communicate with internal stakeholders through various communication channels, including regular bulletins the *Utrip* and *Bilten*, the internal corporate website Krkanet, and many other forms of communication. We plan to present material ESG topics and our achievements on our corporate website and by various social media. We aim to raise awareness through wide communication of how important sustainability approach is for all everyday activities of Krka and our stakeholders, and communicate in an open and transparent manner that Krka is aware of its impact on the environment, society and corporate governance, which we manage comprehensively.

The *ESG Policy* is the commitment to promote and implement sustainability principles in business operations. All subsidiaries of the Krka Group must conduct business in compliance with it, and at the same time also consider the prevailing nature of national legislation of the country where they operate.

The *ESG Policy* outlines sustainability commitments of the Krka Group companies for present and future and represents the grounds for upgrading sustainability governance in relation to the environment, society and corporate governance, which we at Krka have been considering for decades. *Corporate Governance Policy of Krka, d. d., Novo Mesto* adopted by the Supervisory and Management Boards, is another important document on corporate governance of Krka that – in addition to all rules, codices, standard operating procedures and other documents regulating business operations of Krka – also considers sustainability.

We undertake to strive for promotion of sustainability principles and sustainability culture, and their implementation throughout all our activities and business functions, and to spread sustainability culture among internal stakeholders and support their education. We intend to encourage sustainability approaches and introduce them throughout the entire value creation chain, from suppliers to end users, and share them with other external stakeholders as well. We are aware of the impact, expectations and responsibilities we have, and would therefore like to set a good example for others as regards sustainable operations, spread our positive impact, contribute to and attain the desired positive effects. We would like to create new business opportunities, together with our partners develop and attract to long-term cooperation investors and stakeholders who highly regard sustainability principles. Patients and other users of our products and services, employees, strategic partners and other stakeholders and investors, who provide capital for Krka's business operations, are our main concern. Another extremely important area is the environment, and we strive to reduce our environmental impact and attain the goals of the European green agenda, for example to reduce our carbon footprint and become carbon neutral by 2050. Also, we intend to achieve the highest possible degree of compliance of our business operations with the provisions and technical criteria of the *EU Taxonomy Regulation* (Regulation (EU) 2020/852 on the establishment of a framework to facilitate sustainable investment) in relation to revenue generation, investments and expenses.

We plan to verify our sustainability orientation and compliance through independent institutions and agencies to score relevant ESG ratings and work on their further improvement.

5. SUSTAINABILITY GOVERNANCE OF THE KRKA GROUP

The Supervisory and Management Boards of Krka play the leading role in supervision of sustainability governance. In compliance with the *Articles of Association of Krka*, the Supervisory Board has the authority to confirm the strategy of the Krka Group that includes sustainable development. The Supervisory Board also confirms the *ESG Policy* and any related potential amendments. Senior management bodies are responsible for strategic supervision of the sustainability. The Management Board is responsible for integration of the sustainability strategy and establishing sustainability culture, values and operative processes that allow for the Krka Group's long-term existence and value creation. The board approves all material and relevant resolutions on sustainability (i.e. specification of stakeholders and sustainability topics, materiality assessment, sustainability risks from the *Risk Register*, etc.) and is responsible for establishing effective mechanisms for internal controls and risk management and transparent sustainability reporting in compliance with regulations and good practices. The board also specifies and confirms strategic priorities, goals, indicators, and mechanisms for monitoring the achievement of goals (i.e. KPIs) and monitors their implementation. Acting in line with the *Rules of Procedure of the Management Board*, the Management Board has appointed one of its members to be specifically in charge of sustainability and upgrading sustainability governance system at the Krka Group.

Sustainability governance involves clear definition of responsibilities and powers in relation to sustainability at the Krka Group level. The organisational structures and individuals at the Krka Group level are accountable for implementation and spreading of sustainability principles as follows:

a) The Management Board member in charge of sustainability

The Management Board member in charge of sustainability manages and supervises performance of the sustainability project team and leads the Sustainability Board.

b) Sustainability Board

An interdisciplinary project team for sustainability (ESG), composed of representatives from various business areas, is operational. The Management Board appointed members to the team, which is led by the Management Board member in charge of sustainability. Activities of the project team will be transferred to the sustainability board, which will assume the team's functions and authorities, and will be designed like other boards. The Management Board will adopt a resolution on its composition and functioning.

List of the Sustainability Board members:

- President of the Management Board and CEO
- The Management Board member in charge of sustainability (presides the Sustainability Board)
- Other Management Board members
- Sustainability Coordinator
- Assistant Chief Executive
- Director of Marketing
- Director of Sales
- Director of Quality Management
- Director of Corporate Performance Management
- Director of Human Resources

- Head of Public Relations
- Head of Safety and Health
- Director of Pharmaceutical R&D
- Director of Purchasing
- Head of Environmental Protection

Deputies or assistants to the officers listed above can represent individual organisational units or departments if so agreed with managements of the respective organisational units or departments. Other employees and potential independent external members with relevant sustainability-related skills can also participate in the board meetings if so proposed by the Management Board member in charge of sustainability.

The Sustainability Board is planned to meet at least once a year. The body's authority will be to review implementation of the *ESG Policy* and sustainability (ESG) strategy. It will also monitor implementation of key activities and review attainment of sustainability goals, relevant KPIs, and other important sustainability indicators. It will discuss proposed amendments and upgrades to the *ESG Policy* and proposed strategic sustainability goals, KPIs, and the related potential changes. It will examine proposals for changes to the key strategic sustainability areas and materiality assessments. It will also discuss sustainability initiatives and determine key activities and duties in the sustainability area for the upcoming period.

c) ESG Coordinator

The ESG coordinator is a Sustainability Board member and serves as a link between the Sustainability Board, member of the Management Board in charge of sustainability, and ESG managers. The ESG coordinator supervises, facilitates and encourages implementation of the *ESG Policy* and other resolutions adopted by the Sustainability Board. The officer reports to the Sustainability Board on sustainability achievements, attainment of sustainability objectives and activities, assesses the adequacy of the *ESG Policy*, proposes modifications, and participates in sustainability reporting. The officer follows trends, legislation and good sustainability governance practices. The coordinator actively contributes to increasing sustainability awareness and exploiting sustainability-related opportunities and participates in educating and informing employees. The person is the main promoter of sustainability culture apart from the Management Board and Sustainability Board members and ESG managers. The coordinator participates in inclusion of stakeholders and sustainability-related communication with investors, media, expert community, and other relevant stakeholders. The coordinator coordinates and supervises work of ESG managers. The coordinator collaborates with potential external experts and consultants for sustainability.

d) ESG Managers

ESG managers are designated for key business areas. Their duty is to promote strategic sustainability activities and sustainability culture in order to aid attainment of the strategic sustainability goals in their respective areas. They report to the Sustainability Board and the ESG coordinator on performance and achievement of goals. They participate in stakeholder engagement in their respective areas, and assess and monitor sustainability risks and opportunities. They also assess adequacy of the *ESG Policy* and propose changes to the coordinator. They follow trends, legislation and good practices for sustainable approach in their respective business areas, and based on this propose the related activities and participate in



sustainability reporting. They actively contribute to increasing sustainability awareness and exploiting sustainability-related opportunities and participate in educating and informing employees.

- e) **Other boards** are: (i) Director's Committee; (ii) Sales Committee; (iii) Development Committee; (iv) Quality Committee; (v) Investments Committee; (vi) Human Resource Committee; (vii) Information Technology Committee; (viii) Economics and Finance Committee; and (ix) Corporate Identity Committee.

Other relevant boards, which assist Krka's Management Board, discuss specific ESG topics in more detail. They specialise in individual business areas. They are composed of Management Board members, managerial staff, and experts in respective areas. They prepare business policies and strategic guidelines for their respective areas and hold certain decision-making authorities relating to the implementation of annual plans. Certain committees also have authorities relating to risk management.

6. FINAL PROVISIONS

The *ESG Policy* enters into force on the day when adopted by Krka's Supervisory and Management Boards. When adopted, it becomes binding for all Krka Group subsidiaries; however, national legislation of the country where a subsidiary operates prevails. Shareholders and the interested public are informed on adoption of the *ESG Policy* by a public release in the Ljubljana Stock Exchange electronic information dissemination system (SEOnet), the Polish Financial Supervision Authority electronic information dissemination system (ESPI), and on Krka websites.

The *ESG Policy* is a public document and is published on the company's website in Slovene and English. Adequacy of the policy is generally reviewed once a year. Complexity, constantly changing regulatory and business environment, and the importance of the sustainability for the Krka Group call for systematic and regular supervision of the policy's implementation and adequacy. The *ESG Policy* can be amended when proposed so by the Sustainability Board members or ESG managers. The Management and Supervisory Boards approve amendments. The Management Board also confirms any changes made to the material ESG topics from Annex 1. The new *ESG Policy* must be properly made public.

Previous editions of the *ESG Policy*

Date of approval by the Supervisory Board	Description
16. 11. 2022	Adoption of the <i>ESG Policy</i>

Jože Colarič

President of the Management Board

Jože Mermal

President of the Supervisory Board

Annex 1: IDENTIFIED MATERIAL ESG TOPICS AND GOVERNANCE APPROACHES

1. PRODUCT QUALITY AND PATIENT SAFETY

a) Quality, safety and efficacy of medicines and APIs

Medicines on the market must satisfy quality, safety and efficacy requirements. We examine quality of finished products, semi-products, and intermediate products and incoming materials with extensive laboratory testing and state-of-the-art and validated analytical methods, equipment and procedures. All our prescription pharmaceuticals and non-prescription products are tested and comply with all relevant regulations. We also follow stability of products and active ingredients and guarantee for high quality, safety and efficacy throughout their shelf lives. Product quality is defined in the development stage of a product and specified in marketing authorisation documents. We follow standard procedures and requirements throughout the production process, from the purchase of incoming and other materials and services to manufacture of finished products, quality control, warehousing, and distribution. This ensures that our products comply with relevant quality standards and marketing authorisations.

We promptly incorporate legislative changes in our work processes to follow good practices from the development phase onwards. As regards medicines used in clinical trials, we apply new tools and extensive expertise to ensure the level of patient and volunteer safety required by law. The system for following new developments allows us to receive information on time and introduce it into the processes which ensure compliance of product manufacturing with legislation and guidelines.

We have preclinical and clinical trials done to examine efficacy and safety of our products already at their development stages. Medicines made by Krka are equivalent to the originators' products. Pharmaceutical equivalence is demonstrated by *in vitro* dissolution testing, and therapeutic equivalence by *in vivo* bioequivalence studies. In both cases we compare our medicine with that of the originator.

We regularly test and prove efficacy and safety of our products in clinical practice. Many clinical trials include preregistration trials (phase III), post-authorisation safety studies (phase IV), and pharmacovigilance studies.

We test quality of active ingredients in many laboratory tests, in which we use the most sensitive, reliable and validated analytical methods and equipment. Owing to improved synthesis procedures and analyses, quality of the generic active ingredient can be even higher than that of the originator's.

The Certificate of Suitability issued by the European Directorate for the Quality of Medicines (EDQM), is the highest quality standard in Europe. It confirms that an active ingredient complies with the standards laid down in the monograph of the *European Pharmacopoeia*. Krka has received it for many active ingredients.

b) Uninterrupted supply of medicines

In consideration of international business operations, we have established a uniform system which ensures ready availability of our products for patients. We regard local needs and healthcare system specifics to adapt our international strategy to the requirements of individual markets. When doing business, we comply with the *Universal Declaration of Human Rights*, according to which patients have access to uninterrupted treatment with our high-quality products. Providing access to medicines is also one of the cornerstones of our social responsibility and significantly helps us maintain the reputation of a reliable

partner with patients and direct customers. The two vital factors are understanding the distribution cycle in individual markets and developing a sales-and-logistics strategy that allows for ready and constant availability of our medicines.

We guarantee the timely supply of finished products by keeping every phase of product supply under control. Plans of production material inventories are based on as accurate sales forecasts as possible. We check inventories regularly, keep safety stocks of strategically important raw materials, and have several independent resources. We carefully plan optimal utilisation of production capacities and measure production efficiency. We constantly improve processes accordingly. We meet sales requirements, increase our production capacities, and expand contractual collaboration through new equipment and investments. We pursue good manufacturing practices and provide for adequate production environment. In case of major emergencies, we can arrange production of key products at several plants. We systematically follow secondary sales and base detailed plans of sales requirements on the data to provide for availability of our products.

Our direct customers, with whom we establish and keep good business relationships, also have an important role in providing for availability of our products. We carry out surveys in order to check the level of their satisfaction, learn their needs and identify areas in which we could further improve our reputation and quality.

c) *Integrated quality management system*

Our fundamental strategy in terms of quality is to ensure quality by continuously improving our products, processes and services. We achieve this by effective performance of the quality system in compliance with the principles of good pharmaceutical practices (GxP) and regulations governing the quality in pharmaceutical industry. We meet requirements of various clients and demonstrate on-going suitability of processes for achieving the set goals through flexibility, quick adaptation to new developments, market needs and legal requirements, improvements to our processes, investments, advanced work systems, and proper control methods. We therefore systematically address quality-related risks and opportunities in all processes. Our aim is to achieve sustainable development. Careful planning, quality culture of employees and constant development of our processes and services enable us to satisfy the requirements of our internal and external clients and create opportunities for further improvements.

We manage various aspects of our operations in a uniform way which facilitates effective process performance. This determines our attitude to quality, environment, health and safety at work, food safety, medical device safety, information security, and business continuity. The system structure complies with ISO 9001 standard, GxP and HACCP principles, Regulation (EU) 2017/745 (*Medical Device Regulation, MDR*) and ISO 14001, ISO 45001, ISO/IEC 27001, and ISO 22301 standards. To ensure credibility and increase the trust of our partners, we have the system regularly certified by SIQ (Slovenian Institute of Quality and Metrology) and demonstrate its compliance with regulatory and legal requirements in inspections and audits.

The baselines for establishing and developing the quality system are laid out in the umbrella document on quality *Krka Group's Quality Policy* in agreement with the legislation, good practices and standards. We follow all new developments in that regard and systematically introduce them in all processes and management systems. The document outlines a uniform quality policy for all Krka Group subsidiaries. Quality management processes are integrated into corporate management processes and facilitate

implementation of the basic rules for the operation of all processes. We are committed to continuously upgrading the quality system in order to increase process efficiency, quality, and competitiveness of products and services. It is therefore vital that our employees are aware of the importance of the quality system, undergo continuous training, and constantly upgrade their knowledge in quality management. We identify opportunities for improvement and introduce new developments into processes in collaboration with experts from various areas. We call attention to the importance of quality in all processes. We encourage and solicit new innovative approaches in various publications and on our corporate internal web site, and incorporate them into work procedures. Vertical integration of quality allows us to manage product and process quality risks effectively. Quality is vertically integrated through know-how, experience, and understanding of the entire product lifecycle (from an active ingredient to the finished product), in planning, development, quality assurance throughout the manufacturing process, and the company's organisational structure, which supports the integration of quality into all processes.

d) Product labelling and anti-counterfeiting

We have the pharmacovigilance system in place to monitor an individual medicinal product throughout its shelf life. We carefully record and medically review all received information on adverse reactions. We consider information on the suspected adverse reactions related to our medicines from all countries where we hold marketing authorisations and also those from clinical trials. We analyse the data, evaluate any potential new safety information, and assess risks and benefits in relation to individual medicinal products. We consider latest scientific discoveries important for safe administration of medicines and include them in patient information leaflets, and carry out all necessary measures to reduce risks related to a medicinal product. Our pharmacovigilance system complies with legal requirements and EU guidelines as follows: Commission Implementing Regulations (EU) No 520/2012 and (EU) 2021/1281 on the performance of pharmacovigilance activities, and guidelines on good pharmacovigilance practices (GVP). We constantly upgrade and improve the system also in the countries outside the EU where we market our products. We examine its credibility in regular internal and external quality audits. In addition to this, certified regulatory bodies, which also inspect our partners, verify compliance of the systems with legislation and other regulations.

Labelling of the medicinal products is one of the basic requirements specified in Good Manufacturing Practice (GMP) guidelines. It ensures that each product batch is traceable from the start of production until expiry of its shelf life. Our quality system ensures that every unit and each batch are labelled in compliance with the guidelines and registration documents.

Respect for the intellectual property rights is one of the fundamental principles of the Krka Group operations. We take all necessary measures to prevent falsification of our products. The EU and the Russian Federation and the majority of other countries adopted laws on the prevention of the entry of falsified medicinal products into the legal supply chain in consideration of good manufacturing practices. According to the Commission Delegated Regulation (EU) 2016/161 (EU FMD), the EU requires that the safety features consisting of a unique identifier (serialisation) and an anti-tampering device (ATD) are placed on the packaging of medicinal products for human use, and that the unique identifiers are reported to the European Medicines Verification System via the European Hub (EU Hub). This enables identification and verification of the authenticity of medicinal products throughout the supply chain. In addition to the unique identifiers, the Russian Federation laws require records of individual packaging units in a transport box or aggregation, introduction of the 'Crypto Code', and reporting serialisation and aggregation data to

the Russian governmental information system ('Markirovka'). The Krka Group successfully implemented all legislative requirements regarding safety features on 9 February 2019 in the EU and on 1 January 2020 in the Russian Federation. We supply adequately labelled medicinal products to buyers and patients and provide for relevant data reporting to specific systems.

2. TALENT ATTRACTION AND RETENTION

a) Recruitment, development and talent management; Employee diversity, inclusion and participation; Flexible working

Responsible attitude to employees is key to attracting and retaining talent. We understand that our responsibility is trustworthy and professional employee management throughout their employment at the Krka Group. Basic employee-related activities include quality recruitment, employment, induction training, education, development and retention of talent, management, succession development, rewarding achievement, and establishing the culture of collaboration and teamwork.

Our success is founded on employee know-how, experience, and commitment, sound relations and collaboration. We endeavour for our overall operations to reflect responsibility to employees, the environment, and stakeholders. Krka's values lead us in setting the objectives, reaching the results, and cooperating with employees, as well as in their management and development of their potential. Together, we are building a culture of mutual trust, respect, cooperation and teamwork, lifelong learning, and responsible, efficient, and sustainable work. We are distinguished by loyalty, innovations, flexibility, commitment, focusing on attainment of business goals and the Krka Group results.

We foster personal, and professional development of our employees by methodical and systematic training. We retain talent and create succession system by providing opportunities for promotion and career development. Timely talent identification and appropriate management are of key importance, so we pay special attention to development of managerial skills.

We manage risks related to the lack of experts on the labour market by being actively present in the labour market, bolstering Krka Group's image as a reputable employer, working with faculties and schools, and by awarding scholarships. In this way we attract potential employees with whom we meet our strategic, development, and operative plans.

We are committed to high ethical standards. The *Krka's Code of Conduct* lays out principles and rules of ethical conduct, good business practices and standards of conduct in the Group, which are binding for all Krka employees. An important part of the strategy rests on continuous awareness raising through education, management communication with employees, and internal media.

Zero tolerance to fraud According to corporate rules, the Krka Group employees undergo periodic training on corporate integrity and compliance. The Krka Group shows zero tolerance to fraud. Every employee can report any potential fraud via several communication channels.

Providing for equal opportunities Equal opportunities for all employees, regardless of their gender, race, religion, nationality or cultural differences, respect for legal norms and rules, and ethical approach to other people and the wider social community represent the foundations of our work. The principles of non-discrimination and equal opportunities apply to all our employment procedures, work with employees, their inclusion in working processes, personal development, promotion, and remuneration.

Respect of human rights and legislation We respect human rights covered by internationally recognised principles and guidelines, including the United Nations' *Universal Declaration of Human Rights*. We abide by all legal regulations and standards related to human rights in all countries where we operate. We reject all forms of forced labour, unethical practices, and violation of basic worker rights. We respect national legislation, on which safe, healthy and decent work and quality of life for employees are based. In addition to that, we comply with guidelines of the International Labour Organisation (ILO), World Health Organisation (WHO), and the European Agency for Safety and Health at Work (EU-OSHA).

Dealing with inappropriate conduct in interpersonal relations We quickly respond to any identified inappropriate conduct in interpersonal relations in accordance with clear rules and procedures and prevent any forms of mobbing. Any form of harassment and ill-treatment in the workplace is prohibited. We provide for adequate working conditions and an open and creative working environment. We provide for working environment free from any psychological pressure, sexual or other harassment, or ill-treatment by other employees, superiors, or third parties. All employees are obliged to refrain from any inappropriate conduct that could discredit dignity of another person. Anybody, who notices such unwanted conduct, can make a report to a relevant authorised person.

Employee inclusion and diversity We work in diverse cultural environments and foster partner approach to attain common objectives of the Krka Group. Partnership and trust are two of our key values. We strive for diversity and inclusion of all our employees, including the balanced gender structure of senior and executive officers. Together we build a culture based on mutual trust, respect, cooperation, teamwork, lifelong learning, responsible and effective work. We take special care of the vulnerable groups of employees, i.e. people with disabilities, health issues, in social distress, etc. We provide for equal opportunities, regardless of employee's gender, race, colour, age, medical condition or disability, religious, political or any other belief, trade union stewardship, national or social origin, family status, financial condition, sexual orientation, or other personal particulars.

Employee participation We appreciate commitment and contribution of each employee to achieving the Krka Group objectives. We foster awareness that every employee helps create a healthy and successful working environment. We give employees the opportunity to express their opinions by monitoring organisational culture and employee commitment. We analyse the findings to make improvements, which contribute to healthy, efficient and creative environment. We encourage open and regular dialogue between the Management Board, Worker Council and trade unions to ensure employee inclusion and participation in management of areas connected with responsibility to employees.

Establishing ties between science and industry Our employees actively engage in research and education at various universities and participate in joint projects, transferring experience from the industry to the academia. We make education possible for young scientists and researchers, and recognise and award their achievements.

Employee education and development and talent retention We encourage all employees to undergo lifelong education for successful work, career promotion, professional development and personal growth, and also facilitate this. We provide quality and systematic induction of new employees to work and working environment. We place special emphasis on attracting, identifying, developing, and retaining young talent. This ensures that the Krka Group will remain successful also in the future. Employee education and development are centred on responsible management, mutual respect, inclusive dialogue, and collaboration. We recognise, distinguish and reward examples of good management and performance



at the Krka Group level by using various methods of motivating employees, announcing the best managers and the best employees, etc.

Quality of work and living As a socially responsible company, the Krka Group follows its mission, i.e. 'Living a healthy life', in many areas. We ensure safe and healthy working environment and promote a healthy lifestyle. Caring for health is joint responsibility of all employees. We raise awareness about the importance of health by arranging health campaigns for our employees. Healthy diet based on foods from the local environment is also a part of this. We allow for flexible work arrangements, so that our employees can balance work and private life, and comply with all legislative requirements and those of the collective bargains relating to work hours, taking a rest or leave. To provide for well-being and good interpersonal relationships of our employees, we arrange many sports, cultural and charity events that bring employees together and benefit the wider social environment. We also offer holiday accommodation to our employees.

b) Health and safety at work

Safety and health of all our employees, visitors and external contractors at work in Krka comes first. Krka provides a safe and healthy working environment for employees. We follow latest trends, findings and standards of occupational health and safety and fire safety, and promptly incorporate them in all business processes, projects, and technologies. The system used by the parent company is implemented and certified in compliance with the ISO 45001 standard and fully incorporated into the integrated management system, and we constantly upgrade and improve it. Internal and external auditors examine its efficiency. We systematically identify and evaluate all risks and take relevant measures to prevent or mitigate them. Our sound performance in health and safety at work and environmental protection is awarded by the right to use the 'Responsible Care' logo every year.

We assess risks at workplaces and undertake relevant safety measures to reduce them to acceptable levels and ensure constant long-term improvements in working conditions. We also assess risks related to technological procedures in research and development. We identify all hazards for each technological phase separately and consider the employee exposure time and hazard levels to determine safety measures for preventing exposure of employees who perform certain technological procedures.

When there is a risk of infection (epidemic, pandemic), we implement a series of sanitary, health, and organisational measures to prevent introduction and spreading of a potential infection, and ensure uninterrupted work processes. We also have an efficient fire safety system in place, which incorporates systematic preventive measures for reducing hazards. We employ a professional fire brigade, which is qualified to intervene in case of emergency.

We take care of workplace safety and health at work by arranging regular training courses. We check how effectively employees respond to potential emergencies with many fire safety drills, as well as the impact of emergencies on business stability and continuity. Training and drills are carried out by our in-house experts and external contractors. We assess the effectiveness of risk management by external and internal audits, self-inspections, audits, inspections, and management reviews. Our aim is to control and maintain risk at an acceptable level.

We promote healthy lifestyles for our employees and raise awareness of the importance of health and safety at work. The Management Board support the employees, raise their awareness, and facilitate various activities for them. Caring for health is a joint responsibility of all employees, managers, and

professional services. The Works Council and the two trade unions are also incorporated into the system. We implement the health promotion plan to increase the awareness of how important it is to maintain health for quality of life. We regularly update the plan in consideration of suggestions and initiatives given by our employees, agency workers and students.

Our occupational health and safety policy binds us to ensure a safe and healthy working environment:

- We prevent risk of injury or health deterioration for employees and contractors, specify safety measures, train and raise awareness of importance of health and safety at work;
- We maintain good interpersonal relations;
- We consistently carry out safety measures in order to reduce the risk of injury or health damage;
- We carry out preventive medical check-ups for employees and delegate them to job positions suitable for their health;
- We follow legislation, technical guidelines and other requirements in all areas related to occupational safety and health, and introduce them into practice on time and adequately;
- We promote health at work and cooperate with employees in the decision-making process regarding occupational safety and health system;
- We extend our commitment to occupational health and safety policy to all our subsidiaries.

3. ACCESSIBLE HEALTHCARE

a) Product range

Cardiovascular agents account for more than 50% of our portfolio, which agrees with the *2030 Agenda for Sustainable Development* aiming to reduce deaths caused by noncommunicable diseases by one third by 2030. Cardiovascular diseases are the leading cause of death due to noncommunicable diseases. We contribute to the goal not only with agents for the treatment of hypertension, hyperlipidemia and diabetes, but also by organisation of educational programmes for healthcare professionals, providing them with access to latest medical knowledge and information for use in their everyday practice. We therefore pursue our goal, which is to provide the best possible treatment options for patients. We foster transparent and traceable relationships with medical professionals.

Our comprehensive range of products for the treatment of most common civilisation diseases ensures that each patient can get affordable and best possible therapy. Physicians can choose from many innovative generic medicines that combine several active ingredients and prescribe the most suitable therapy for each patient for the best treatment outcome. We plan to increase our portfolio of medicines for treating common chronic noncommunicable diseases and add to it especially agents in innovative combinations for the treatment of high blood pressure, blood-clotting disorders, diabetes, and cancer. This will further contribute to attaining the objective, which is part of sustainable development goals (SDG) set by the United Nations.

b) Affordable medicines

Generic medicines are equivalent to the originators' products for which product patent protection has expired or has never been granted. They contain the same active ingredients and their quality, safety, and efficacy are equivalent to the originators' products. In addition to registration documents and bioequivalence studies, also clinical practice supports the fact. Generic medicinal products are gaining importance worldwide, because they are of high quality and an affordable alternative to originators' medicines.



As one of the leading generic manufacturers, we deliver on the objective to produce high quality, state-of-the-art and affordable generic medicines for the most common diseases of our time. More than 50 million patients from all over the world use Krka medicines every day. Our business focuses on caring for their health. Our medicines add up to great savings for patients and public health care budgets, making us an important partner of national healthcare systems and patients. We will put effort into increasing our portfolio of generic medicines in our traditional markets and entering new markets also in the future.

In particular we focus on understanding needs of our established as well as new markets. We are present in nearly 70 countries. Our largest markets include the Russian Federation, Poland, Germany, Ukraine, and Romania. We also operate in countries with medium and low GDP per capita, which generally encounter great macroeconomic risks. We are also one of the leading medicine suppliers in most countries of Central Asia, including Tajikistan, Kyrgyzstan, Uzbekistan, Turkmenistan, and Mongolia, and also in Iran, Iraq, the Republic of South Africa, Vietnam, Ghana, Sudan, Libya, and Lebanon.

c) R&D for affordable healthcare

Krka allocates approximately 10% of annual revenue to research and development. Scientific and technological progress is rapid and markets are increasingly complex. We can only remain competitive in the generic market through continuous investment in knowledge and state-of-the-art equipment. We are committed to developing quality, effective and safe medicinal products for the patients. Therefore, we have a broad product portfolio and constantly extend our key therapeutic classes with new or revised products.

Product development is based on our innovative technological solutions, so we do not infringe competitors' patent rights. In this way we can deliver our products to patients on time, i.e. immediately after patent expiration and acquisition of marketing authorisations. By introducing new and innovative API synthesis, state-of-the art technologies and optimisation of technological procedures, we guarantee permanent availability, top quality and safety of our products, and competitive prices.

In addition to innovative technological approaches, we also develop innovative products in complex pharmaceutical forms with added value for patients, including modified-release pharmaceutical forms, bilayer tablets and dispersible tablets. We file several patent applications every year for new technological solutions and products to protect them from competitors. Achievements of our scientists are noticed also in the wider environment. We have received several innovation awards from the Slovenian Chamber of Commerce and Industry.

To develop value added medicines and place them on markets on time, we adopt rational approaches to research and development and set optimal patent strategies. The vertically integrated model is the foundation for managing patent, development, legislative, production, and marketing requirements and risks. By managing the entire process, we can research, develop, evaluate, authorise, and manufacture in-house active pharmaceutical ingredients (APIs) and finished products. The adopted development strategy and project approach help us manage products in all phases of their lifecycles, and we pursue in the process scientific objectives and control timelines and costs. R&D results and understanding of markets and legislative requirements enable us to prepare complex registration documentation and obtain marketing authorisations on time.

Quality, safety and efficacy are of key importance already at early stages of development. Our know-how and management of synthesis and technological procedures enable us to provide APIs and final products

of highest purity. We follow international guidelines presented by ICH for medicines for human use and VICH for products for veterinary use.

We confirm safety and efficacy of new products already at their development phases in preclinical and clinical studies. We always conduct clinical trials in line with the applicable legal requirements, good practice guidelines, the *Helsinki Declaration*, and Regulation (EU) 2016/679 (*General Data Protection Regulation*). We ensure safety of the participants, transparency, ethics, and high quality of research by complying with the above-mentioned regulations. This is also confirmed in regular inspections, conducted by regulatory authorities.

We strive to use simple and energy-efficient technological procedures, which contribute to affordable prices of our products. Development complies with our environmental policy and the ISO 14001 standard. We ensure that technological procedures have minimal impact on the environment and hence reduce our carbon footprint, water consumption and organic solvent volumes therefore, following circular economy.

d) Effective registration procedures

Effective development process and registration procedures are our competitive advantages. They guarantee that we are among the first suppliers on the market after the expiration of patent and/or marketing exclusivity.

We manage regulatory risk associated with changes in legislation from early stages of development and throughout the lifecycle of a product. We constantly follow latest scientific discoveries and new regulatory requirements for APIs and finished products and consider them in the development, preparation of the registration documentation and strategies, and in managing registration procedures. The Development Committee or subsidiaries' supervisory bodies discuss and approve the acceptability of any increased risks related to registration procedures. Development solutions for individual products and content of marketing authorisation documents are regularly verified at official consultative meetings with regulatory bodies. We also participate in working groups of various industry associations for example the international association Medicines for Europe and Access VetMed. We actively involve in drafting legislation in this way.

Our registration procedures are time- and cost-efficient. We ensure that our products comply with the latest scientific findings and are of high quality throughout their lifecycles. We constantly improve our products and upgrade them in compliance with new guidelines and requirements. Relevant regulatory bodies examine and approve all changes.

e) Expert support for healthcare professionals

Indirect customers or healthcare professionals are doctors, veterinarians and pharmacists, who prescribe, recommend, and dispense our products on a daily basis, so they constitute an important link with patients and other end users. We give them latest, clear, accurate and balanced information on therapeutic classes, therapies, and our products. This allows them to take professional decisions on best possible therapies for their patients and users. We are in direct contact with them, and give them information also in electronic formats or prints. We communicate responsibly with the expert community, in accordance with legislation and other regulations related to business operations, including product marketing regulations, good business practice, Medicines for Europe's recommendations and the *Code*, and personal data protection regulations. Two directives, the *Directive 2001/83/EC on the Community code relating to medicinal*

products for human use and its subsequent amendments; and *Directive 2001/82/EC on the Community code relating to veterinary medicinal products* and its subsequent amendments; and the applicable national legislation of the countries where we do business represent the broadest legal framework. All Krka employees must act in accordance with *Krka's Code of Conduct*, while all employees of Marketing and Sales must also comply with *Krka's Code of Promotion* that details promotional activities.

We play a part in the professional development of doctors, pharmacists and veterinarians. We organise or support professional meetings and conferences where they can upgrade their knowledge, learn about new guidelines, exchange opinions and experience, and establish contacts. Meetings take place in various countries where we are present with our products.

As a response to our stakeholder needs, we intensified educational activities and creation of added-value tools and contents that contribute to effective disease detection and facilitate communication with patients. Doctors and pharmacists can access educational information on our thematic web pages, which we constantly upgrade.

Our medical representatives regularly undergo professional training so that they can inform health professionals about the latest treatment guidelines and give them accurate and current information about therapeutic classes and our products. We also make certain that they have appropriate communication skills, are familiar with legal and other regulations and standards of work, and also comply with them. We especially emphasise the importance of applying ethical standards. We use e-tests to regularly verify their level of knowledge.

f) Initiatives to raise awareness of healthy lifestyles and identification of widespread diseases

Our mission is 'Living a healthy life' and to achieve it we carry out many activities for our employees and lay public that bring in focus problems related to healthcare and the importance of risk factor identification for individual chronic diseases, above all cardiovascular and mental, and promote activities that contribute to a healthy lifestyle.

We use various kinds of communication in the process, including personal and digital. We support raising awareness of healthy lifestyles and identification of widespread diseases through professional associations. Our websites raise awareness by giving information, e.g. [What Does Your Heart Beat For?](#) about dangers of high blood pressure and cholesterol levels, and [Neuropathic Pain](#) about neuropathic pain. An important source of information about health-related topics is also our [eHealth](#) portal, which is one of most important portals of this type in Slovenia. That they can trust the source is very important for the patients looking for online health information.

4. GOOD LEADERSHIP AND GOVERNANCE PRACTICES

a) Resilient and flexible vertically integrated business model

Vertical integration and connection of development and production know-how and processes are essential advantages of our development strategy. As we manage the entire process, we can introduce quality, safe, effective, and competitive products to the markets, continuously maintain their market position, and ensure their long-term and stable availability. We use the vertically integrated model to manage patent, development, legislative, production, and marketing requirements and risks. As we manage the entire process, we can do research, develop, evaluate, authorise, and manufacture in-house active



pharmaceutical ingredients (APIs) and finished products, arrange their distribution, sales and marketing, and besides all that also monitor customer satisfaction. This guarantees flexibility and resilience of our business model, especially in critical and unpredictable situations, when business continuity is important.

We streamline the major part of investments to production of finished products, increasing and upgrading facilities for development, research, and analysis, which sustain quality of our products. This provides for coordinated functioning of our research and development, production and control, which embody the essential advantages of our vertically integrated business model.

We maintain the vertically integrated development model through investments, annual achievements, and research and development results with regard to:

- Medicines and therapeutic areas by providing for opportunities for research, development and evaluation of medicines with which we enter into new therapeutic areas and produce new combinations of APIs;
- Active ingredients by introducing innovative preparation procedures for active ingredients and new routes of synthesis;
- Pharmaceutical forms by preparing advanced pharmaceutical forms that allow for easier dosage and administration;
- Research and development by introducing state-of-the-art development and technological processes and invest in research-and-development capacities.

Business continuity, guaranteed by our business model of vertical integration, involves the risk management process and incorporates regular risk identification, analyses, and evaluation, and operational strategy upgrades. We amended procedures, strategies and risk assessments by new actions to ensure business continuity despite increased risks, e.g. the COVID-19 pandemic, crisis situation in certain countries, and interrupted supply chains.

We analyse their impact on operations to estimate the criticality of processes and risks to operations. *Business Impact Analysis; Risk Assessment; and Business Continuity Management Strategy* resulted from our efforts. The documents are authored by Business Continuity Officer in cooperation with persons engaging in critical processes. They are discussed and approved by the Management Board. We take effective measures to protect our employees, property and other key resources, and prevent emergencies and disasters. We adopted action plans and disaster relief measures in case of emergency, actions for mitigating direct damage, and plans for emergency operations until restoration to normal operations, and test them periodically. We prepare business continuity plans for each critical process or service based on the *Business Continuity Management Strategy*. The Quality Committee discusses the adequacy of the implementation of these plans annually. In 2020, Krka's Management Board also included measures in the event of a pandemic into the *Business Continuity Management Strategy*, because a pandemic can incur risks in several areas, e.g. supply chain interruptions, increase in employee absences, impediments in services by external contractors. We provide for adequate availability of critical resources and hence uninterrupted production and sales of key products by identifying and implementing appropriate preventive and other measures.

The purpose of the business continuity management system (BCMS) is to provide for relevant measures and procedures for uninterrupted production and sales of our key products in the event of major incidents and disasters. We implement BCMS according to the adopted strategy and policy, and update it continuously according to the ISO 22301, *The Business Continuity Management Standard*.

b) Legislative and regulatory compliance

When working and carrying out tasks, all employees consider fundamental ethical principles of integrity, loyalty, professionalism and applicable regulations, and Krka's internal rules. We constantly increase employee awareness of any potential fraud, non-compliance and other violations, and ways of managing them, accountability in their detection and reporting. We comply with our reference codex, i.e. the *Corporate Governance Code*, adopted by the Ljubljana Stock Exchange and Slovenian Directors' Association. We have not implemented certain the recommendations in full. However, we have always worked towards realising these recommendations and providing for appropriate ways to implement them. We publish relevant disclosures in the annual report each year. We also comply with most provisions of the *Corporate Governance Code for State-Owned Enterprises* adopted by the management of the Slovenian Sovereign Holding with the approval of the supervisory body of the holding, and more than half of stipulations from the *Best Practice for GPW Listed Companies 2021* relating to the companies listed on the Warsaw Stock Exchange.

The umbrella documents governing corporate compliance throughout the Krka Group are as follows: *Krka's Code of Conduct*; *Rules on Fraud Prevention, Detection and Investigation*; and *Integrity Plan*. The *Krka's Code of Conduct* lays out principles and rules of ethical conduct, good business practices and standards of conduct at Krka, which are binding for all Krka employees. It regulates areas such as respect of labour legislation, protection of confidential information, personal data protection, transparent reporting, management of risks related to frauds and abuses, conflict of interests, promotion, cooperation with business partners, fair competition, environmental protection, research and development, and social responsibility. It is published on our corporate website and/or websites of our subsidiaries. *Krka's Code of Conduct* and *Rules on Fraud Prevention, Detection and Investigation* are available in 29 languages. Our subsidiaries consider specifics of their relevant national legislation. The *Rules on Fraud Prevention, Detection and Investigation* determine key objectives, principles and rules for fraud management, duties and responsibilities of Krka employees with that respect.

In 2020, we drew up the *Integrity Plan* based on good practice (the *Corporate Governance Code for State-Owned Enterprises*) that describes risks and internal controls with respect to integrity, ethics, and compliance of business operations, and proposes improvements. We make updates to the plan every year. The plan represents our commitment that we will make constant improvements to corporate compliance. The probability of occurrence of adverse events and their consequences is estimated as low, medium, and high. Individual risk assessment is made in consideration of potential harm and probability of its occurrence. Further corrective actions are taken if necessary with respect to the risk level and established internal controls.

The Integrity Plan comprises as follows:

(i) Investment; (ii) Acquisition of fixed assets; (iii) Execution of major maintenance works; (iv) Raw material purchases; (v) Insider trading; (vi) Shareholder relations; (vii) Recruitment and human resource management; (viii) Personal data processing; (ix) Documentary-and-financial control; (x) Accounting processes; (xi) Independence of internal and external auditors; (xii) Fraud risk or non-compliance with corporate instructions in subsidiaries; (xiii) Marketing of prescription pharmaceuticals, non-prescription products, and animal health products; (xiv) Sales of Krka products; (xv) Sponsorships and donations; (xvi) Gift receiving and giving; (xvii) Environmental management; (xviii) Use of information technologies; (xix) Product quality; (xx) Health and safety at work; (xxi) Systemic risks related to integrity and compliance.



Standard operating procedures and internal rules specify compliance of business operations with legislative and regulatory requirements.

At the Krka Group level, we provide for regular education of employees as regards the importance of corporate compliance and corporate integrity. Employees take refresher courses every two years, while Marketing employees, who are in contact with healthcare professionals, healthcare providers, and direct customers, undergo training once every year. New employees are informed accordingly at induction seminars. Krka's various departments check customers, suppliers and business partners.

A Chief Compliance Officer is appointed at the Krka Group level. The officer informs the Supervisory Board on planned activities through the *Integrity Plan* and reports once a year to the Management Board. Our subsidiaries with at least 250 employees employ their own compliance officers.

We make sure that the persons who have access to inside information are aware of the confidentiality levels and sensitivity of such information. We prevent any potential abuses and insider trading by implementation of internal rules on trading in Krka's financial instruments and control mechanisms for employees and third parties that handle such information. A restricted time period is specified for all persons with access to internal information, within which they are forbidden from trading in Krka's financial instruments.

Internal auditors carry out their duties in the Krka Group on the basis of medium-term and annual work plans in accordance with the applicable rules (the *International Standards for the Professional Practice of Internal Auditing, Code of Ethics*). Internal auditors work with the Krka Supervisory Board and its Audit Committee as well as with external auditors. With respect to standards, Internal Audit operations are subject to independent external quality audits. An external auditor reviews the financial statements of the parent company and consolidated financial statements of the Krka Group. The auditor reports on findings to the Management Board, Supervisory Board, and Audit Committee of the Supervisory Board.

c) Management diversity, independence and competence

The Supervisory and Management Boards adopted the *Diversity Policy*. Key areas are gender, age, and qualification profile diversity of the management and supervisory bodies. The policy aims at balanced gender structure, suitable interdisciplinarity and age structure to provide for transfer of experiences and knowledge. By 2026, we aim to implement the 40-33-2026 model (i.e. 40% of least represented gender on the Supervisory Board, and 33% on the Management and Supervisory Boards combined). The following bodies are involved in drawing up, monitoring, and implementation of the diversity policy: (i) Human Resource Committee of the Supervisory Board; (ii) Supervisory Board; (iii) Management Board; (iv) Works Council; (v) Any committees involved in procedures for selecting members to management and supervisory bodies; and (vi) Human Resources of Krka.

The Management Board is a five-member body, composed of the President of the Management Board, members and a worker director. Their term of office is six years, and all members can be reappointed. According to the *Articles of Association*, a management board member can be anybody who in addition to the legal requirements meets at least another two conditions, i.e. holds a university degree and has at least five years working experience in top managerial positions in large companies. The Supervisory Board details further requirements. The Supervisory Board and Works Council together specify requirements for a worker director. Upon their appointment, members are assessed for independence. Procedures for appointing the Management Board follow the recommended good practices, in particular the *Corporate*

Governance Code for Listed Companies adopted by the Ljubljana Stock Exchange and the Slovenian Directors' Association.

The composition of the Supervisory Board is stipulated by the *Articles of Association*. The board is composed of nine members: six are elected by the AGM, while the three employee representatives are elected by the company's Works Council. The President of the Supervisory Board is always elected from the AGM-appointed members. Members are appointed for a five-year term and can be reappointed. The election procedures are conducted in compliance with the recommended good practices, in particular the *Corporate Governance Code for Listed Companies*.

All members are asked to complete the questionnaire on conflicts of interest. The questionnaire is available on the Krka website. The *Rules of Procedure of the Supervisory Board* specify members' conduct in case of a conflict of interest. Supervisory Board members themselves evaluate performance of the board by closely following the methods in the *Supervisory Board Assessment Manual* prepared by the Slovenian Directors' Association.

d) Performance-based remuneration

Securities of Krka, d. d., Novo mesto (Krka) are traded on the regulated market. We therefore drafted a remuneration policy for management and supervisory bodies in line with Article 294 (a) of the *Companies Act* (ZGD-1). The policy will be further upgraded.

The remuneration policy is based on Krka's long-term development strategy and encourages the Management Board to achieve Krka's strategic objectives, pursue long-term development and sustainable business operations. Emoluments, reimbursements, and other benefits for Management Board members are specified in work contracts drawn up between the Supervisory Board and individual Management Board members. Fixed remuneration is determined as a multiple of the average salary of Krka employees in the last three months. The multiples are determined by the Supervisory Board upon the appointment of the Management Board and differ with respect to the extent of areas covered by a member of the Management Board. In accordance with internal acts, members of the Management Board are also entitled to bonuses, compensations, and other payments to which Krka employees are also entitled (years of service, continuity of service, anniversary bonuses, Christmas bonus, annual leave pay, other bonuses, compensations, and payments in accordance with internal acts, except performance bonus).

The Supervisory Board takes a decision on the variable part in accordance with the opinion given by the authorised committee of the Supervisory Board and the valid remuneration policy approved by the AGM. Performance is evaluated based on the Krka Group consolidated financial data, except when performance criteria specify otherwise.

The Supervisory Board measures the Management Board's performance by financial and non-financial criteria. These encourage the Management Board to achieve the objectives specified in Krka's long-term development strategy and to be focused on long-term development and sustainable operations.

Financial criteria prompt Krka to launch and sell products of maximal customer value in as many markets as possible. Effective and efficient production and performance of other business functions are very important, as well as good working capital management and risk management. Non-financial criteria contribute to achieving the same objectives in the long term, while the two sets of criteria, especially non-financial, facilitate also sustainability governance. All performance criteria contribute to achieving Krka's

primary objective, i.e. to engage in gainful activities to maximise the company's value, earn profits and at the same time act to the benefit of the company, employees, shareholders, and society. The variable part of remuneration is determined with respect to long-term results and their sustainability, by pondering the past and current business operations.

The remuneration, reimbursements, and other benefits of Supervisory Board members do not directly depend on Krka's performance. In addition to attendance fees, members receive fixed amounts for exercising their functions and additional compensation, i.e. for membership on committees, presiding the supervisory Board or acting as a deputy to its president, presiding committees, and for special undertakings. Amounts of all remuneration types are determined by the resolutions of the AGM.

e) Data privacy, integrity and protection, and cyber information security

Data privacy, integrity and protection, and cyber security of Krka are important for business operations of the entire Krka Group. We apply the CIA triad (CIA stands for confidentiality, integrity and availability) that requires companies to implement the policy of data protection. Confidentiality prevents sensitive information from unauthorized access attempts. Integrity involves consistency, accuracy and trustworthiness of data over the entire lifecycle. Data must not be changed in transit, or altered by unauthorized persons. Availability means that information and data must be consistently drawn up for authorised access. This involves properly maintaining hardware and technical infrastructure and systems that hold and display the information. We also apply **ALCOA+** set of principles, which guarantee that data are attributable, legible, contemporaneous, original, and accurate.

Information security management system of Krka adheres to at least the following latest valid standards, recommendations, laws, and subordinate acts:

EU directives, recommendations and standards for the industry (some most important on information security) that we comply with are as follows:

- Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (*General Data Protection Regulation*);
- Regulation of the European Parliament and of the Council concerning the respect for private life and the protection of personal data in electronic communications (*ePrivacy Regulation, ePR*);
- Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (*Directive on electronic commerce*);
- *Basel II*, the second of three Basel Accords;
- *Model Requirements for the Management of Electronic Records, MoReq*;
- *FDA 21 CFR, Part 11*;
- *The Rules Governing Medicinal Products in the European Union, Volume 4: Good Manufacturing Practice Guidelines for Medicinal Products for Human and Veterinary Use, Annex 11: Computerised Systems*.

Management of cyber security is governed by standards ISO/IEC 27001:2013, ISO/IEC 27002 and *The Open Web Application Security Project* standard, OWASP.

Krka has been certified according to the international standard ISO/IEC 27001. The standard sets out requirements that a company must meet in order to be granted the certificate. The standard comprehensively covers information security, which means that it does not apply only to information

technology and information in the electronic format, but to information in all possible formats and media. It lays out many controls, which are exclusively organisational in nature, not relating to technology at all.

We manage information security risks through an ISO 27001-certified Information Security Management System (ISMS). The ISMS is a separate business process within Krka's quality system. The Management Board appointed the Information Security Officer to lead the ISMS process, including key organisational units and business processes in the controlling company. The officer reports on ISMS to a Management Board member four times a year. A comprehensive report on the Krka Group information security is discussed annually by the Information Technology Committee.

Krka specifies the criticality of information resources (information systems and services) using annual criticality assessments of business processes and information resources to implement the business process. The criticality level of business services is considered in all information systems, including infrastructure systems. Given the criticality in planning, construction, and use of information systems, we implement all relevant information and cyber security elements. We have identified threats and risks regarding resource availability, confidentiality, and integrity for all critical information resources (information systems, equipment, premises, and employees using the information systems). We have duplicated computer capacities for all critical information resources to mitigate risks during major emergencies.

We also mitigate information security risks using modern tools such as advanced threat protection (ATP), security information and event management (SIEM) system, and vulnerability management.

We devote great attention to data integrity by ensuring compliance with regulatory requirements for data completeness, persistence, availability, legibility, accuracy, origin and descriptiveness throughout the prescribed data retention period. We pursue the principle of data integrity in development, production, control, distribution, product quality assurance, and pharmacovigilance. Particular attention is given to the development and implementation of information systems and introduction and management of laboratory and production equipment. We ensure source data integrity by performing validations and qualifications of equipment, change control and management of any process deviations.

Personal data protection is of vital importance, and as an international group we are required to manage them in conformity with national legislation of all countries where our subsidiaries and representative offices operate. The Management Board appointed Data Protection Officer at the company and Krka Group levels, who ensures that personal data are protected in accordance with EU regulations or national legislation insofar as it lays down different or stricter rules.

f) Prosperous business operations and financial strength

Our business strategy aims at achieving long-term business objectives and stability of business operations. We endeavour to achieve growth in terms of value and volume, as well as relevant business profitability, because this enables us to create adequate economic and added value in the long term. Stable cash flows from operating activities allow for uninterrupted settling of operating liabilities, financing research, development and investments, and give opportunities for potential acquisitions that could be financed with our equity capital. They help us maintain a stable capital structure, high liquidity, and adequate allocation of capital through investments, long-term stable dividend policy, and treasure share repurchase programme.



We allocate at least 50% of net profit of majority shareholders for dividends each year, which in addition to increasing value of the company ensures extra profitability for investors, who are important stakeholders, in exchange for equity financing and accepting risk related to ownership of Krka's shares.

Good business performance and financial stability give the Krka Group resilience in the changing business environment and against external shocks and strengthen our position of a reliable partner in the value chain that through high economic impact enables wider society, suppliers, customers, and other stakeholders to grow together with us. Krka is primarily financed by equity and – should the necessity for debt financing arise – intends to maintain any potential debt at a low and sustainable level and not jeopardise long-term business operations.

g) Innovative technologies

State-of-the-art technologies and optimisation of technological procedures guarantee permanent availability and top quality of our products and competitive prices. In addition to innovative technological approaches, we also develop innovative products in complex pharmaceutical forms with added value for patients, including modified-release pharmaceutical forms, bilayer tablets and dispersible tablets. We file several patent applications every year for new technological solutions and products. Innovative technological procedures are presented in detail in item 3(c), 'R&D for affordable healthcare'.

We encourage inventive work by quarterly awards, a token award with a thank you letter from the President of the Management Board and CEO, presentation of proposers on Krkanet and in our bulletin *Bilten*, interviews in the *Utrip* internal magazine, annual meetings of proposers, and awards and recognitions that the best employees receive for inventive work on Krka Awards Day.

The inventive work system leads to continuous improvement of the quality system and hence the integrated management system and generates savings through useful proposals and improvements. Our corporate campaign *Your Effectiveness Counts* encourages our employees to continuously look for solutions and improvements for even higher quality of their work. We try to inspire them to resolve issues related to economy, production, logistics, technology, engineering, administration, environment, business, information science, quality, and health and safety at work. Useful proposals that are easy to implement, and complex improvements with notable effects, matter.

5. COMPLIANCE, INTEGRITY AND TRANSPARENCY

a) Ethics in clinical trials, R&D, production and all business practices

We at Krka respect intellectual property rights of third parties and develop our products in consideration of the patent situation. We closely follow all patent applications and valid patents throughout their development and in case of relevant changes adjust our development strategy accordingly. We protect our know-how and therefore prevent competitors from violating our intellectual property rights.

We ensure credibility of data at all stages of development in compliance with the CIA model and ALCOA+ principles and requirements of *The Rules Governing Medicinal Products in the European Union* (EU GMP, Annex 11), *FDA 21 CFR, Part 11*; and ISO 27001. We follow the rules and procedures for data protection and handle all confidential data of our partners with great care.

We recognise major importance of clinically tested medicines and therefore monitor their efficacy, safety and quality before and during registration procedures and also after obtaining relevant marketing



authorisations. We therefore conduct many bioequivalence studies, do research in pre-authorisation phases, and support post-authorisation clinical studies.

Like other generic pharmaceutical manufacturers, we must unequivocally demonstrate that our medicines are of high quality, safe, and effective by including the results of preclinical and clinical trials in the registration documentation. Studies are conducted in line with the latest professional and regulatory guidelines.

We also support studies in regular clinical practice to monitor efficacy and safety of treatment with our medicines in daily use and follow various therapeutic areas, where they are used.

We do business in all countries in compliance with national regulations and requirements and promptly apply relevant changes. We collaborate with regulatory bodies in a transparent manner in all registration and inspection procedures.

All clinical trials (on healthy volunteers and patients) are conducted in line with the applicable legal requirements, good practice guidelines, the *Helsinki Declaration*, and Regulation (EU) 2016/679 on the protection of natural persons with regard to personal data processing. Patients and healthy volunteers are included in a trial only if they sign the informed consent form. Investigators inform them about the course of the trial and any risks involved. This ensures safety for the subjects, transparency, ethics, and high quality research, which is also acknowledged by regulatory and inspection bodies. We apply good pharmacovigilance practices in monitoring and reporting on adverse events. We publish results of interventional clinical studies in the *EU Clinical Trials Register* to provide for transparency of clinical trials. More than 350,000 patients from 27 countries have participated so far in over 150 clinical studies with our key medicinal products from the main therapeutic areas.

Physicians as investigators conduct post-authorisation clinical studies, and we are one of the few generic pharmaceutical companies that supports them. The studies demonstrate clinical efficacy of our products, so we importantly contribute to better understanding and upgraded therapies for patients.

All our employees are familiar with *Krka's Code of Conduct* and bound to act in compliance with it. Also in research, we cooperate with reliable and trusted partners who do not pursue ethically questionable practices.

We have set up systems for ensuring quality of clinical studies and safety of the involved patients, and the pharmacovigilance system for prevention of any harm due to adverse reactions in all end users of our medicines. We ensure quality through: (i) Highly qualified personnel who comply with all applicable laws and guidelines; (ii) Internal rules; (iii) Use of adequate equipment and computer systems; (iv) Risk management; (v) Careful selection of contractual partners; (vi) Clinical study performance monitoring; (vii) Reporting on patient safety and safety of all other participants in clinical trials; and (viii) The deviation investigation system. Organisational units of the parent company manage the global system of clinical studies and pharmacovigilance, while subsidiaries and representative offices manage activities in their particular countries.

b) Anti-corruption

Fraud and corruption prevention is governed by *Rules on Fraud Prevention, Detection and Investigation*. The document is based on specific legislation, standards, and good practices. Updates are made bi-annually. It is available in 29 languages on our corporate websites.

Krka applies the principle of zero tolerance as regards prevention of fraud and corruption and corporate compliance. This means that no unethical, unprofessional, or unlawful conduct of employees and business partners is allowed. We do not exploit business opportunities, assets, and information to gain personal and economic advantages for ourselves or any third parties. We do not promise any benefits or give presents in order to influence decision-making of administrative bodies, officials, business partners or anybody else. We likewise do not accept any gifts or other benefits that could influence our decisions for work.

The employees can make reports at compliance.officer@krka.biz on any alleged irregularity. Our subsidiaries with more than 250 employees have followed our example and set up their own channels. The compliance officer investigates the reports and generally appoints a working team for each case separately by engaging experts qualified in the respective area. We guarantee anonymity to reporters and provide for their protection against any potential retaliatory measures. When a case is closed, we adopt corrective measures if necessary.

When involved in marketing activities, subsidiaries follow national legislations and *Krka's Code of Promotion*, which is available on corporate websites. Activities for marketing prescription pharmaceuticals are further detailed in *Krka's Code of Promotion*, and in operational instructions for employees visiting healthcare professionals, and holding professional meetings, education, training, and company visits. Cooperation with healthcare community refers in particular to healthcare workers, healthcare organisations, patients and patient organisations.

In 2021 and over the past five years, Krka did not fund any political campaigns, political organisations, lobbyists, or lobbying organisations.

The Krka Group companies are members of those advocacy groups, where their membership is obligatory or considered a common practice in the industry.

We publicly disclose any transfer of assets to healthcare professionals, healthcare organisations and patient organisations on our websites not later than by 30 June every year for the past calendar year.

The *Krka Group Development Strategy*, which must be approved by the Supervisory Board in accordance with Article 6.18 of the *Articles of Association*, serves as the umbrella document regulating sponsorships and donations. Activities are carried out in accordance with *The Krka Group Sponsorship Manual* governing sponsorships and donations. In accordance with our basic mission, 'Living a healthy life', we allocate most of our sponsorships and donations to projects related to health and quality of life.

c) Transparent and accessible reporting

We are a public listed company whose shares are listed on the Ljubljana Stock Exchange (LJSE) and the Warsaw Stock Exchange (WSE). The *Reporting Rules* specifies procedures relating to our obligation to make public all pieces of controlled information and communicate them in accordance with the regulations. We comply with national laws and EU legislation (e.g. *Regulation No 596/2014 on market abuse, MAR*) and act

in accordance with other regulations on internal and controlled information reporting, financial statements, and business reports, which we regularly make public in SEOnet, the Ljubljana Stock Exchange electronic information dissemination system, and Polish ESPI, (Electronic Information Transmission System) managed by the Polish commission for financial control (KNF). We also publish reports and information on business performance on corporate websites and in internal media. This makes them available to all internal and external stakeholders and general public. We also regularly draw up the annual financial calendar of public communications and release all materials in Slovene and English.

Our codes of reference are: (i) the *Slovenian Corporate Governance Code for Listed Companies*, adopted by the Ljubljana Stock Exchange and the Slovenian Directors' Association, (ii) *Ljubljana Stock Exchange Rules*, and (iii) *Guidelines on Disclosure for Listed Companies* of the Ljubljana Stock Exchange. We have not implemented all recommendations in full. However, we have always worked towards realising these recommendations and providing for appropriate ways to implement them. We publish relevant disclosures in the annual report the every year. We also comply with most provisions from the *Corporate Governance Code for State-Owned Enterprises* adopted by the management of the Slovenian Sovereign Holding with approval by the holding's supervisory body, and more than half of stipulations from *Best Practice for GPW Listed Companies 2021* relating to the companies listed on the Warsaw Stock Exchange.

We draw up consolidated financial statements of the Krka Group and financial statements of Krka, d. d., Novo mesto. In accordance with the resolution adopted by the 11th AGM of 6 July 2006, all financial statements comply with the *International Financial Reporting Standards* (IFRS) adopted by the EU and are included in annual, interim and quarterly business reports. Annual reports are audited.

We draw up business reports that include a section on sustainability in compliance with the global standards for sustainability reporting, the *GRI Standards*. We intend to adjust our sustainability reporting with the upcoming legislation, especially with the *Corporate Sustainability Reporting Directive (CSRD)*, the *European Union Sustainability Reporting Standards (ESRS)*, and other global standards on sustainability reporting. We also plan to subject our sustainability reports to external inspections and/or audits in compliance with the legislation.

We also intend to upgrade quality and transparency of sustainability reporting and communications about the ESG topics and achievements that we would like to make known to the interested public in a timely manner. Transparent and accessible reporting is of key importance for various stakeholders and general public in order to recognize Krka as a sustainable company and is also important for maintaining our reputation of a recognised sustainable company and therefore increasing attractiveness for investors and other stakeholders. To this end we constantly endeavour to maintain correct and open relations with investors and other stakeholders.

d) Fair marketing and sales practices

When involved in marketing activities, our subsidiaries follow national legislations and *Krka's Code of Promotion*, which is available on corporate websites. *Directive 2001/83/EC* and the *Code of Conduct* by the international association Medicines for Europe constitute the broadest legal frame we comply with. Activities pursued by employees when marketing prescription pharmaceuticals are further detailed in the *Krka's Code of Promotion*, and operational instructions for visits to healthcare professionals and professional meetings, education, training, and company visits. We give healthcare professionals integral, accurate, up-to-date and balanced information on our medicines and the treatment doctrine. Our



relationships with the expert community are transparent and traceable, and we strictly follow all laws and regulations in that field. All employees collaborating with the expert community must be familiar with *Krka's Code of Promotion*, and we regularly check their knowledge with e-tests.

We cater for proper advertising of our medicines and give special attention to organising and supervising the work of employees in the marketing network. Our employees regularly undergo training, and we test their level of knowledge, skills, and how familiar they are with instructions for work, legislation, and applicable regulations. When marketing our products, we consistently comply with legislation, recommendations of Medicines for Europe, and ethical norms related to advertising pharmaceuticals. We include these in employee education and the ensuing tests. We place particular focus on business compliance, so marketing is also included in the company's *Integrity Plan*, discussed by the Management Board. We also comply with the personal data protection legislation in marketing and sales.

We systematically monitor the satisfaction level of direct and indirect customers. The Quality Committee discusses the report for each year. We monitor sales at the primary level (sales to direct customers, primarily wholesalers) and if possible, also at the secondary level (wholesalers' sales to their customers, mainly pharmacies) and at the tertiary level (sales to end users in pharmacies). We ensure that inventories are optimised and balanced throughout the distribution chain. We duly monitor pharmacy chains and any changes by individual markets, and adjust our actions accordingly. Everything stated above is regularly discussed at the Sales Committee meetings.

We regularly monitor and analyse compliance of marketing activities. Sales Committee and also the Management Board of Krka discuss the analysis results at the Group level. The *Krka Group Code of Conduct* and the *Quality Manual* define the principles of employee ethics and responsibilities, while internal rules detail collaboration with customers.

We are aware of the importance of our customers, so we carefully collect market and market segment information. We generally conclude purchase agreements when doing business with buyers. If this is not possible, the defined general sales terms apply in lieu of the contract.

In order to ensure the responsibility of direct customers and proper handling of our products, we have concluded with each direct customer an appropriate quality assurance contract, which sets out proper handling of our products based on the standard of good distribution practice (GDP).

We manage receivables to ensure transparency of sales and fulfil our responsibility to shareholders. Instructions on managing receivables and receivable insurance policy commit us to managing receivables correctly.

Our marketing activities address the professional community (prescription pharmaceuticals) and lay public (non-prescription products and food supplements). We give professional community and lay public relevant, professional, up-to-date, and balanced information on our products via various channels, e.g. personal contacts, professional meetings, and digital tools. Responsible persons examine all promotional materials with due care before giving their approval, and guarantee that the materials are professionally, ethically and legally suitable. All employees, who work with the professional community, are properly qualified, and we regularly test their knowledge. We carry out marketing activities in compliance with legislation and the adopted ethical principles. The *Krka's Code of Conduct* is binding for all employees, while implementation of marketing activities is specified in detail in the *Krka's Code of Promotion*. This is translated into official languages and adapted to laws of the countries where our subsidiaries operate. It

is used to train all employees who have contacts with the professional community. We regularly examine their knowledge by e-tests.

We provide the lay public with information about non-prescription products and products for companion animals increasingly more often via digital channels. The list of our websites includes a total of 84 product websites in 20 countries, in seven countries also thematic websites for raising public awareness of individual diseases and a healthy lifestyle. The professional community can access our password-protected educational portal in ten countries.

We intend to continue our efforts for responsible and ethical sales and marketing of our products. We plan to include the principles of the upcoming EU directive on diligent review of corporate sustainability in marketing-and-sales practices.

e) Human rights

Equal opportunities for all, respect of legal norms and an ethical approach to people and the wider social community represent the foundations of our work.

We respect human rights set out in internationally recognised principles and guidelines. We operate in line with all regulatory requirements and standards relating to human rights in all countries where Krka is present. We respect the dignity, personal integrity, and privacy of each individual. We also respect the freedom of speech and expression of opinions, and we always treat others with respect. We communicate openly with our employees, regardless of their professional qualifications and leadership position. All forms of unfair and unauthorised work are prohibited. Any discrimination against employees is prohibited. We treat all employees equally, regardless of their nationality, race or ethnicity, national or social origin, gender, colour, medical condition, disability, religion or belief, age, sexual orientation, family status, trade union stewardship, financial condition, or any other personal circumstance.

Our company signed the *Commitment to Respect Human Rights in Business* instigated by the Ministry for Foreign Affairs of the Republic of Slovenia. The document was signed by 18 major Slovene companies.

We follow all legal regulations and standards related to human rights in all countries where we operate.

We provide for equal opportunities, regardless of employee's gender, race, colour, age, medical condition or disability, religious, political or any other belief, trade union stewardship, national or social origin, family status, financial condition, sexual orientation, or other personal particulars.

The non-discrimination principles are set out in the *Krka's Code of Conduct*.

f) Supply chain business practices

We have a complex and broadly subdivided vertically integrated business model, which requires responsible and sustainable purchasing of raw materials, materials, and services entering into our value creation chain. We strive for responsible and long-term partnership with our suppliers. We develop good business relations and encourage growth and development of all involved parties and their environments in order to ensure timely and high-quality supplies. We periodically check our suppliers' quality systems by audits, working meetings, and assessments of the supplier quality. We draw up annual assessments of our suppliers, in which we evaluate the quality of our cooperation and in this way identify key suppliers. We conduct supplier audits in accordance with quality standards and Krka guidelines, taking into



consideration the price, quality, delivery terms, reliability, regulatory compliance, compliance with our guidelines and the company's social responsibility. We implement the policy and practice of involving local suppliers and contractors when – in addition to acceptable prices – responsiveness, flexibility and frequent or constant involvement of suppliers and contractors in investment and service processes are vital.

We ensure constant alternative sources of raw materials to reduce dependency on individual suppliers and provide for uninterrupted supply chain operations. We work with more than 70 suppliers holding valid ISO 45001 certifications and more than 200 suppliers holding valid ISO 14001 certifications.

Purchase contracts oblige suppliers to comply with all relevant laws and regulations in production, including environmental, safety, and healthcare legislation applicable in the countries where the suppliers' production plants are situated. Contracts include the anti-corruption clause resulting in null-and-void sanction. We use key performance indicators to monitor the adherence to the clause. All employees in Purchasing are qualified in accordance with corporate rules, i.e. (i) *Krka's Code of Conduct*; (ii) *Rules on Fraud Prevention, Detection and Investigation*; and (iii) *Rules on Defining and Preserving Business Secrets*. We are a member of the Purchasing Association of Slovenia and participate in their annual conferences. We aim for responsible and sustainable purchasing, built on trustworthy and transparent collaboration with our suppliers. We undertake to constantly promote honouring ethical, environmental and social aspects throughout the supply chain. We intend to further integrate sustainability principles in line with the *Proposal for a Directive on Corporate Sustainability Due Diligence*.

6. PLANET AND CLIMATE CHANGE

Management of direct and indirect carbon emissions; Waste management; Efficient use of energy and natural resources; Management of hazardous materials

We take care of the environment, respect environmental regulations, and cooperate in this respect with the local community and beyond. The definition of responsibility to the natural environment is included in our environmental and energy policies, which bind us to take care of the environment in accordance with the requirements of the newly issued ISO 14001:2015 standard and to prevent or reduce our environmental impact to the largest extent possible. All employees are included in the integrated environmental management system, which is specified in detail in the internal document *Environmental Management System*.

In 2021, we marked 20 years since Krka established its integrated *Environmental Management System* (EMS) that complies with the environmental standard ISO 14001. The certificate commits us to constantly reduce all our impacts on the environment. We also follow the revised edition of the ISO 14001:2015 standard. We have therefore integrated environmental care in the earliest development stages and projects. Successful audits confirm that we have made improvements in all areas that impact the environment. We are granted the right to use the responsible care logo every year due to our efficient work in the area.

Our operations impact employees, natural environment, local and wider communities, so we seek to reduce the environmental impact. We maintain the related risk at acceptable levels.

In order to achieve the set goal, we undertake to:

- Consider the sustainability aspect throughout the lifecycle of a product;

- Constantly reduce our impact on the environment, and improve the situation as regards our environmental impact in every way as we aim to achieve goals of the *European Fit for 55* package, the *European Green Deal*, carbon neutrality by 2050, the *Resolution of the Republic of Slovenia on Long-Term Climate Strategy until 2050*, and the *Taxonomy Regulation (Regulation (EU) 2020/852 on the establishment of a framework to facilitate sustainable investment)*, and national legislations of the countries where we operate;
- Draw up the decarbonisation plan for the Krka Group;
- Reduce the impact on climate changes in accordance with the best available techniques, guidelines, and legislations;
- Incorporate care for efficient use of energy, water, and other natural resources in our current operations, development strategy, and investments;
- Increase the proportion of alternative and renewable resources;
- Reduce specific emissions of greenhouse gases according to the emerging decarbonisation programme;
- Apply the circular economy system in the waste management process;
- Upgrade the hazardous material management system and reduce environmental risks;
- Regularly monitor emissions for compliance with the legislation and environmental protection permits;
- Ensure constant monitoring of direct and indirect carbon emissions in accordance with the *Greenhouse Gas Protocol (GHG Protocol)*;
- Include the responsibility towards the natural environment to the largest extent possible in the activities of subsidiaries outside Slovenia;
- Increase employees' responsibility for sustainable development through education and growing awareness about the environmental issues and promote the responsible environmental policy also throughout the value chain;
- Ensure the preservation of the ecological, biotic and landscape features of the natural world;
- Encourage the use of the alternative environmentally less harming means of transport to commute to work and act towards sustainable mobility;
- Reduce our carbon footprint and other impacts transport has on the environment by upgrading our car pool, purchasing electric vehicles, replacing air transport by sea transport, double-deck loading, and selecting suitable contractors;
- Report as transparently as possible about our environmental impact and indicators in accordance with the established international standards, laws and regulations (GRI, CSRD, etc.);
- Set sustainability goals and relevant KPIs in compliance with our principles, promptly monitor their pursuit, update goals, and report in a transparent manner on achieved results.

Improvement of the environment also depends on good relationships with the stakeholders in the social environment, especially with our immediate neighbours, because we impact their living space and the quality of their lives. Every other year, we organise a traditional meeting for local residents. We provide them with information on our activities, performance, and plans related to environmental protection. We therefore engage in an open dialogue and exchange of opinions, and consider the obtained information in planning environmental goals and programmes.

Local community members and other stakeholders can use the established complaint system to file a complaint, a question or a suggestion relating to environmental protection. Publicly available information on environmental protection and contact details are published on www.krka.si.

7. ECONOMIC IMPACT AND TAXES

a) Contribution to local community development

Social responsibility is one of our basic principles. We consider social needs in our daily business, because we are aware that this also affects business operations and development of the Krka Group.

The *Krka Group Development Strategy*, which must be approved by the Supervisory Board in accordance with Article 6.18 of the *Articles of Association*, serves as the umbrella document regulating sponsorships and donations. The *Krka Group Sponsorship Manual* governs performance of activities related to sponsorships and donations. In accordance with our mission 'Living a healthy life', we allocate most of our sponsorships and donations to projects related to health and quality of life, which also agrees with United Nations' sustainable development target number three (good health and well-being), to which we contribute the most by our core business.

Our aim is to foster long-term partnerships that encourage inclusive and responsible social development, scientific research, multigenerational and interdisciplinary cooperation, adherence to diversity principles, and healthy lifestyles. We are aware of our impacts on different sustainability areas, as we are an international pharmaceutical group and one of the largest companies in Slovenia. We therefore consider principles of social responsibility and needs of the social environment in our daily business in accordance with our strategic guidelines.

We build partnerships through sports, culture, healthcare, science, education, humanitarian actions and by contributing to the protection of the natural environment in line with the set criteria. We specify the needs of our partners in regular contacts, long-term sponsorships, annual meetings with sponsorship recipients, and preparing new sponsorship and donation contracts. Our sponsorship and donation committee examines all sponsorship and donation applications. We also engage in sponsorship programmes and donor activities in all our key markets. We strengthen brand awareness, maintain and consolidate relationships with various stakeholders.

Partners in Science We have been awarding Krka Prizes since 1971 to attract young researchers, whom we encourage to undertake development and research. The Krka Prizes Council has played a key role in making research work popular among students, pupils and mentors. We also support projects of various educational and scientific institutions designed to upgrade the infrastructure and to provide scholarships, above-standard education for pupils, secondary school and university students, research and development, and participation in national and international competitions.

Charity and Volunteering We have encouraged volunteering since Krka was established, and have since 2012 been joining charity and volunteering actions in the traditional Krka's Week of Charity and Volunteering. We support several non-profit, non-governmental and non-political organisations by regular donations. We collaborate with humanitarian organisations to extend emergency aid in case of natural disasters and other kinds of need to people in Slovenia and abroad.



Support for Healthcare Institutions Associations and societies from various healthcare areas contribute to an improved quality of life and safety for patients. We therefore support many associations and societies that raise awareness and educate chronic patients about disease prevention and the importance of quality of life. Our goal is to provide for available treatment and best possible outcome, so we make donations to healthcare providers for purchasing state-of-the-art medical devices and instruments that make work easier for healthcare professionals and ensure high level of services.

Through Sports to Health We promote many sporting activities which contribute to a healthy lifestyle. We donate the greatest portion of funds to clubs and associations in the local environment. We encourage especially those organisations that give young people the opportunity to take up recreational or professional sports in addition to mass participation.

Krka Clubs and Sports Societies Krka has lent its name to 17 sporting and cultural clubs and societies. We support them because they encourage young people to lead a healthy lifestyle, take care of their physical and personal development, build team spirit and friendship, be persistent, and develop a healthy winning attitude. This is the only way for us to jointly strengthen values of partnership, trust, creativity and efficiency that are of key importance for the development of the Krka Group.

Committed to Culture An important segment of our employees' lives is culture. We support various cultural genres and activities that importantly contribute to society. We support many art projects in order to bring arts near to wide and close social milieus.

Social responsibility is reflected in all areas of our operations. Our long-term cooperation with the local community and encouraging contribution to its development, not only through sponsorships and grants given by the Krka Group, but also by actions of many Krka employees, are a part of the Krka tradition. Responsibility to social environment is an investment in the future, because responsible management of natural and social resources facilitates sustainable development.

b) Tax policy and tax transparency

The Management Board has adopted the *Krka Group Tax Strategy* and *Krka Group Tax Code of Conduct*. The two documents set out the policy, objectives, guidelines, and principles of tax management, including transfer pricing, based on principles and rules of ethical conduct and good business practices and standards of conduct, which are defined in Krka's *Code of Conduct*.

The principles that the Krka Group follows in the tax field are to: (i) Act in accordance with the legislation of the country in which we operate; (ii) Settle tax liabilities voluntarily and on time; (iii) Avoid risky tax decisions; (iv) Consider tax perspective when changes occur or when introducing new business models; (v) Monitor changes in tax legislation and continuously train employees involved in the tax process; (vi) Work with tax authorities and ensure open, fair and constructive cooperation; and (vii) Maintain partnerships. We ensure this through the appropriate organisation and operation of the Krka Group's tax function and clearly defined responsibilities.

We have been granted a special tax status, which we maintain and carry out horizontal tax monitoring. This earns Krka special reputation and trust as regards taxes and builds awareness among stakeholders and the interested public that Krka accounts for and pays its tax liabilities regularly and on time and applies a transparent model of operations.