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Cover photo description: Neural stem cell culture Fluorescent light micrograph of a group of neural stem cells in culture, showing the stem cells migrating out of the central neurosphere. Neural stem cells are able to differentiate into neurons and also a potential source of cells to replace damaged or lost brain cells. Credit: Riccardo Cassiani-Ingoni





The Company

IBSA is a privately owned pharmaceutical company, founded in Lugano in 1945 by a group of Swiss biologists. After its first steps on the domestic market, IBSA quickly strengthened its position internationally thanks to a consolidated global expansion strategy.

Today, IBSA is present on **5 continents and** over 80 countries, including the USA. The company experienced a key moment in 1985, when the current management acquired its ownership, completely redefining its vision and strategy and bringing it for the first time on the international scene. Since then, an extraordinary and intense development program has been launched to expand the company's assets and create a competitive product portfolio.

As a result, IBSA today has achieved a **leading** position in the global markets in specific therapeutic areas.

Following this extensive expansion, IBSA today counts on 10 companies, between affiliates and representative offices in Europe, China and United States, and boasts a product portfolio covering 9 major therapeutic areas.

Over the years, the Group has grown considerably, also beyond Swiss borders and today employs a total of 1400 people, distributed among its headquarters, branches and production sites, with an additional 200 employees through its strategic partner, Laboratoires Genevrier in France. Today IBSA is the largest privately owned pharmaceutical company in Switzerland, the fourth largest operator in the Fertility sector, after the major multinationals, and one of the world leaders in products based on hyaluronic acid.

MISSION

to enhancing the life quality of patients from a physical, emotional, psychological and relational point of view. In this perspective, the company provides cost-effective, reliable and innovative products and services to prevent and cure diseases, fulfill the needs and desires of healthcare professionals, and contribute towards the mitigation of public health issues. IBSA is a caring employer and delivers superior value to all stakeholders in a responsible, ethical and sustainable way.



VISION

IBSA is strongly committed

IBSA strives to shape drugs into their best form, to make them more patient-friendly and provide treatments that better patients'. quality of life.

IBSA develops special technologies that qualitatively improve existing therapeutic molecules and solutions. The company aims to stand out as the creator of innovative pharmaceuticals and administering systems of proven and superior efficacy.





IBSA At a glance











employees in the last

30 years and today







6

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from a network of menopausal women and delivered to our factories

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INA





Foundations







IBSA in the world

HEADQUARTERS Lugano, Switzerland

OFFICES Lodi, Italy Rome, Italy Budapest, Hungary Qingdao, China Bratislava, Slovakia Istanbul, Turkey Warsaw, Poland Copenhagen, Denmark Moscow, Russia Parsippany NJ, USA Washington DC, USA

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PRODUCTION & WAREHOUSING Lugano, Switzerland (13 sites) Lodi, Italy (2 sites) Cassina de' Pecchi, Italy Qingdao, China

The Group avails itself of one commercial partnership: Laboratoires Genevrier, in France





Business model

IBSA operates in the market through a peculiar business model based on some fundamental principles:

SUPPLY CHAIN AND QUALITY CONTROL

The production of medicines involves the combination of the active ingredient with the excipients in solid, liquid or gel form: **IBSA acquires the active ingredients from its branches**, while the excipients and the packaging materials are mainly European. All suppliers are subjected to **systematic controls** covering multiple aspects, in particular their **quality control system** and their **respect for the environment**.

VERTICAL INTEGRATION

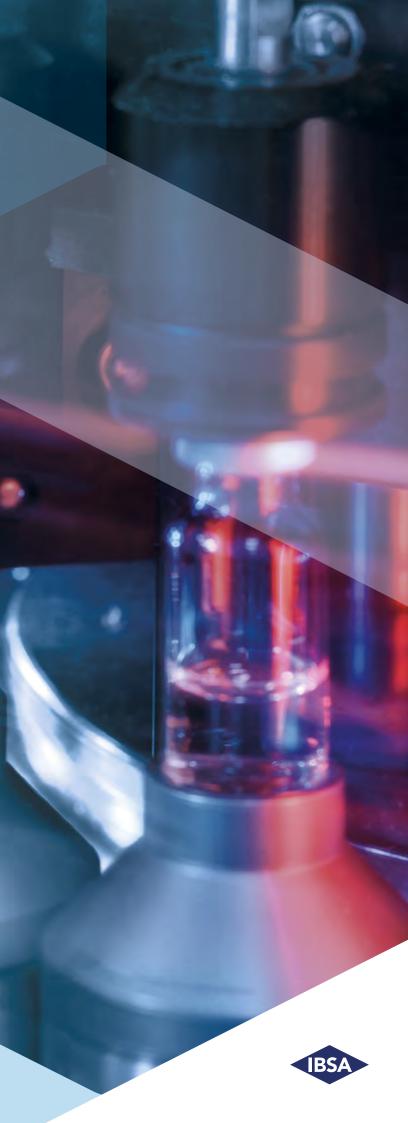
Most of the products – and active ingredients – are made internally and, throughout all the manufacturing stages, are controlled with vertically integrated processes. This ensures the finest quality of the finished product, a direct control on all the processing stages, greater speed and flexibility, as well as the reduction of risks along the supply chain.

FOCUS ON EFFECTIVE THERAPIES TO IMPROVE THE PATIENTS' QUALITY OF LIFE

IBSA is **strongly committed to the development of effective therapies in non-life-threatening areas**, while exerting a strong social impact, both in terms of cost and quality of life.

INTERNATIONAL PRESENCE

IBSA has a **direct presence** in Switzerland, Italy, France, Hungary, Poland, Slovakia, Turkey, Russia, Scandinavia, China, United States, and **indirect** through major trading partners to which it grants licenses for the distribution of its own products in over 80 countries.



IBSA concentrates its activities in the areas in which it can make a real difference and improve the quality of life of patients, making ready-to-use solutions available to patients and health professionals. IBSA currently has 65 exclusive registered patents, while several other products and patents are under development. A significant part of its research is devoted to innovative, cost-effective therapies which satisfy important unmet needs in the field of medicine. IBSA is present in 9 major therapeutic areas, with its appreciated products used all over the world (in alphabetical order).

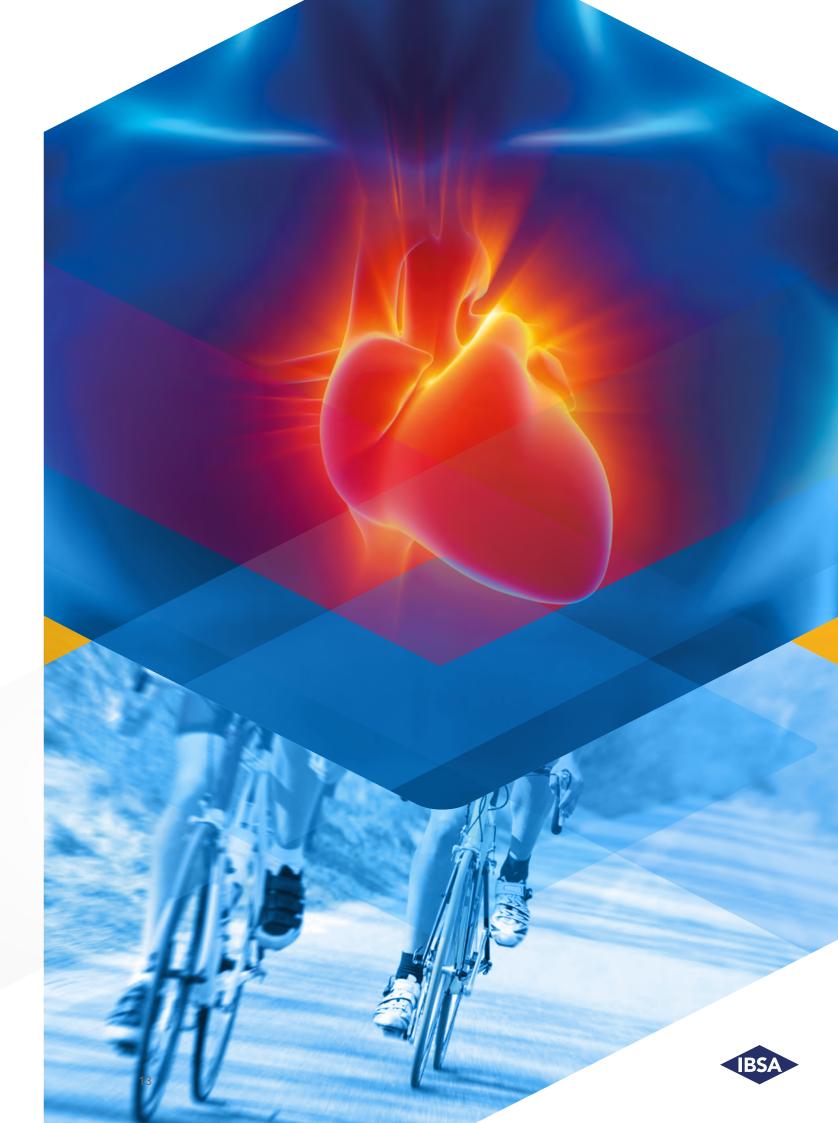
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Cardiometabolic

Cardiometabolic diseases are conditions affecting the heart or blood vessels; they represent **the** leading cause of death worldwide. Over the last two decades the interest in omega-3 polyunsaturated fatty acids (PUFAs) has grown, thanks to their antidyslipidemic, anti-inflammatory, antiarrhythmic and antithrombotic properties. When not sufficiently provided with the diet, omega-3 obtained by esterification of triglycerides extracted from fish oil can be assumed alternatively as drugs. IBSA products contain omega -3 fatty acids (EPA/DHA) which have been certified as sustainably

sourced by the NGO Friends of the Sea and have obtained the IFOS Five Star Certification for their purity, freshness and concentration. IBSA's omega-3 are enclosed in a soft gelatine capsule that preserves their integrity and stability over time.

Recently in the cardiovascular area IBSA has also developed two nutraceutical formulations containing monacolin k and other components that **help maintaining the normal cholesterol levels in the blood.**





In some skin conditions, such as severe wounds and burns, topical medications containing hyaluronic acid (HA), a natural biopolymer that is also found in the human body, plays a key role in the skin's cicatrisation process. In the dermatology area IBSA has developed a portfolio of products that contain **highly purified hyaluronic acid** obtained through a certified, patented, biofermentation process:

- a cream formulation and a medicated gauze pad indicated for the treatment of non-infected wounds and burns, including ulcers of different origin and postsurgical wounds.
- the same pharmaceutical forms are also available as a **synergic** combination of HA and silver sulfadiazine, an effective antibacterial molecule. This topical combination leads to new therapeutic options for reducing the bacterial burden in the surface wound compartment. The hyaluronic acid line is completed by a **spray** and a gel formulation indicated for cutaneous irritations of different origin (i.e. wind, sun, cold, sweat, shaving, aesthetic treatments and tattoos).

Among the numerous medical conditions that can affect the skin, **psoriasis** is a very common one, which may turn into a real disability for many people, affecting their

daily life and leading to severe psychological problems (24% of patients with severe psoriasis experience depression). Moreover, the disease follows a frustrating pattern of remissions and relapses, with stress playing an important role. There is no cure, but medicaments with corticosteroids such as Betamethasone Valerate (BMV) are an excellent symptomatic treatment. BMV has antiinflammatory, antipruritic and vasoconstrictive properties which makes it effective in reducing the symptoms of psoriasis. This treatment is often carried out under occlusion to increase its efficacy. The innovative BMV plaster, which has been recently developed and now available in different countries worldwide, combines the efficacy of BMV under occlusion to the controlled release of the active principle, as well as to an **improved** compliance of the treatment.





The dermoaesthetic area offers a full range of products based on a patented and innovative approach aimed at counteracting the physiological reduction of hyaluronic acid in the skin, thus restoring hydration, elasticity and skin tone. This approach is an expression of the **synergistic action** derived from the use of selected hyaluronic acid produced using patented IBSA technology, which when used in concert **create optimal conditions for preventing and fighting the aging process**.

- A line of dermal fillers indicated for **volume restoration**: they are based on cross-linked HA of non-animal origin and produced through an innovative technology that assures **high tissue** integration, thus resulting in natural and long-lasting results. In order to achieve the best clinical efficacy, all formulations are developed specifically for each indication by using a combination of hyaluronic acid at different molecular weights, thereby creating distinct visco-elastic properties.
- A line of dermal fillers that aim at counteracting skin laxity through tissue remodelling: they are based on stabilized hybrid cooperatives of high molecular

weight HA (H-HA, 32 mg) and low molecular weight HA (L-HA, 32 mg). These are the first line-products developed with a specific technology patented by IBSA which provides **unique rheological characteristics** to the solution allowing the administration of higher concentrations of HA without increasing the viscosity.

• A line of dermal fillers based on **ultrapure natural HA** with a molecular weight of around 1 million Daltons, which is very close to the natural molecular weight of endogenous hyaluronic acid. These products are indicated for bio restructuration procedures, and aim at **restoring the physiological conditions of healthy skin**: hydration, firmness and brightness.





THERAPEUTIC AREAS Endocrinology

Among the numerous elements of the endocrine system, the thyroid has been widely studied for decades due to its many functions: it affects heart rate, cholesterol levels, body weight, energy levels, muscle strength, skin condition, vision, menstrual regularity, mental state and a host of other conditions. As thyroid hormones affect cellular mechanisms, they help to control how the body uses energy and how well cells, tissues and organs work. An underactive thyroid can cause a number of health problems, such as obesity, joint pain, infertility, heart disease and depression. Thyroid disorders are widely underdiagnosed and under-treated, especially in developing countries. Hypothyroidism is one of the most common chronic disorders worldwide, affecting up to 2% of the planet's population and up to 4-6%

patients to commit to lifelong thyroid hormone replacement therapy. The guidelines recently

published by the American

Thyroid Association recognize **levothyroxine as the most**

prescribed therapeutic choice for the treatment of hypothyroidism.

in Western countries, making it necessary for most IBSA has developed and patented a **new manufacturing system that is a milestone advancement** in a field that has been at a standstill for several years. IBSA drugs for thyroid hormone replacement therapy are available in a **wide range of strengths and**

in liquid

formulations developed for better compliance, such as soft gel capsules and an oral solution.

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Soft Gel Caps

Manufactured exclusively with PEARLtec® state-of-the-art equipment, soft gel caps are moulded from two gelatin films pressed together by a rotary die machine.

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Just before hermetically sealing the two outer shelves of the capsule through a heated wedge, the levothyroxine-containing solution, known as the capsule's fill, is injected with a filling pump. Encapsulation occurs at a temperature of about 40 °C.





THERAPEUTIC AREAS Human Reproduction

Human Reproduction is probably the most debated field in medical science, as infertility has been a major scientific and social preoccupation throughout human history and difficulty to conceive has always been a serious problem for couples all over the world. It is estimated that for 15% of couples in Europe and in the USA, 12.5 % in China and around 10% in Middle-East countries **having a child is a serious and complex struggle** that can create a heavy psychological burden. The IBSA portfolio in this area

offers innovative and qualitative tools for controlled ovarian hyperstimulation (COS) and luteal phase support (LPS) within Artificial Reproductive Techniques (ART) programs. IBSA has developed several pharmaceutical preparations

containing highly purified gonadotrophins of human origin (HP-FSH, HP-hMG, HPhCG) thanks to an innovative purification process that provides a range of isoforms inspired by nature while delivering the highest level of purity. Thanks to IBSA technology, a new formulation of progesterone for subcutaneous administration to support the luteal phase in ART programs is now available.

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THERAPEUTIC AREAS Pain and Inflammation

Pain can impair people's daily routine, preventing them from moving, working and living a normal life. That is why the history of pain relief is long and dates back to more than 5000 years ago.

Across Europe, an estimate of **500 million working days are lost** every year as a result of chronic and acute pain, with an enormous social and economic impact.

Among the different treatments available for pain, non-steroidal antiinflammatory drugs (NSAIDs) have been and still are used extensively. **Diclofenac** is the most widely prescribed NSAID worldwide, effective in a wide variety of conditions such as muscular, tendon and joint injuries, back pain, menstrual cramps, dental pain and headache.

The anti-inflammatory and pain relieving activity of diclofenac is mainly related to the inhibition of COX-2, the isoform of cyclooxygenase involved in pain and inflammation development. In addition, diclofenac has other anti-inflammatory and analgesic properties that go well beyond the pure COX-, inhibition. The diversity in diclofenac's mechanisms of action may suggest the **potential for a** relatively more favourable profile compared with other NSAIDs. Innovative formulations containing a soluble salt of diclofenac (diclofenac epolamine or DHEP) have been launched on the global market by **IBSA**. Thanks to its favourable permeation characteristics, DHEP **provides** optimal absorption and prompt relief from pain caused by soft

Transparent liner

Hydrogel

tissue injury, musculoskeletal disorders and other clinical conditions characterized by acute and chronic pain.

The DHEP topical patch for the local treatment of acute pain and inflammation due to strains, sprains, bruises and OA flares is one of the most relevant and well-known **IBSA products.** IBSA patch acts directly and locally on the painful area for several hours, thus avoiding the passage of the drug through the gastrointestinal system. Moreover, a new version of the patch has been recently developed by IBSA with the addition of heparin as excipient and enhancer, with the aim to increase the release of the active principle from the patch and consequently its efficacy. Another innovation in this area is represented by a diclofenac formulation in **prefilled injection** and ampoule that is used in acute pain management. Its subcutaneous administration has many advantages compared to the intramuscular delivery; in addition, this new formulation offers the possibility of using different dosages for a more accurate and targeted therapy. Very recently, the product has also been approved for the bolus i.v. injection when treatment or prevention of post-operative pain in the hospital setting is required.

Felt backing

Patch is composed of 2 layers: one adhesive layer (hydrogel) containing the active principle (diclofenac epolamine), covered by an adhesive and transparent liner, and one outer layer (felt backing) where hydrogel is applied





Respiratory diseases are second only to cardiovascular conditions in terms of mortality, incidence and costs. Among the biggest causes of respiratory death in Europe are pneumonia and chronic obstructive pulmonary disease (COPD).

> Climate change is likely to have mostly adverse effects on health. These findings have been well described by the WHO. In Europe, as elsewhere, deaths from chronic respiratory and lung conditions are expected to increase in the future. Despite the fact that emphysema and asthma often have no cure, **nebulized** solutions containing Hyaluronic Acid are helpful in the treatment of the main symptoms and acting as an adjuvant therapy - they may reduce the need for bronchodilators; together with other more specific medications for each of the condition considered, this treatment is **effective against** both upper and lower airways, narrowing and enhancing ventilation and air flow to and from the lungs. On the other hand, the **efficacy of** N-Acetylcysteine as a mucolytic is widely known and drugs containing this active compound **can cure** symptoms in patients suffering

Worldwide hundreds of millions of people suffer every day from chronic

respiratory ill-health. According

to the World Health Organisation

people have asthma, 210 million

people have COPD while millions

often under-diagnosed, chronic

respiratory conditions.

(WHO) global estimates, 300 million

more have allergic rhinitis and other,

Rhinitis is another condition in which the use of nebulized Hyaluronic Acid is helpful, together with other medicaments such as antihistaminics and corticosteroids in the allergic type. Diclofenac, a cyclooxygenase inhibitor, which belongs to the category of nonsteroidal antiinflammatory drugs (NSAIDs), is widely prescribed as an anti-inflammatory drug for the mouth

and the throat. IBSA offers a full range of mucolytics such as N-acetylcysteine. The pipeline in this therapeutic area has recently been enriched with other products containing hyaluronic acid for different respiratory diseases. Among these a HA solution for aerosol therapy is indicated for the restoration and maintenance of physiological conditions of the mucous membranes in upper and lower respiratory tract diseases.

Powder and solvent Preparation: When the ring is removed

from both acute and chronic

bronchitis.

When the ring is removed, the stopper is screwed down thus the powder gets in the liquid; the solution is shacked shortly until the liquid is without turbidity.





THERAPEUTIC AREAS Osteoarticular

Rheumatic diseases are painful conditions characterized by inflammation, swelling, and pain in the joints or muscles.

Because of aging, injuries and traumas, being overweight, heritability, overuse on one side and lack of physical activity on the other, joints and related structures such as bones, ligaments and cartilage may present a series of degenerative disorders which negatively affect daily activities. Among these conditions the most

frequent is osteoarthritis (OA), which is currently one of the leading causes of disability worldwide. In EU, OA causes moderate to severe disability in around 40 million people.

OA causes the protective cartilage to wear away and the exposed bones to rub against each other, resulting in a general deterioration of the joint, pain and stiffness after periods of inactivity or excessive use. Knees, hips, hands and spine are the most commonly affected joints. IBSA products for the treatment of joint diseases, are:

- IBSA's leading product for OA, that is an oral drug containing highly purified, pharmaceuticalgrade chondroitin sulfate, effective in treating the pain and functional impairment caused by OA. Additionally, the drug **slows** the progression of structural changes in joint tissues/cartilage.
- A family of medical devices consisting of a physiological solution of **highly purified** HA in a ready-to-use syringe for intra-articular injections, available in different volumes and concentrations. They are indicated for pain or reduced mobility due to degenerative processes, post-traumatic diseases or joint alterations. HA has the capability to increase the viscosity of the synovial fluid. Injections of HA are effectively used in joints suffering from OA (knee, hip, small joints such as hand) as well as in other pathological conditions of tendons.
- This family has been further enlarged in the latest years with a new member, a very innovative product containing a solution of "Hybrid cooperative complexes of hyaluronic acid" obtained with a thermal treatment patented by IBSA.

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Urology

Among the most disturbing conditions affecting the quality of life of male and female patients are those associated with pelvic region disorders. Urologist and uro-gynecologist visiting patients are well aware of how challenging the treatment of these conditions may be. The patients afflicted by recurrent urinary tract infections (rUTI), interstitial cystitis (IC/BPS), radiation or chemotherapy cystitisstruggle with a damaged bladder urothelium and irritants contained in the urine leak into the bladder submucosal tissues causing strong pain and inflammation. IBSA products are:

- a prefilled syringe containing a combination of hyaluronic acid and chondroitin sulfate which, instilled in the bladder, can prevent damage of the urothelium, enhancing its healing process.
- soft gels capsules, an oral formulation containing hyaluronic acid and chondroitin sulfate, in association with quercetin and curcumin, which, thanks to its anti-oxidant action, is useful in the treatment of pelvic pain and discomfort due to cystitis.

Other vaginal diseases may also benefit from topical treatments with HA, fat-soluble extract of Centella asiatica and liposoluble extract of Chamomilla vulgaris. This formulation is available as vaginal suppositories or vaginal douche, which may result useful in treating vaginal irritation, itching, and uncomplicated atrophic vaginitis.

More recently, IBSA has also focused its interest on male disorders, such as erectile dysfunction (ED) developing an innovative orodispersible film (ODF) of sildenafil, a novel drug-delivery system that allows a fast oral disintegration of the active ingredient into the mouth, also without the need of water for administration, thus ensuring patient's compliance and acceptability.



The first product combining together high concentration of sodium hyaluronate (1,6% w/v) and sodium chondroitin sulfate (2% w/v) in a pre-filled syringe.





CSR Sustainability commitment

IBSA is dedicated to acting responsibly to foster social advancement, reduce environmental impact and achieve long term economic prosperity.

IBSA is a **fervent believer in the well-being of individuals** – patients and employees – and the pursuit of this objective is an **integral part of its culture** and a paramount company goal. IBSA therefore aims to produce value for a wide group of stakeholders by:

- offering more efficient, safer products that respond to the needs of doctors and patients;
- creating employment opportunities within its group and for its business partners;
- contributing to progress in healthcare;
- **investing in its employees** and their wellbeing;
- adopting best environmental and social protection practices.

Developed internationally and with an approach that complies with the requirements of the Global Reporting Initiative (GRI), CSR is implemented at local level through the creation of **social projects and activities** that are based on the incentives and needs of the different countries in which IBSA operates.

Environmental responsibility and mobility

IBSA has always been committed to the constant and progressive reduction of its impact on the environment and is working towards improving its results in terms of energy consumption and emissions of CO₂ equivalent. With regard to mobility, the company has also undertaken to reduce the impact caused by commuting from home to work by its employees: IBSA currently encourages the use of public transport with the Arcobaleno project and is studying other projects in the field of sustainable mobility for the near future.

Wellbeing, quality of life and satisfaction of IBSA people

The testimonies of IBSA's employees speak of a pleasant, calm and stimulating working environment, which is confirmed by the very low turnover in human resources. The company aims to continue along this path and ensure that its people feel considered and appreciated as a fundamental part of a successful company.

In 33 years the Group has grown to a considerable size, despite the objective difficulties of the global economic crisis; more recently, IBSA has undertaken different initiatives aimed at strengthening its organisation, encouraging collaboration between the internal departments and promoting the wellbeing of its staff.

These initiatives include:

 assistance, including financial assistance, to employees that face serious difficulties;

30

 a new wages policy, with particular reference to an objective-based incentive

• in-house training courses (languages and various other

specialist courses);

by the company;

Together, etc.).

 the promotion of individual wellbeing, with the provision of osteopathic services financed

• the organisation of social and leisure events (Family Day, All

All these activities have a single common denominator: to increase internal cohesion, wellbeing and cooperation, in the knowledge that only an organisation that is in harmony can express its maximum efficiency both inside and outside the company organisation.



CSR Foundations

Being part of IBSA means building together, with care and attention to the needs of people, contributing to making the most of their talent and motivation, guided by the idea that dialogue and the fusion of genders and generations leads to greater harmony and an awareness of personal professionalism and that of others. This approach raises a new awareness and openness to a broader concept of sharing and collaboration, by contributing to a climate of wellbeing that continually improves both the life of the company and life within the company.

In this regard, IBSA has set up three Foundations:

IBSA Foundation for Scientific Research: an international non-profit organisation set up in Lugano in 2012, which promotes research, spreads scientific culture and supports the education of young students and researchers through forums, workshops, fellowships and

The Foundation is a solid testimony of IBSA's social responsibly (CSR), because promoting research means encouraging a better quality of life for the future.

The Foundation therefore aims to educate and inform the scientific community, but also to increase public awareness of issues regarding healthcare and subjects that have a strong impact on society and health, reflected in people's quality of life. In this regard IBSA promotes initiatives such as *Let's Science!* and *Art&Science*, created to involve the wider public as well as students, with the intention of spreading scientific awareness and culture in a non-conventional manner, while maintaining the exactness of the content.

IBSA Foundation for Children:

created in 2008, the main goal of this foundation is the management of the Primi Passi IBSA day-care facility for 30 children aged 4 months to 4 years old, created to offer practical help to IBSA employees in the Canton of Ticino. Open also to the local population, great attention day-care's environment and every aspect has been designed furnishings and objects made out of sustainable materials, several sensory paths have been recreated to encourage little explorers to go and "discover".

33

IBSA Foundation for the management of the Social Security Fund for Personnel: founded in 1958, well before it was compulsory to do so by law, the aim of this foundation is to manage the assets of the pension fund of IBSA employees in the Canton of Ticino. The social security services offered are superior to those required by Swiss law for company pension funds and assure employees' financial peace of mind during retirement and in the event of health-related problems.

ellowships



- IBSA Switzerland IBSA Italy IBSA Hungary IBSA China IBSA Slovakia IBSA Turkey IBSA Poland IBSA Scandinavia
- IBSA Russia
- **IBSA USA**

IBSA Headquarters Lugano, Switzerland

ibsagroup.com



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IBSA Company Brochure, September 2018



