

SeeNews

PHARMA REPORT



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Disease Awareness Campaign in Transplantation
“To give life”

CONTENTS

1. Introduction	4
2. About the authors	5
3. Key findings.....	8
4. Bulgaria on the international R&D map.....	9
5. Regulatory framework at national level.....	12
6. Regulatory framework at EU level.....	14
7. Vendor's Landscape.....	16
8. Financial analysis.....	20
9. Industry trends and forecasts.....	25
10. Methodology.....	28
11. Disclaimer.....	29
12. List of Sources.....	30

1. INTRODUCTION - DEFINING PHARMA INDUSTRY AND ITS SEGMENTS

The pharmaceutical industry includes the discovery, development, manufacture and marketing of drugs and medications. For the purpose of the current report, and based on the Statistical classification of economic activities in the European Community (NACE Rev. 2), we have identified four main segments of the pharmaceutical industry:

- Manufacture of pharmaceuticals – includes companies producing basic pharmaceutical products and pharmaceutical preparations. The activities covered include, among others: manufacture of medicinal active substances to be used for their pharmacological properties in the manufacture of medicaments; processing of blood; manufacture of chemically pure sugars; manufacture of medicaments, chemical contraceptive products for external use, medical diagnostic preparations, biotech pharmaceuticals and preparation of botanical products for pharmaceutical use.
- Wholesale of pharmaceuticals – applies to the wholesale of all kinds of pharmaceutical and medical goods.
- Retail sale of pharmaceuticals – includes pharmacies classified under the NACE Rev. 2 code 47.73, Dispensing chemist in specialised stores.
- Research and development of pharmaceuticals – divided into two major branches: research and experimental development in biotechnology and other research and experimental development in natural sciences. Companies in the first branch can be active in genomics, pharmacogenomics and genetic engineering; sequencing, synthesis or engineering of proteins and peptides; cell and tissue culture and engineering; process biotechnology techniques; gene therapy and viral vectors; bioinformatics; nanobiotechnology. The second branch of activities encompasses research and development in the field of medical sciences, including interdisciplinary research, most often in the form of clinical trials.



2. ABOUT THE AUTHORS

ABOUT SEENEWS

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ASTELLAS: LEADING LIGHT FOR LIFE

Astellas is a global pharmaceutical company - a leader in the development of innovative medicines, which is represented in more than 50 countries around the world.

Dr. Stamen Bankovski is the Executive Director of Astellas for Bulgaria, Hungary and Romania. He has been working for the company since 2014, having previously held the positions of Director for Bulgaria and Executive Director for Hungary. He has nearly 25 years of experience in the pharmaceutical industry.

1. Astellas is one of the leaders in the modern pharmaceutical industry. Turning to your R&D efforts, how is your pipeline looking and what are your most significant milestones in the coming year?

Astellas is one of the leading innovators in the pharmaceutical sector, succeeding two major Japanese companies with over 100 years of history. We are currently in the global Top 20 of the biopharma industry. We hold these good positions with our strong focus on our core strategic model to create leading innovations. Many of our new developments sound futuristic, but some of them are already a fact in real medical practice - such as personalised medicine, gene therapy, genome sequencing. Our company invests resources and efforts mainly in developing drugs and therapies that have not existed at all as a therapeutic approach before. Many of these are the gold standard or first-in-class in areas such as urology and transplantology. In recent years, we have also made serious progress in oncology, which has allowed us to



rank among the top six oncology companies in Bulgaria. Astellas has developed one of the most effective therapies for prostate cancer, and this product is now the second biggest onco drug in Bulgaria in terms of revenue.

Our ambition to be one of the leading companies in oncology is supported by our serious investment in research and development (R&D). We are currently developing entirely new and first-in-class therapeutic approaches to address unmet medical needs in the treatment of bladder cancer, stomach cancer and pancreatic cancer, which also have the potential to become the future gold standard of treatment.

Hematology is another area of particular interest to us. At the end of 2019 we received an European approval for our innovative therapy for the treatment of acute leukaemia, and since the beginning of last year it is also available and paid for by the National Health Insurance Fund for Bulgarian patients. This therapy represents serious progress in the difficult treatment of this severe

disease. Last year, we also received the registration worldwide of innovative treatment for anaemia associated with chronic kidney disease, which we hope will also be available in Bulgaria soon.

2. What will be the defining treatment for such socially important diseases in the future and what is the expected contribution of Astellas?

The pharmaceutical industry is increasingly focusing its efforts in finding more efficient and safer solutions for patients. Companies in this sector devote a large percentage of their revenue to R&D, outpacing all other sectors.

Astellas is no exception and invests 17% of the company's global annual turnover in the development of new molecules in various therapeutic areas. Of course, many of these molecules do not make it to the final phases of research and to the consumers, and this is why the development cost of each new drug is now almost double what it was just a few years ago. On the other hand, it is the allocation of large financial resources to research by companies that has made it possible to improve the quality of life and increase the life expectancy for millions of patients with various medical conditions around the world.

A significant part of Astellas' research is in highly innovative areas such as gene therapies and regenerative medicine, where we talk about growing tissues and whole organs from stem cells. These are areas that not in the distant future, but very soon will give a new impetus to medicine and the transformation of the lifestyle of patients.

3. Most recently, you were elected Chairman of the Management Board of the Association of Research Pharmaceutical Manufacturers (ARPharM). What are the Association's priorities and on which topics and issues will you focus your efforts on?

Since its inception a quarter of a century ago, the main objectives of the Association have been to contribute to the improvement of Bulgarian citizens' health and to ensure a better quality of life by improving access to

modern, quality, efficient, and safe medicinal products manufactured at the highest international standards.

One of my main tasks will be for ARPharM to continue the fruitful communication with the institutions and organisations in the health sector in the country as well as to support a healthcare policy that guarantees access to innovative and modern treatment for Bulgarian patients and at the same time creates a favourable environment for investment and economic development.

An example of such a fruitful partnership is the "Together for More Health" initiative involving the Bulgarian Medical Association (BMA), the Bulgarian Pharmaceutical Union (BPhU) and ARPharM. In collaboration with institutions and experts from different fields, we are looking for opportunities to strengthen the healthcare system by increasing efficiency and achieving sustainability of healthcare investments. We believe that the Bulgarian healthcare system needs to be strengthened through more public investment, better staffing and improved efficiency to achieve better patient outcomes. The pandemic has also had a negative impact on some segments of the healthcare system, the consequences of which, such as lagging behind in the treatment of chronically ill patients, for example, will continue to have repercussions and need more attention and prioritisation in the long term.

The need for digital transformation is the other major challenge for the Bulgarian healthcare system and its solution is of strategic importance for improving the quality of healthcare in the country.

3. KEY FINDINGS

This analysis of the Bulgarian pharmaceutical industry covers 3,660 local companies operating in four segments: manufacture of pharmaceuticals; wholesale of pharmaceuticals; retail sale in pharmacies; research and development (R&D) of pharmaceuticals. Based on the analysis of the data, we identified the following key findings concerning the current state and development of Bulgaria's pharmaceutical industry in the three-year period 2018-2020:

- The pharmaceutical industry expanded in size in 2020, increasing its aggregate operating revenue by 12.1% y/y to EUR 6.855 bln. The COVID-19 pandemic proved to be an opportunity for the industry as it accelerated its annual growth rate from 10.3% in the previous year. Forecasts based on the compound annual growth rate (CAGR) in the period 2018-2020 show that the aggregate operating revenue of Bulgarian pharmaceutical companies could exceed EUR 9 bln by 2023.
- The largest segment is wholesale of pharmaceuticals, which accounted for 67% of the overall operating revenue of the industry in 2020. It was also the fastest growing with an annual growth rate of 13.7%. Pharmacies increased their turnover by 11.2% in 2020 and were the second largest segment with a share of 22% of Bulgaria's pharmaceutical market. The manufacturing and R&D segments together made up slightly more than 10% of the industry.
- The pharmaceutical industry in Bulgaria had a total of 31,992 full time employees (FTEs) in 2020. Assuming that employment continues to expand at the CAGR of 1.9% observed in the period 2018 – 2020, almost 2,000 new employees will join the industry by 2023. Pharmacies were responsible for 37.5% of the employment in the industry in 2020. However, the fastest growing employer is R&D, which is expected to add more than 2,000 new employees in the next three years and double its headcount by 2023 in comparison with the beginning of the analysed period in 2018.
- Retail sale of pharmaceuticals in pharmacies dominated the market in terms of number of vendors - a total of 2,430 companies operated in this segment in 2020, equalling two thirds of all pharmaceutical companies in the country. Wholesalers were 1,130, or 31% of the total, while manufacturers and R&D providers together formed less than 3% of the overall pool.
- Employment expenses of pharmaceutical companies in 2020 expanded by 11.3%, a notch down from the 11.4% recorded in the previous year. Despite the slight deceleration, salary costs and social security contributions, which form the bulk of personnel expenses, far outstripped employment in the industry, which added 1.2% to its 2019 headcount, thus leading to an increase in the average wage per employee.
- During the pandemic-hit 2020, the comparatively slower expansion of manufacturing activities, which account for the bulk of material expenses in the pharmaceutical industry, led to a slowdown in the increase of these expenses in the whole industry, to 1.4% on an annual basis, compared with 7% in 2019.

- Sofia is the centre of Bulgaria's pharmaceutical industry – more than 36% of the total number of pharma companies are registered in the capital.

Concentration in Sofia is most evident in the R&D segment, as the city is home to the headquarters of 75% of the vendors operating in this segment. On the other hand, pharmacies are the most uniformly distributed entities with a quarter of them in Sofia and another quarter in the other six biggest cities.

4. BULGARIA ON THE INTERNATIONAL R&D MAP

Bulgaria has been part of major international drug development projects and this is evident by the fact that the Bulgarian Drug Agency (BDA) has granted over 40 approvals for the conduct of studies at Bulgarian clinical sites. The trials relate to programmes of international pharmaceutical companies such as Merck & Co, Novartis, AbbVie, Gilead Science, Amgen and Johnson & Johnson, among many others. The projects cover multiple therapeutic areas, including oncology, dermatology, neuroscience, rheumatology, infectious diseases and pulmonology. The true engine of medicine is innovation and the country's own drugs innovation scene is buzzing, with over sixty companies active in the area of research and development (R&D).

One of them is the startup **Micar Innovation (Micar21)** which describes itself as a drug discovery factory. The firm relies on its proprietary platform which combines artificial intelligence and scientific research. Micar uses computer-aided drug design to predict accurately how strongly a potential drug compound will bind to a protein target. The compounds with predicted high affinity for the target then only need to be synthesised in the lab. From the very beginning, Micar21's team has been concentrated on the CCR1-CCR10 cellular receptors. These control the migration and positioning of immune cells in tissues and are critical for the function of the innate immune system. Two of these receptors in particular, CCR5 and CCR7, have certain mutations that make individuals resistant to diseases such as HIV.

CCR5 has been at the core of Micar21's research, and the company already has reached a breakthrough with a novel drug molecule, called MIC4578, for the treatment of chronic pain.

The molecule is currently being developed by Micar21's spin-off, Bolka Pharmaceuticals. As part of its strategy, Micar21 is engaged in the discovery and development of novel drug candidates until the preclinical phase. The potential medicines are then licensed to a commercial

partner or new spin-off for further development.

Apart from MIC4578, Micar21 has a full pipeline of projects in the areas of immuno-oncology, neuroscience, infectious diseases, inflammation, longevity, oncology, cardiovascular diseases and dermatology. The pipeline includes potential drugs such as:

- MIC1045 for cancer metastasis
- MIC1930 for COVID-19 and flu
- MIC1445 for psoriasis
- MIC1720 for rheumatoid arthritis
- MIC1720 for asthma
- MIC0540 for longevity
- MIC6479 for pancreatic cancer
- MIC9211 for alcohol use disorder
- MIC2211 for hyperekplexia
- MIC2231 for stiff person syndrome
- MIC2634 for iminoglycinuria rare disease
- MIC6701 for colorectal cancer
- MIC2091 for cardiomyopathy
- MIC8471 for acne
- MIC8411 for melasma

The firm made headlines in 2020 with its drug project against COVID-19. The compound blocks the action of the two proteins CCR5 and CCR7, simultaneously. As a result, human cells are expected to become resistant to infection. While there are treatments targeting CCR5, the involvement of CCR7 is a novelty. The dual approach is also expected to offer a better drug safety.

Based on its innovative work, Micar21 has received a number of awards, including “Investor of the year 2018”, “Innovative Enterprise of the Year”, “European CIDIC Award” and “Best Biotech Startup of the year 2017 in CEE”.

The COVID-19 crisis also sparked project in the academic and scientific circles. A team of scientist from the **Bulgarian Academy of Sciences** invented a vaccine candidate against the pandemic disease. The shot has passed trials in mice and is ready for human testing. The vaccine is based on components of the virus which are recognised by the immune system and are part of the whole viral shell, not just a single protein. Therefore, the vaccine is expected to generate a more comprehensive immune response.

Furthermore, the vaccine uses viral components which remain unchanged over time. The team of scientists identified components which were present in an earlier coronavirus which caused the severe acute respiratory syndrome (SARS) outbreak in 2002 - 2003. The combination of multiple stable components ensures an immune response independent of viral mutations. Adding to the novelty element, the vaccine components are delivered into the human body via nanoparticles which are recognised specifically by antigen presenting cells, a type of immune cells responsible for the start of an immune response. In contrast, nanoparticles used in other vaccines could reach all types of cells in the body. The novel approach allows the formation of an immune response using a lower quantity of vaccine, which should result in fewer side effects.

The potential vaccine will be administered in two doses, the first one in the form of injection and the second one via an inhaled formulation. The inhalation is expected to stimulate mucosal immunity. The technology could also be used against other infectious diseases including influenza.

The vaccine project has been funded by The Institut Pasteur, a French non-profit organisation, and a donation campaign.

Separately, a team of scientists led by **Prof. Dr. Leandar Litov**, head of Atomic Physics Department at the University of Sofia, initiated work on a COVID-19 drug project. The team is pursuing two different approaches.

On the one hand, the scientists are working to identify a molecule which could block part of the viral proteins that invade the human cell. The potential drug would be used in the early stage of the disease. In the second project, the team is trying to discover a therapeutic agent that could suppress the “cytokine storm”, a severe immune overreaction which is observed in the advanced stages of the disease and is life-threatening.

The project won financing under a programme launched by the Bulgarian government in May 2020. The financing, however, was delayed after a participant appealed in court against the competition process.

Bulgarian companies also play a key role in international R&D projects. **Fidelis Research**, a Sofia-based company specialising in procurement of human biological specimens, has been a tissue sourcing partner in a large-scale project for the US National Cancer Institute, part of the US National Institute of Health (NIH), since 2016. The project is aimed at understanding the molecular basis of cancer that is not fully researched or cannot be researched through genomics.

Fidelis is collecting tissue at more than 15 active sites in Bulgaria, Romania, Serbia and Turkey. Samples are collected, immediately prepared for medium-term storage in a biobank facility and periodically shipped to the USA.

Each patient donor provides samples of a tumour tissue and an unaffected adjacent tissue, as well as whole blood. Patients with acute myeloid leukaemia (AML), a type of blood cancer, donate whole blood and bone marrow aspirate. The material shipped for each solid tumour case includes whole blood frozen immediately after collection, tumor tissue as well as normal adjacent tissue.

The project covers a number of cancers, including head and neck carcinoma, lung squamous cell carcinoma, acute myeloid leukaemia, pancreatic ductal adenocarcinoma, bladder carcinoma, cervical squamous cell carcinoma, liver hepatocellular carcinoma, stomach adenocarcinoma, thyroid carcinoma, lung adenocarcinoma, glioblastoma, cutaneous melanoma, sarcoma, brain lower grade glioma, esophageal carcinoma, prostate adenocarcinoma and uveal melanoma.

Fidelis Research, whose biospecimen collection services are used in projects by pharmaceutical and biotechnology companies, has extended its global reach through a number of partnerships over the years. In October 2020, the company's bespoke sample collection solutions reached customers in Japan through a non-exclusive distribution agreement with Japanese KAC Co Ltd. In June 2020, the Bulgarian firm joined forces with Austrian-based precision medicine company Allcyte GmbH, now part of pharmatech Exscientia. Fidelis and Allcyte agreed to jointly offer large pharmaceutical and biotech companies the opportunity to test the activity of drug candidates in viable human tissue samples of actual cancer patients. As part of the project, Fidelis agreed to source human biospecimens from over 60 clinical sites in Europe. Allcyte committed to providing its Pharmacoscopy high content imaging platform which could help direct a potential treatment to specific patient cohorts. The companies have successfully collaborated on numerous

projects in hematological malignancies and solid tumors since 2018.

In November 2018, Fidelis Research signed a partnership to use the resources of Sofia Tech Park's in vitro laboratory to process biological samples, isolate primary cultures and develop cell lines for medical research. The collaboration enhanced Fidelis service offering and strengthen its capabilities to conduct own research on new molecules and biomarkers both in-house and in partnership with its clients.

This overview of innovative projects only touches briefly on the vast potential of the Bulgarian pharmaceutical and biotechnology R&D segment. Many companies are showcasing the country's capacity to become an innovation hub for the pharmaceutical industry in the SEE region and they have all been included in our financial analysis for this report.



5. REGULATORY FRAMEWORK AT NATIONAL LEVEL

Bulgaria has an established place among the European countries with an up-to-date medicinal regulation. The country passed the Act for the amendment and supplementation of the Pharmaceuticals and Pharmacies Serving Human Medicine Act in 2000. The act defined new terms such as “medicine”, “medicinal product”, “medicinal substance”. Medical devices were included in the scope of the act, while texts concerning clinical trials were updated.

By virtue of the act, the Bulgarian Drug Agency (BDA) was created as part of the Ministry of Health. It was defined as a body to supervise the quality, efficiency and safety of medicines. Its expanded functions include:

- To issue manufacturing authorisations of medicines;
- To put forward proposals before the Minister of Healthcare for the issuance of marketing authorizations and for the wholesale trade in medicines;
- To carry out chemical and pharmaceutical expertise for quality assessment regarding marketing authorisations and to register clinical trials with medicines conducted in the country;
- To register drugstores;
- To coordinate medicines import and issue sales authorisations of medicines;
- To issue certificates of medicines and the origin of medicines;
- To control the manufacturing, retail and wholesale trade with medicines, clinical trials and the advertisement of medicines;
- To make laboratory analyses when suspecting deviations in the quality, efficiency and safety of medicines;
- To organise a system for the registration, analysis and summary of adverse drug reactions, as well as possible medicinal interactions between different medicines and to undertake the respective measures;
- To perform the functions of a national coordinator and consultant on issues related to the quality, efficiency and safety of medicines;
- To carry out a consultative, scientific, informational and editorial activity in the sphere of the pharmaceutical sector;
- To participate in activities related to the work of international bodies, organisations and agreements in the area of medicines, to which Bulgaria is a party;

Amendments to the Pharmaceuticals and Pharmacies Serving Human Medicine Act were made in 2003 with the aim of addressing differences with European legislation. By virtue of the changes, the BDA acquired the authority to issue marketing authorisations of medicinal products. Thus, the agency acquired independence for the first time in its competence.

BDA performs its regulatory activity in cooperation with a number of specialised commissions. These include:

- Specialised Commission for Assessment of the Therapeutic Efficiency and Safety of the Medicinal Products (SCATESMP);
- Specialised Commission for Assessment of the Therapeutic Efficiency and Safety of the Medicinal Products – phytogalenic and homeopathic (SCATESMP – PHGH);
- Specialised Commission for the Authorization of the Conduction of Clinical Trials (SCACCT);
- Central Ethics Commission (CEC);
- Specialised Commission for Assessment of the Therapeutic Efficiency and Safety of the Medicinal

products – vaccines and medicines(SCATESMP – V);

- Specialised Commission for Assessment of Medical Devices (SCAMD);
- Specialised Commission for determining the belonging of the products (SCDBP);

Overall, the role of the agency is to implement the goals of the National Health Strategy of the Ministry of

Health. The BDA also participates in activities related to the work of the European Medicines Agency (EMA) and other EU and international bodies and organisations. The agency has the tasks to international treaties to which Bulgaria is a party.



6. REGULATORY FRAMEWORK AT EU LEVEL

Innovative medicines in Bulgaria and other EU member states are authorised under the centralised authorisation procedure at EU level. This allows pharmaceutical companies to market their drugs in all member states, including Bulgaria, through a single EU authorisation.

The centralised procedure is **compulsory** for human medicines containing a new active substance to treat:

- human immunodeficiency virus (HIV);
- cancer;
- diabetes;
- neurodegenerative diseases;
- auto-immune disease and other immune dysfunctions;
- viral diseases;

Additionally, the centralised procedure is **obligatory** for:

- drugs derived from biotechnology processes, such as genetic engineering;
- advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines;
- medicines for rare diseases;
- veterinary medicines for use as growth or yield enhancers;

The centralised procedure is **optional** for:

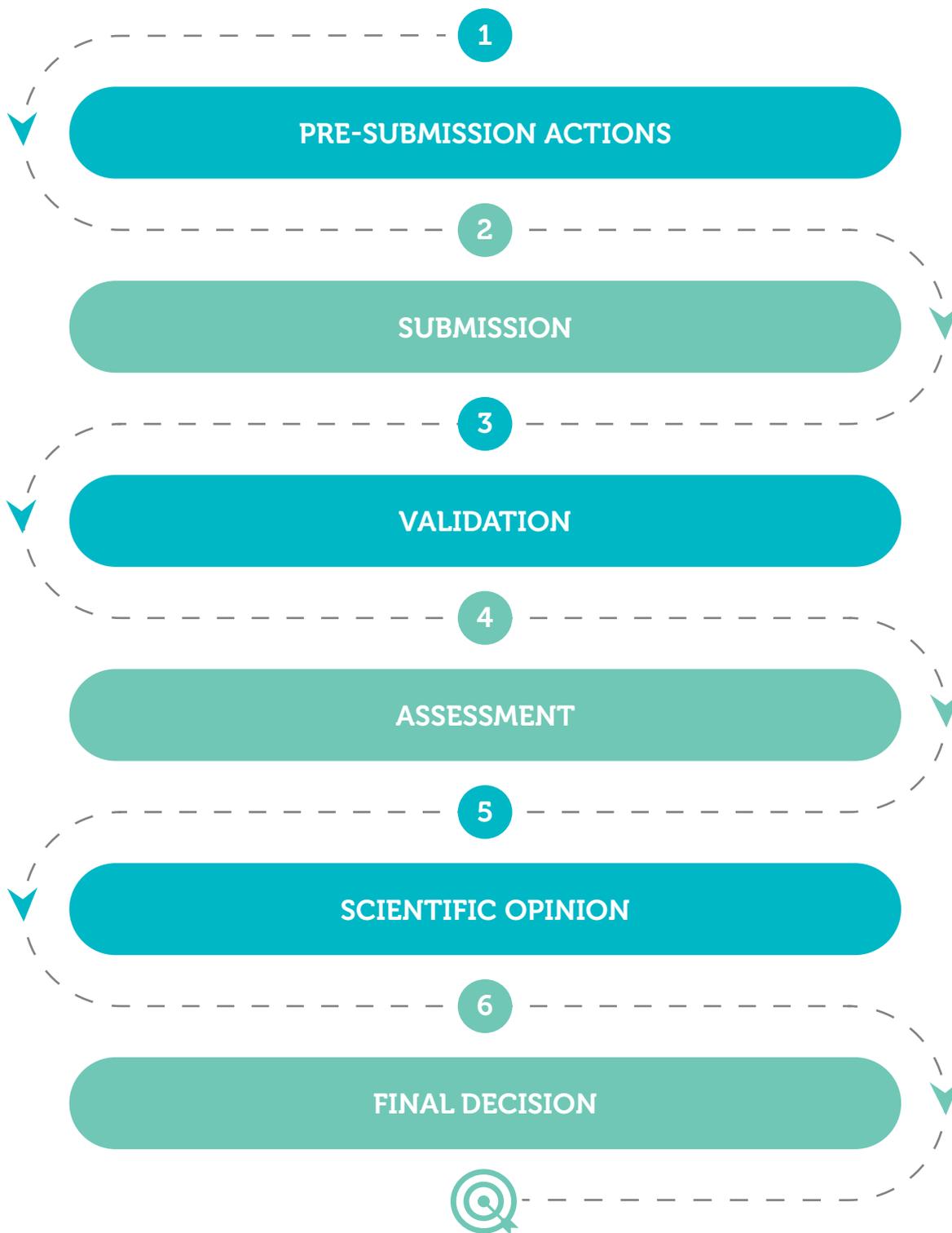
- drugs containing active agents for indications other than those stated above;
- medicines that are a significant therapeutic, scientific or technical innovation;
- medicines whose authorisation would be in the interest of public or animal health at EU level;

Today, the great majority of innovative medicines have to pass through the centralised authorisation procedure in order to be marketed in the EU. The process involves the following steps:

- **Pre-submission actions** - before submitting marketing authorisations with the European Medicines Agency (EMA), pharmaceutical

companies make eligibility requests to find out if a product can be evaluated under the centralised procedure. The request is made 18 months to 7 months before the submission of the application. As a second step, firms are required to send a notification of their intention to file an application. This should be done seven months before the planned submission. The EMA's human medicines and safety committees then appoint rapporteurs to conduct the scientific assessment of the product candidates. The next step involves pre-submission meetings allowing pharmaceutical companies to obtain procedural and regulatory advice from the EMA. Finally, applicants should re-confirm the submission date initially communicated to the agency.

- **Submission** of a marketing authorisation application - applications are submitted through an electronic gateway or web client.
- **Validation** - The EMA validates the application to make sure that all elements required for scientific assessment are available. If additional data are needed, the agency will require the applicant to supply those.
- **Assessment** - Applications are evaluated by the EMA's Committee for Medicinal Products for Human Use (CHMP). Aspects related to risk management are assessed by the Pharmacovigilance Risk Assessment Committee (PRAC). The Committee for Advanced Therapies (CAT) provides its input when applications relate to advanced-therapy medicines. The evaluation takes up to 210 active days.
- **Scientific opinion** - After the evaluation, the CHMP issues a scientific opinion on whether the medicine may be authorised or not. The EMA sends the opinion to the European Commission which makes the final decision on the application.
- **Final decision** - The European Commission takes the final decision within 67 days of receipt of the CHMP opinion. Once authorisation is granted, it is valid in all EU member states as well as in the European Economic Area (EEA) countries Iceland, Liechtenstein and Norway.



7. VENDOR'S LANDSCAPE

NUMBER OF COMPANIES BY SEGMENT

Trading of pharmaceuticals is by far the largest segment on the Bulgarian pharma market in terms of number of companies. Over 97% of all vendors analysed in this report are engaged in either wholesale or retail sale of pharmaceuticals. Furthermore, retailers are more than double the number of wholesalers and account for 66.4% of the total number of companies analysed. However, it should be noted that although some retailers are registered as separate companies, they are actually part of pharmacy chains.

The other two pharma industry segments - manufacture of pharmaceuticals and R&D in pharmaceuticals, have small shares in number terms. Nevertheless, they play a key role in the industry's advancement, bringing higher value-added products and practices on the market. The segment of pharmaceutical manufacturers is comprised of two sub-segments: manufacture of basic pharmaceutical products, represented by only two companies, and manufacture of pharmaceutical

preparations, with 35 companies. The manufacture of pharmaceutical preparations sub-segment includes companies engaged in the production of popular prescription and over-the-counter medicines. In turn, the manufacture of basic pharmaceutical products involves the production of medicinal active substances to be used for their pharmacological properties in the manufacture of medicaments, for example - antibiotics, basic vitamins, salicylic and acetylsalicylic acids.

The R&D in pharmaceuticals segment encompasses 63 companies engaged in research and experimental development on natural sciences and engineering.

NUMBER OF COMPANIES BY LOCATION

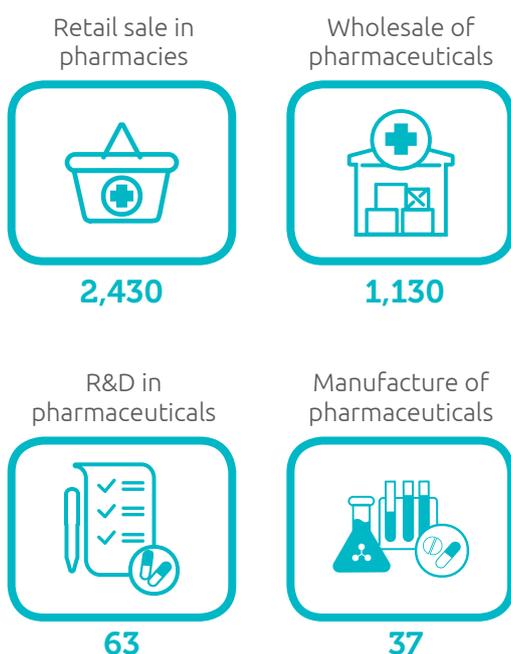
The simultaneous effect of two factors – population and business environment, determine the geographical distribution of the pharma companies in Bulgaria. The capital Sofia boasts the largest number of pharma companies in all of the industry's segments. More than 36% of all vendors are registered in Sofia, or more than double the combined share of the other three largest cities in the country – Plovdiv, Varna and Burgas.

Segment-wise, concentration in Sofia is most evident in the R&D in pharmaceuticals segment, where more than 75% of the companies are headquartered. The remaining part of the companies are scattered across the county, reflecting the underdeveloped environment for R&D activities in the pharma field outside the capital city.

Wholesalers mostly prefer Sofia as well – with its warehousing and logistics infrastructure, the capital city has attracted 65% of these companies. Plovdiv is another major centre for pharmaceuticals wholesalers, boasting more than a hundred companies in the field. Varna is also worth mentioning as the coastal city is home to nearly 5% of the pharma wholesalers.

Sofia's favourable business environment, ease of access and availability of workforce determine its position as the administrative hub of the country's pharmaceutical

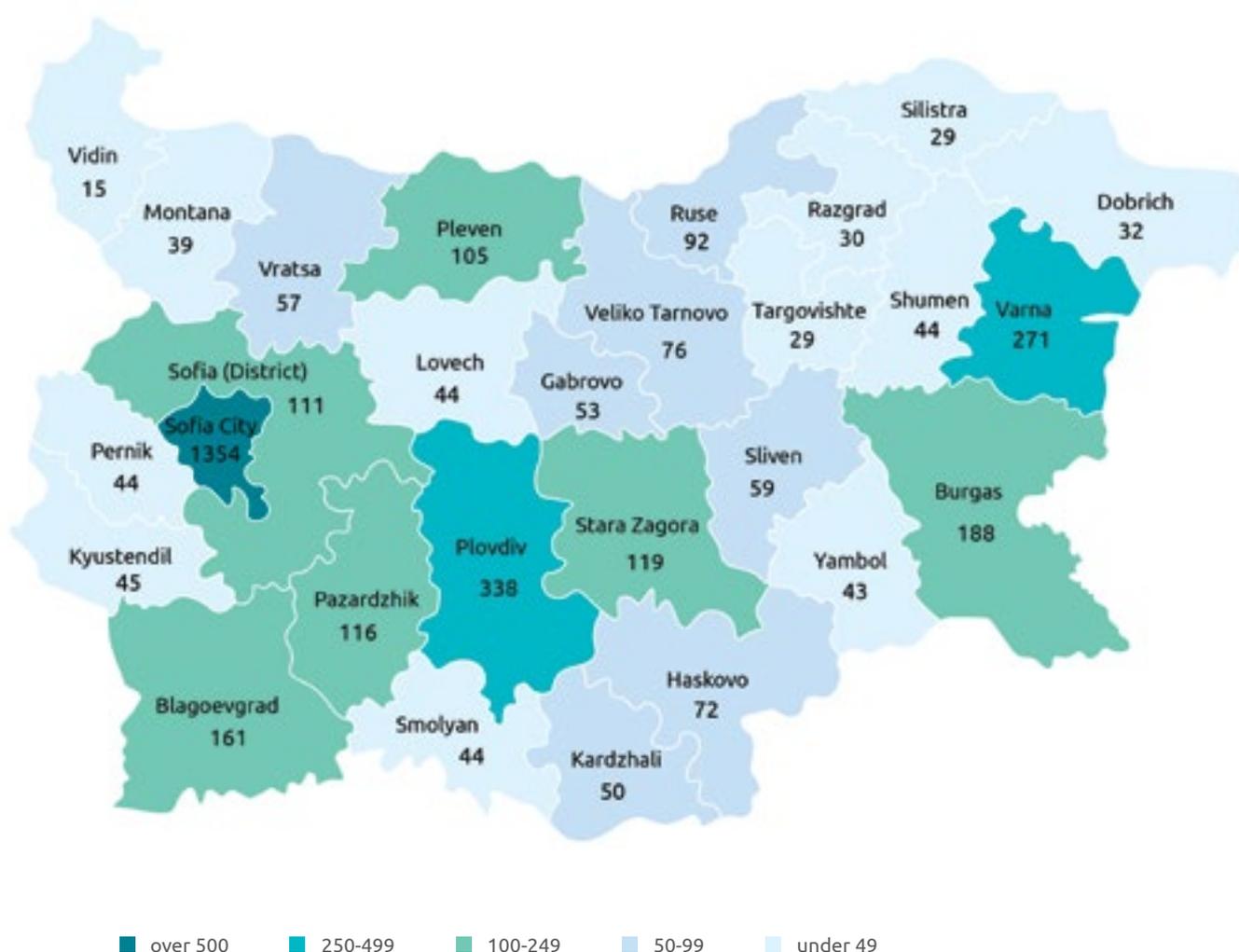
Fig 1. Number of companies by segment



manufacturers. More than half of the pharma producers are based in the city and most of them operate their production facilities there as well. Other important pharmaceutical manufacturing centres in the country, are the towns of Dupnitsa, in southwestern Bulgaria, Troyan, in central Bulgaria and Razgrad, in northeastern Bulgaria.

The lowest share of Sofia-based companies operate in the retail sale segment. About a quarter of the pharmacy operators are headquartered in the capital, while another 25% are registered in six of the other major Bulgarian cities.

Fig 2. Number of companies by location





Inovexa is a Bulgarian product and analytical development laboratory specialised in generic dossier development of finished pharmaceutical forms for oral use. Operational since May 2020, Inovexa is the first independent private Bulgarian pharmaceutical company solely focusing on generic R&D as a core activity. Tsvetan Popov has 20 years of experience in generic multinational companies and is a managing director at Inovexa.



Mr. Popov, can you tell us a bit more about Inovexa's core operations and the services you provide?

Based in Sofia, Inovexa's development centre has experimental and analytical laboratories which are fully equipped to perform lab-scale prototype and method development for tablets, capsules and granules. Both the premises and the equipment are brand new and designed as per the most current pharmaceutical standards. Inovexa has capabilities and technologies to develop mini and micro tablets, pellets, bi/tri-layer tablets, tablets in capsules, capsules in capsules, all types of functional and cosmetic coatings, mono and combination products. In the analytical lab, we perform method development and validation using the latest analytical technologies, incl. equipment validation and diagnostics.

Since our development centre went live two years ago, Inovexa has already developed four products in a partnership with Antibiotic Razgrad, who manufacture the products and sell them under their own label in Bulgaria. Two of the products already have been launched in Bulgaria and two others are pending

regulatory approvals. In 2022, the partners expect to finalise five new development projects followed by six others, which are at different stages of development. In addition, Inovexa has signed contracts and has ongoing negotiations for contract- and co-development projects with leading European generic houses. The company is working on several complex generic product developments for modified release formulations and products with no or limited generic competition.

So, Inovexa is in fact active on other markets as well?

Our dossiers are developed in eCTD format, which means they are suitable for filing in Europe and many other countries which recognise EU standards, including from regions such as Eastern Europe, the Middle East and North Africa and Asia. Outside Bulgaria, the products are commercialised through licensing B2B partnerships with generic companies who have a strong commercial presence in those countries. This is a common model in the industry and allows us to grow the size of Bulgaria as an exporter of intellectual property on the pharmaceutical industry map.

Tell us a bit more about your team.

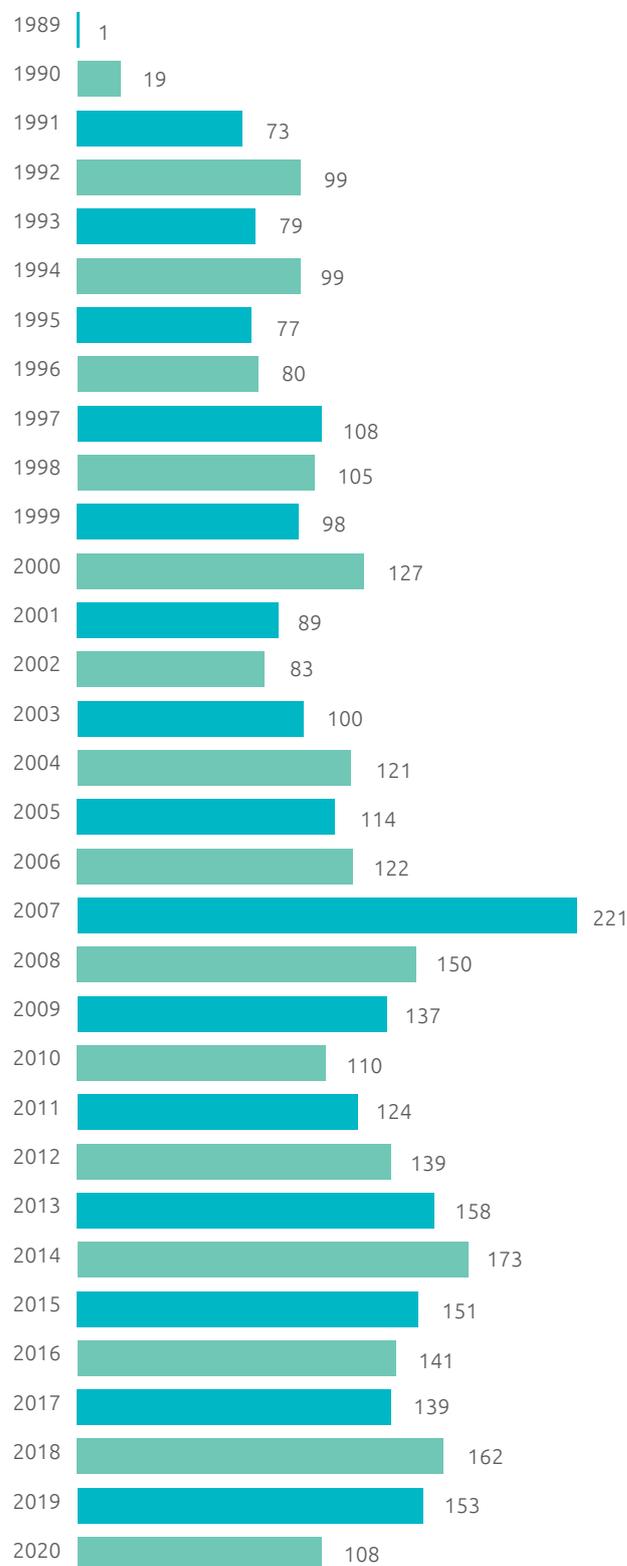
Currently, Inovexa employs eighteen industry experts in the fields of pharmaceutical technology and formulation development, analytical method development, pharmaceutical operations and business development. The team brings an extensive knowledge and expertise gained in international pharmaceutical operations environment.

Being among the pioneers in the pharma R&D field in Bulgaria, one of the key objectives of Inovexa is to continuously develop and grow a knowledge and talent pool focused on research and science. The company provides internship and junior development programmes to high-performing university graduates. Following our belief to invest in people development, diversity and sharing of expertise, the company currently has two interns and one expat position. Going forward, we plan to continue attracting foreign expertise and young talent.

NUMBER OF COMPANIES BY INCORPORATION DATE

The pharma industry grew in company number terms most notably in the period 2010-2019 when 1,450 companies were established, or nearly 40% of all companies analysed in the report. The number of newly registered companies in this period represented an increase of almost 15% compared to the preceding decade. However, the sharpest spike in company registrations was booked in 2007 when large pharmacy operators had to reorganise their activities due to regulatory reforms. In 2008, the regulatory framework on retail of pharmaceuticals underwent another change, reverting some of the regulations introduced in the previous year and the number of new registrations contracted for several years. This was followed by a period of two-digit growth in newly registered pharma companies up until 2015. In the last five years, 2016-2020, the number of new registrations declined by more than 8% on annual basis. However, the industry may enjoy another expansion in the coming years, fuelled by the country's sustainable export orientation, including untapped potential in higher value-added goods and services, competitive employment costs, along with skilled and experienced staff in the pharma industry, as well as red tape reduction and low corporate tax.

Fig 3. Number of Companies by Year of Establishment



8. FINANCIAL ANALYSIS

REVENUE ANALYSIS BY SEGMENT

Bulgaria’s pharmaceutical industry accelerated its annual growth in 2020 to 12.1%, up from 10.3% in 2019. It reported an aggregate operating revenue of EUR 6.855 bln in 2020, an increase of EUR 739 mln year-on-year. The industry was among the few that benefitted from the COVID-19 pandemic and expanded its activity due to rising demand for pharmaceutical goods.

All four segments supported the strong performance in 2020, although at significantly varying rates. Wholesale of pharmaceuticals, consisting of trading companies with distribution networks, was both the largest segment in value terms and the fastest growing one. In 2020, it accounted for more than two thirds, or 67%, of the operating revenue of the whole industry. This share has expanded gradually throughout the period 2018-2020, determined by the above-average annual growth rate of 13.7% reported by the vendors in the segment.

Retail sale of pharmaceutical products was the second most important segment with operating revenue of EUR 1.521 bln, slicing a share of 22% of the pharmaceutical industry. Meeting the increased demand for drugs and other medical products during the pandemic, pharmacies in Bulgaria boosted their aggregate operating revenue by 11.2% in 2020, compared with a more modest annual growth of 7.4% in the previous year.

The 37 vendors engaged in manufacturing of pharmaceutical preparations and basic products registered aggregate operating revenue of EUR 630 mln. Although the segment’s size still expanded in 2020, it did so at an annual rate nearly twice lower than in the previous year – 4.3% versus 6.8% in 2019. The slowdown can be largely attributed to supply chain issues and the strict lockdown between March and May 2020.

Smallest in absolute value, but showing the strongest growth potential, was the R&D segment. In 2020, it generated EUR 111 mln in revenue, thus accounting for

1.6% of the pharmaceutical industry’s overall operating revenue. Despite continuous expansion throughout the period, the R&D segment temporarily lost pace in 2020, during the economic uncertainty amid the pandemic. Thus, the previously record-high annual growth rate of 23.9% was decimated to 7.9% in 2020. Still, R&D reported by far the strongest CAGR in the industry for the 2018-2020 period, of 16%, and should flourish again from 2021 onwards, reflecting the increased investment interest in pharmaceutical research.

Fig 4. Operating Revenue in the Pharmaceutical Industry by Segments



- Manufacture of pharmaceuticals
- Wholesale of pharmaceuticals
- Retail sale in pharmacies
- R&D in pharmaceuticals

EMPLOYMENT ANALYSIS BY SEGMENT

The successful performance of Bulgaria’s pharmaceutical industry in 2020 was in line with the expansion of its headcount even during the first year after the COVID-19 outbreak. The total number of full-time employees in the industry reached 31,992 in 2020, growing at an annual rate of 1.2%. The growth rate

was twice slower than the 2.5% registered in 2019 as a result of stagnating new employment and high levels of economic uncertainty immediately after the initial shock in March 2020. However, a period of recovery of labour demand in the industry followed, supported by the advancing demand for pharmaceutical goods during the pandemic. In the period 2018-2020, the pharmaceutical industry's headcount expanded by a compound annual growth rate (CAGR) of 1.9%.

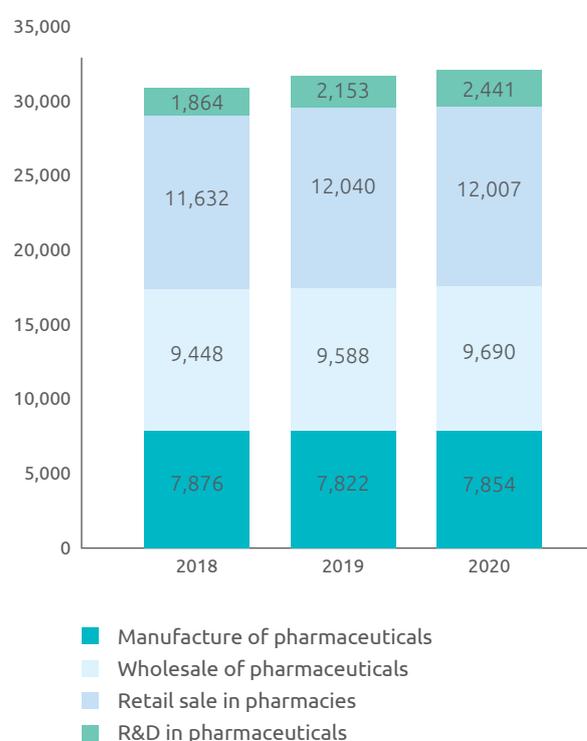
At segment level, employment dynamics varied significantly. Pharmaceutical research and development activities strongly grew in popularity throughout the analysed period. In 2020 alone, companies operating in this segment employed 13.4% more people than in the previous year. In 2019, the annual growth rate was even higher – 15.5%. Although R&D is by far the smallest among the four pharmaceutical segments in absolute terms and employs less than 8% of the industry's overall headcount, its increase by nearly 300 people is responsible for the bulk of the aggregate industry employment growth in 2020. Furthermore, 90% of this workforce expansion is attributed to the four largest vendors in the R&D segment.

Conversely, while the smallest segment grew at the fastest annual rate, the largest employer in the industry – retail sale in pharmacies, was the only one that registered an annual decrease of its headcount in 2020, by 0.3%. Still, this step back was preceded by an increase of 3.5% in the previous year, which keeps pharmacies the segment with the second highest CAGR for the whole period and suggests that the stagnation in employment in retail of pharmaceutical products is temporary.

As for the two remaining pharmaceutical segments, wholesale headcount grew by 1.1% on an annual basis in 2020, reaching 9,690 people. Despite the slight slowdown in comparison with the previous year, when the number of employees advanced by 1.5%, the segment maintained a three-year CAGR of 1.3%. Manufacture of basic products and pharmaceutical preparations notched up its number of employees by 0.4% last year, returning to growth after the 0.7% decrease in 2019. However, this was not sufficient and made manufacture the sole pharmaceutical segment whose headcount in 2020 was lower than that in the beginning of the analysed period, corresponding to

a negative three-year CAGR of 0.1%. Most vendors in the segment, with the exception of one of the largest manufacturers, have either kept stable or decreased the number of their employees since 2018, which, supported by the slowest growth of operating revenue among all segments, indicates that new investments and expansion of capacity were put on hold even prior to the pandemic.

Fig 5. Full Time Employees in the Pharmaceutical Industry



LABOUR COSTS ANALYSIS BY SEGMENT

In 2020, labour costs, including salaries and social security contributions, in Bulgaria's pharmaceutical industry climbed by 11.3% y/y to EUR 535 mln and, a rate nearly ten times faster than that of new employment and similar to the rise of the overall operating revenue in the sector, which expanded by 12.1% in comparison with 2019. Aggregate personnel expenditure of the vendors in the industry had increased at an even stronger rate of 11.4% in the previous year. Personnel costs were continuously on the rise throughout the period 2018-2020 in all segments

of the pharmaceutical industry. However, growth was not spread uniformly.

As with employment figures, the R&D segment registered the fastest annual rise in labour costs in 2020. Although the segment's employment costs of EUR 73 mln were still the lowest in the industry, they went up by 14.4% last year, following an even stronger expansion of 19% in 2019. A comparison with the rate of increase of the employees indicates that new appointments, and not an increase of costs per employee, have been the major driver for the growing aggregate labour costs in this segment.

Wholesale of pharmaceuticals, the segment with the largest labour costs in the industry, of EUR 260 mln in 2020, registered the second fastest annual growth rate – 12.3%. This represents an acceleration compared with the previous year, when expenses for employees in the segment had grown by 10.5% annually. The other two pharmaceutical segments – manufacture and retail in pharmacies, reported annual growth rates that did not match the industry average. Overall labour costs of drugs manufacturers advanced by 10.2% year-on-

year in 2020, nearly doubling the 2019 rate of 6.1%, and amounted to EUR 95 mln. On the other hand, pharmacies, which had been the second fastest growing segment in terms of labour costs in the previous year, cooled down their growth rate to 7.9% in 2020 from 13.7% in 2019. This deceleration is related to the slight annual decrease of headcount in the segment.

MATERIAL EXPENSES ANALYSIS BY SEGMENT

The material expenses of Bulgarian pharmaceutical companies expanded by 1.4% year-on-year in 2020. This is a significant slowdown in comparison with 2019, when growth rate stood at 7%, and can be attributed to capacity expansions being put on hold especially during the first half of 2020.

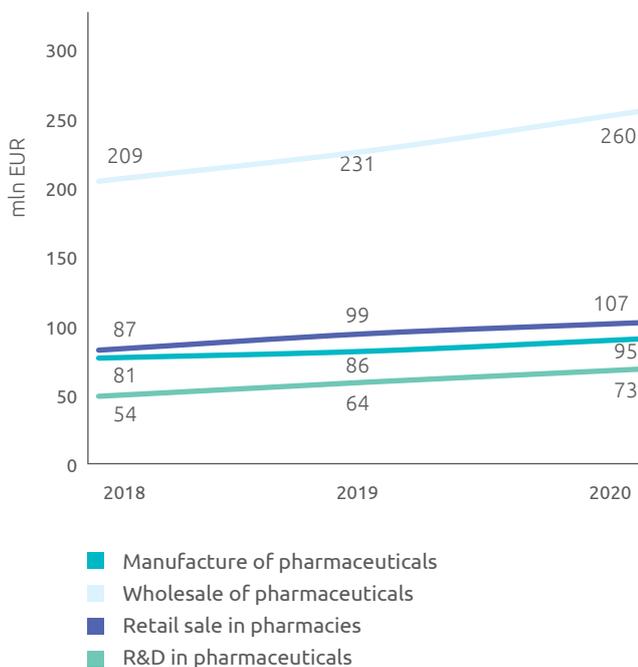
The industry's aggregate material expenses amounted to EUR 366 mln in 2020, having grown at a three-year CAGR of 4.2% registered between 2018 and 2020.

Due to the different nature of activities, material expenses represent widely varying proportions of the operating costs of vendors in the four pharmaceutical segments. Unsurprisingly, manufacturing incurred 89% of all costs for materials, despite being represented by only 1% of the companies in the industry. Its annual growth rate of 1.3% almost matched the industry average. The segment recorded aggregate material expenses of EUR 327 mln in 2020.

Wholesale of pharmaceuticals had the second largest material costs in 2020, of EUR 28 mln. However, during the three-year period under consideration, this was the slowest growing segment in the industry, with a CAGR of 2.2%.

On the other end of the spectrum are pharmacies and R&D companies. As these two segments are specialised in trade and clinical trials, respectively, material expenses play a negligible role in their cost structure. Expanding by 43% y/y, R&D in pharmaceuticals registered the highest annual increase in material expenses, to EUR 2.2 mln, but accounted for only 0.6% of the industry total. Within the last two years, R&D

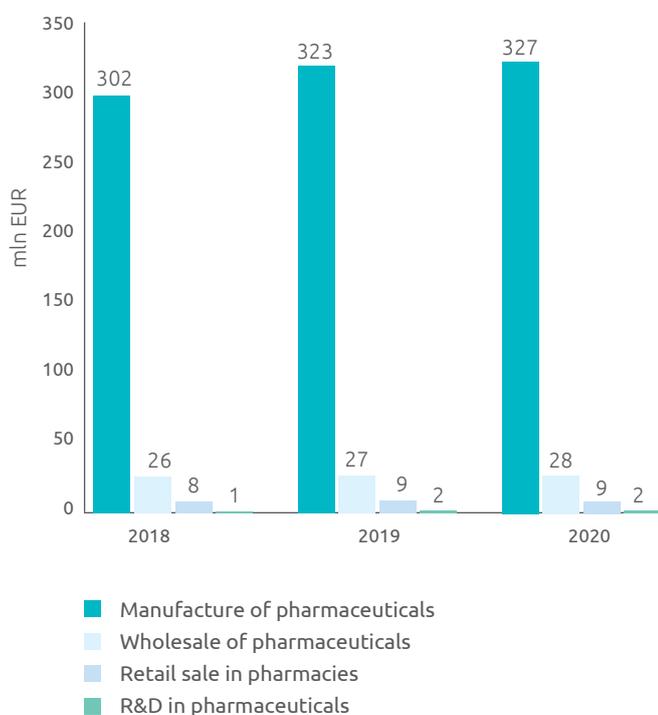
Fig 6. Personnel Costs in the Pharmaceutical Industry by Segment



vendors more than doubled their overall material costs.

Retail sale of pharmaceuticals in pharmacies was the only segment to decrease its material costs on annual basis in 2020, by 2.1% to EUR 9.1 mln from EUR 9.3 mln in the previous year. This setback was preceded by a 15.7% annual increase in 2019, which made pharmacies the segment with the second fastest growing material costs during the 2018 – 2020 period with a CAGR of 6.4%, above the industry average of 4.2%.

Fig 7. Material Expenses in the Pharmaceutical Industry by Segment



PROFITABILITY ANALYSIS BY SEGMENT

The pharmaceutical industry was among the industries that fared well the COVID-19 pandemic.

In 2020, it registered an aggregate net profit of EUR 465 mln, up by 19.4% compared with 2019. Thus, the annual growth rate accelerated from the previous year, when it stood at 12.5%. All segments except R&D activities, which lost 9.4% of its 2019 net profit in 2020, contributed to the rising profitability of the industry.

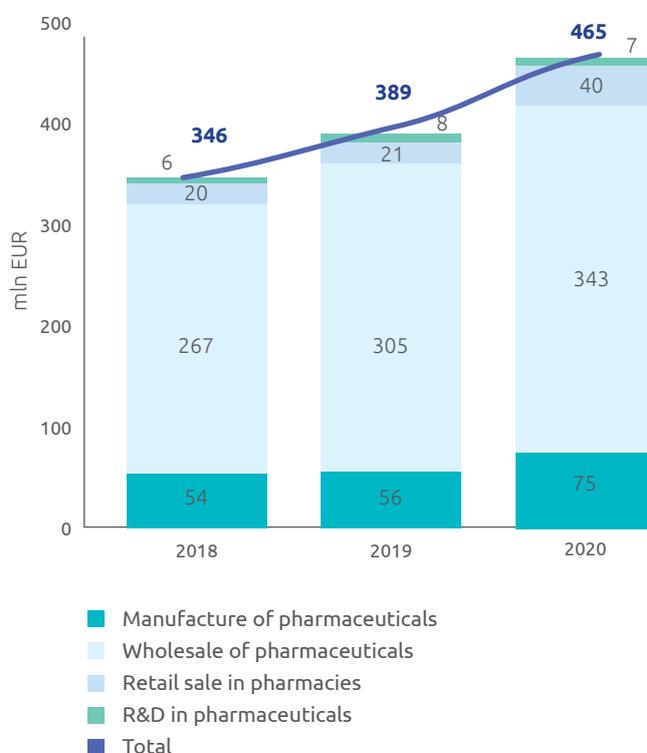
Pharmacies benefitted the most from the soaring demand for drugs and medical products and almost doubled their overall bottom line to EUR 40 mln from the EUR 21 mln booked in 2019.

Wholesale of pharmaceuticals recorded an annual increase of 12.5% to EUR 38 mln in 2020.

The manufacturing segment boosted its net profit by more than a third – to EUR 75 mln from EUR 56 mln, accelerating its annual growth rate almost tenfold in comparison with the previous year, when it had advanced by 4%.

About 82% of all Bulgarian pharmaceutical vendors which reported financial results for 2020 registered a net profit. This share corresponds to the percentage of companies with positive financial result in the previous year, indicating that pharmaceuticals have been and remain a steadily profitable industry.

Fig 8. Financial Result of the Pharmaceutical Industry by Segment



LONG-TERM INVESTMENTS

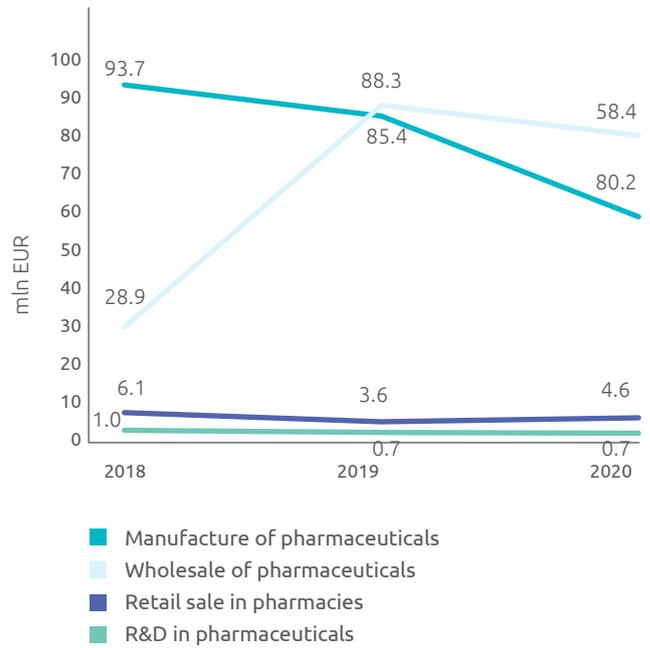
The Bulgarian pharma industry’s combined investment in long-term assets amounted to EUR 143.9 mln in 2020. Investments dropped by 19.2% compared to the record-high EUR 178.0 mln booked in 2019.

Investments in long-term assets made by the different pharma segments fluctuated throughout the years, but the manufacturing and wholesale segments were constantly the largest investors. Their combined investments exceeded 90% of the industry’s total in each year in the 2018-2020 period.

Although investments varied during the period under review, the manufacturing segment was the leader each year, with an aggregate investment of EUR 237.5 mln for the whole period. Wholesalers also had significant, although smaller investments in long-term assets, totalling EUR 197.5 mln for 2018-2020.

The rest of the industry segments acted more conservatively. Retail sale in pharmacies spent a total of EUR 14.3 mln on long-term assets in 2018-2020, while R&D in pharmaceuticals reported a combined outgoing investment cashflow of EUR 2.3 mln in the period under review.

Fig 9. Investments in Long-Term Assets



9. INDUSTRY TRENDS AND FORECASTS

The pharmaceutical industry in Bulgaria enjoyed a successful performance in 2020, becoming one of the very few sectors of the economy to benefit from the global health and economic crisis caused by the COVID-19 outbreak. The latter left its mark in the following two years as well, with some of the changes in the pharma industry being here to stay. Demand for medicines and pharmaceutical goods proved resilient to the recession and is expected to remain on the rise in the short to medium term. The R&D segment holds the biggest potential for exponential growth as new technological advancements will likely fuel growth at a rate far above the average of the industry.

Furthermore, as a consequence of the global supply chain interruptions in multiple sectors, caused by the pandemic and more recently by the war in Ukraine, European corporations increasingly seek risk diversification to guarantee the adequate supply of medicines as part of Europe's strategic security.

This could be an opportunity for Bulgarian producers of pharmaceutical products and preparations to position themselves as an integral part of the supply chains of the European pharma industry.

An additional incentive for the possible relocation of production facilities or securing raw material suppliers in geographical proximity is the EU's goal to minimise carbon footprint, an objective which all businesses, including pharma companies, will have to meet in the near future.

Bulgaria's pharmaceutical industry is projected to maintain its expansive growth by 2023 in terms of market size, vendors numbers and financial performance. Its aggregate turnover is projected to reach EUR 9.375 bln by 2023, growing at a CAGR of 11% per year. Among the segments, R&D is expected to advance at the fastest rate, of 16% annually, followed by wholesale of pharmaceuticals, which is projected to

grow at a CAGR of 13% in the same period. The industry headcount will also be steadily on the rise, although at a considerably lower speed, due above all to limitations of available workforce. The overall number of pharma employees is seen exceeding 33,850 by 2023, up from 32,000 as of end-2020. Once again, pharmaceutical R&D and clinical trials will be the hottest segment with employment set to expand by 14.4% annually by 2023. In terms of profitability, the performance of the industry is also expected to improve further and, provided that its net financial result grows at the CAGR of the period 2018 – 2020, its aggregate net profit could be in excess of EUR 725 mln in 2023.

DINKOV, MAXIMOVA, RUSEVA-SAVOVA

MODERNISING ONLINE PHARMACIES' REGULATION UNDER BULGARIAN LAW FOR EMBRACING INNOVATION AND DIGITISED SUPPLY CHAIN SOLUTIONS

Mrs. Zlatina Ruseva-Savova is the Managing Partner of Dinkov, Maximova, Ruseva-Savova, a law firm rendering a quick response, world-class quality and solution-oriented legal services. She has long-standing experience in advising multinational life-sciences, pharma and trade companies on their strategic projects and day-to-day business in Bulgaria.

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Does current Bulgarian legislation answer the needs of e-pharmacies?

According to a recent study of the top pharma supply chain trends, conducted by CosmoTrace, online pharmacies are expected to grow further in 2022 and beyond.

The increasing complexity of the supply chain ecosystem and innovative eCommerce models bring about the need for the adoption of upgraded, new legal provisions with regard to sales of Over-the-Counter ('OTC') medicines by online pharmacies. With good reason, projects in this area are created and operated as agile processes.



Can you outline some proposed legislative changes?

Currently, effective Bulgarian legislation does not provide workable solutions to meet the evolving needs of online pharmacies and consumer attitudes. Identified areas of improvement that would address supply chain bottlenecks include, for example:

- Possessing the 'right of use' of a website (sub-domain) of a third-party is not covered under current legislation, but an online pharmacy is required to have an 'own' Internet website, although the effect may be the same in both cases in practice;
- B2B integration platforms and certified third-party sellers could be introduced, so that consumers will be able to enjoy access to a broader range of products;
- Embracing flexible transportation/shipping and direct-to-patient delivery patterns would ensure same-day drug delivery throughout the country. One possible legislative change could be that e-pharmacies are expressly allowed to deliver

OTC medicines to the customers by also using licensed transportation vehicles of a third-party seller (eCommerce partner) in contrast to “own ones or at their disposal” , where all temperature storage, relative humidity, direct sunlight and other applicable transportation conditions shall be complied with. International and humanitarian aid law permits for medicines to be transported even by airplanes, which obviously are not owned or held by their retail sellers;

Adopting such amendments would increase the value-based healthcare, competitiveness and will make existent state-of-the-art European solutions available to the Bulgarian consumers too.

How to mitigate patient health-related risks while modernising online sales of medicines legislation?

Observing good distribution practices, on-demand distribution process visibility and transparency are needed at all times. It would be feasible to also introduce a regulation for Good Distribution Practice in the online sale of medicinal products, as there is currently only one relating to wholesales.

Putting quality assurance system and processes in place, following the model of countries such as Germany, for example, would facilitate trust among all stakeholder. This measure could be either mandatory or voluntary, as quality checks are performed by multinational players in any event. Assuring good patient-pharmacist connection for adequate treatment is crucial.

Introducing “new pathways of implementation of the supply chain to patients without jeopardising their health” has been addressed in academic publications (for example, S. Kochev, M. Pesheva, E. Grigorov (2015b) .

How do you see e-pharmacies of the future?

Some European Union (‘EU’) Member States have already made a shift. German, Danish and other online pharmacy platforms deliver medicines across the EU. In Germany, OTC drugs can be mailed to patients globally, but “import regulations of the receiving country should be verified in advance” . According to

the European Parliament : (i) in southern EU Member States and Germany “online purchases of medicines are not allowed if they are on prescription in the country of destination”; while (ii) in the Scandinavian states online sales are possible “as long as online pharmacies do not actively advertise in other Member States” .

Bulgaria is following the approach of Austria and France where e-pharmacies are allowed to sell OTC medicines only. Other countries such as Germany, Denmark, Spain, Italy and Sweden have also allowed prescription drugs to be sold over the Internet , as allowed by Directive 2001/83/EC. Prescriptions issued by doctors or dentists in other EU/EEA countries can be dispensed by a Danish pharmacy.

Blockchain technology will continue to increase its importance in the distribution of drugs for detecting low-standard and counterfeit medicines that enter the supply chain.

¹<https://blog.cosmotrace.com/serialization/top-8-pharma-supply-chain-trends-2022>

²Art. 41, Para. 1 of Regulation No. 28 of 9.12.2008 on the structure, procedure and organization of the work of pharmacies and the nomenclature of medicinal products (‘Regulation No. 28’).

³Art. 42, Para. 2 of Regulation No. 28.

⁴“Online trade with medical products - essence, aspects, function”, Varna Medical Forum, Vol. 4 (Suppl. 2), 183.

⁵European Parliament www.europarl.europa.eu/doceo/document/E-8-2018-002879_EN.html; *Distribution and Marketing of Drugs: Jurisdictional comparisons, European Lawyer reference series, the Chapter on Germany* by Dr. C. Willhoeft and Field Fisher Waterhouse LLP, 2013.

⁶www.mdpi.com/journal/pharmacy.

10. METHODOLOGY

The current pharmaceutical industry report encompasses 3,660 companies from four pharmaceutical segments in Bulgaria. Pharmaceutical vendors missing complete financial data for 2020 are taken into account in the vendors landscape part of the report, but are not included in the financial and employment analysis.

The report preparation took place between May and June 2022.

FINANCIAL ANALYSIS

The financial analysis consists of six chapters, each based on the main indicators used – operating revenue, employment, personnel costs, material costs, long-term investments in fixed assets and profitability. The analysis is made based on the aggregate values of the included companies, distributed according to their core activity.

The identification process consists of the following steps:

- The initial pool of companies is derived by individual desktop check of all companies in our database with industry classification in one of the following fields (NACE rev. 2.0): 21.10; 21.20; 46.46; 47.73; 72.11; 72.19.
- Manual desktop research to classify each company into one of the previously defined segments. In cases a company performs activities in more than one segment, it is classified only in the segment which can be defined as primary.

We have used the official non-consolidated company records of all vendors to collect information about financial indicators such as operating revenue, salary costs and expenditure for social security contributions, material expenses, long-term investments in fixed assets, net profit and loss for the three consecutive years - 2018-2020.

The time analysis is based on the aggregated indicators

of all companies for 2019 and 2020. Forecasts for the period 2021-2023 are calculated based on the compound annual growth rate (CAGR) of the companies in the respective segment in the three-year period under review. All calculations are in euro, converted at the fixed Bulgarian lev (BGN) to euro exchange rate of EUR 1 = BGN 1.95583.

NON-FINANCIAL CHAPTERS

This report examines the current state of the pharmaceutical regulations and presents the direction in which they will evolve in the future, both at EU and national level in Bulgaria.

We have gathered data through desktop research of official sources, such as European institutions, Eurostat, government institutions and news outlets.

For each company in the Vendors landscape chapter we have identified: headquarters (according to the official company records the Trade Register) and incorporation date (based on the date of official entry into the Trade Register). The distribution of companies by geographic location is based on their headquarters, regardless of the actual location of their facilities, often spread across multiple districts.

The examples for innovative R&D projects that highlight the place of Bulgaria's pharma industry on the global map are presented through case studies based on desktop research.

11. DISCLAIMER

The information provided in the Pharmaceuticals Sector in Bulgaria Report does not, and is not intended to, constitute financial advice, and is not to be acted on as such. Instead, all information, content, and materials available in the Pharmaceutical Sector in Bulgaria Report are for general informational purposes only to permit you to learn more about the development of this sector in Bulgaria.

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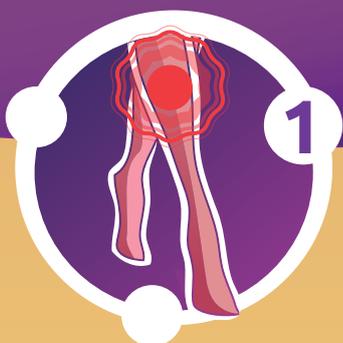
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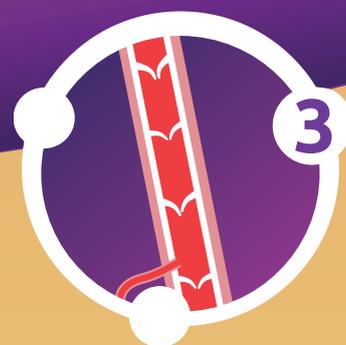
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