City of Munich
Department of Labor and Economic Development

2021

Biotechnology and Pharmaceutical Industry in the European Metropolitan Region Munich (EMM) 2021

Executive Summary

Facts and figures

In 2020, the European Metropolitan Region Munich (EMM) was home to 373 biotechnology and pharmaceutical companies with a total of 33,400 employees.

The EMM accounted for 165 biotechnology companies in 2020. An additional 63 biotechnology companies have either been founded or moved to the region since 2015, with 16 new companies launched in 2020 alone. A number of acquisitions, fusions, departures from Munich, and company closures explains why the total number of companies remains almost the same as in 2013. The number of staff employed by biotechnology companies has risen to 18,500, which reflects the sector's tremendous 91 % growth since 2013.

Some of the 31 pharmaceutical companies in the region are local sales offices of major international pharmaceutical companies which have their German headquarters in the EMM, while others are medium-sized companies conducting research and development in the region. Pharmaceutical companies employed some 5,900 people in the EMM in 2020.

51 Contract Research Organizations (CROs) with 2,300 employees are based in the EMM. These organizations carry out or coordinate preclinical and clinical studies for biotechnology and pharmaceutical companies, thus playing an important role on the path to gaining authorization for drugs and medical devices.

In addition, 126 Life Science companies are active in the region and are classified as part of the EMM's pharmaceutical and biotechnology sector. They are an important economic factor in the EMM, employing some 6,700 people.

While the number of companies is almost the same as it was in 2013, the sector's success is visible in the clear rise in employment numbers and projects in the pipeline.

The majority of companies are optimistic about the future, with 80 % expecting their business prospects to improve in the next three-to-five years. 95 % of the companies surveyed have their German headquarters in the EMM. When it comes to international markets, 98 % of the companies are active in the EU, 63 % in the USA, 35 % in Japan and 34 % in China. These countries are also leaders in other markets of interest to the companies.

EMM success factors

Product pipeline of companies in the EMM

One focal point of biotechnology and pharmaceutical companies in the EMM is the development of drugs and diagnostics.

There are currently 126 candidates in clinical development, with 35 projects in clinical phase III. The number of drugs developed by local SMEs which have been authorized for use has doubled from six to 12 since 2013.

The majority of substances in clinical development relate to cancer therapy, followed by therapies against autoimmune diseases.

Excellent research landscape in the EMM

Generating and sharing knowledge for future innovations is key to a region's success. A number of excellent and renowned universities are based in the EMM, including the Ludwig-Maximilians-Universität München (LMU), the Technical University of Munich (TUM), the Catholic University of Eichstaett-Ingolstadt, and the University of Augsburg. The region has a total of almost 170,000 students, along with scientists at 16 research institutions.

Start-ups in the EMM

The Munich Metropolitan Region offers entrepreneurs in the biotechnology industry ideal conditions for doing business and is one of Germany's start-up hotspots. 56 biotechnology companies have been founded in the EMM since 2015, and the curve is continuously rising. In addition, seven existing companies have set up branches in the region.

Partnerships

When it comes to cooperation within the biotechnology sector in the EMM, what particularly stood out in the Bio^{M} survey was cooperation between companies and research institutes based in the region. A large number (around 27 %) of those surveyed said they had benefited enormously from the cooperation between industry, research institutions, and universities.

Challenges

However, companies in this sector face various challenges. International pressure from competitors and the difficult German investment climate are two equally prominent examples. There is a shortage of laboratory and office space on a regional level. Bureaucratic obstacles such as the German Foreign Trade and Payments Act ("Außenwirtschaftsgesetz") have also increased pressure on the industry.

Impact of the coronavirus pandemic on the industry

Pharmaceutical and biotechnology companies have attracted an enormous amount of attention since the coronavirus pandemic began. From the very start the industry was seen as the key to overcoming the pandemic.

To this end, major programmes were launched across the world, and particularly in the USA. The primary focus was on researching, developing, and producing vaccines against the virus. Additional programmes focused on developing therapies against COVID-19 and preventing future pandemics.

In Germany, the federal government launched a EUR 750 million „National Special Program to Promote COVID-19 Research" („Nationales Sonderprogramm zur Förderung der COVID-19-Forschung") in 2020 and funded the biotechnology companies BioNTech from Mainz with EUR 375 million and CureVac from Tübingen with EUR 230 million from the special vaccine development program. The vaccine from BioNTech Pfizer became the world's first to gain authorization, including for use throughout the EU in December 2020.

EMM companies and the fight against COVID-19

World-class testing systems, vaccine development, and excellent therapy concepts from the region

Numerous companies and scientists from the EMM were working on testing systems and vaccine candidates from the moment the pandemic began, as well as on developing drugs. In the company survey on the coronavirus pandemic carried out in early 2021, 70 % of respondents said they were involved in the development, production, or sale of products, supply parts, or services relating to the pandemic.

For example, various world-class testing systems were developed in the EMM. Numerous products were authorized for use, from PCR and antigen tests and analysis methods for the precise genomic classification of new mutations, to highly specific serologic tests for detecting antibodies against the SARS-CoV-2 virus, and rapid self-tests.

Additional vaccines are also being developed in the EMM. The region's biotechnology companies are notable both for their research into "second generation" vaccines which are also highly effective against virus mutations, and their international partnerships.

In addition to innovative COVID-19 analysis methods and vaccine candidates, there are also many excellent approaches to therapy in the EMM. A total of 22 outstanding therapy concepts from Bavaria were submitted as part of the "BayTherapie2020" funding programme, of which 20 came from the EMM.

Funding programme "BayTherapie2020"

Funding is essential in order to implement therapeutic developments, particularly in late clinical phases. The EUR 50 million Bavarian funding programme "BayTherapie2020" supports five companies in developing therapies against COVID-19.

New pandemic research centre in Penzberg – lighthouse project for the region

A new campus for research into infections, immunity, and pandemics is to be built in Penzberg, near Munich. The centre, which will be part of the Fraunhofer-Gesellschaft, will work with Roche Diagnostics and the Ludwig-Maximilians-Universität München to investigate the role of the immune system in infectious diseases.

A total of around EUR 80 million is to be invested in implementing the project, with the Federal Government and the State of Bavaria providing an equal portion of the funds. Around 50 scientists from the fields of medicine, microbiology, and IT will work at the new location.

Survey on effects of the coronavirus pandemic – plenty of positives but also some concerns for the EMM's biotechnology companies

Bio^{M} conducted an initial survey among companies in Bavaria's biotechnology cluster in May 2020 and repeated it in 2021. The 2021 survey yielded the following main results:

- 70 % of the companies surveyed offer products or services which can be used in the fight against SARS-CoV-2/ COVID-19.
- 82 % of respondents had few or no concerns about the consequences of the coronavirus pandemic on their companies, while 18 % were concerned.
- While 35 % of respondents reported an increase in sales, 31 % reported no notable impact, and 34 % suffered a decline in sales, in some cases quite severe.

- 17 % of companies requested financial aid from the Free State of Bavaria or the Federal Government.
- Supply bottlenecks, organizing working from home and work procedures, hygiene measures within the company, and the difficult issue of childcare were reported as the biggest challenges the companies faced.
- 26 % of companies adapted their productions channels and/or supply chains, 24 % increased production, while 2 % reduced it. 20 % increased their staff numbers, while 9 % introduced short-time working ("Kurzarbeit"). 2 % of companies were forced to make redundancies.
- 18 % of respondents were looking for cooperation partners to develop COVID-19-related products and services. The more than 110 entries on the Bio^{M} COVID-19 platform impressively demonstrate the willingness of companies in Bavaria's biotechnology cluster to collaborate.

Desires and requests of EMM companies in the coronavirus pandemic:

- Financial support, including for non-coronavirus-related projects
- Better availability of laboratory space
- Reliable framework conditions
- Vaccination and testing services
- Better childcare options
- Ending travel restrictions/opening of borders
- Greater visibility of biotechnology

The coronavirus pandemic led many players in the field of healthcare to collaborate and pool their knowledge and resources. This was a tremendous feat on the part of those involved, resulting in numerous successful testing and diagnostic systems and authorization for highly effective vaccines. It remains to be seen whether the positive impact on the biotechnology and pharmaceutical industry will persist in the coming years or fade away once the pandemic has been defeated.

Developments and industry trends

Its many areas of application and potential for innovation make biotechnology a key cross-sector technology of the 21st century. Nevertheless, the survey showed a clear trend towards personalized medicine, cell and gene therapy, and the use of artificial intelligence and Big Data and digitization in general. Other clear trends included the development of vaccines and immunotherapies.

Digitization

On the whole, Germany has a good health system. At the same time, it is one of the most expensive compared to other countries, and overall performance is only slightly above average. Consistent and targeted digitization would be one means of improving performance.

New digital options include online consultations, health telematics, electronic patient files, electronic prescriptions, and health apps. Digital methods like artificial intelligence (AI) and machine learning (ML) also play an ever greater role in recording and treating illness and disease, as well as in the development and authorization of therapies. Availability in usable formats, qualities, and quantities, as well as evaluation of the tools, is essential in this area. At the same time, clear ethical and data protection standards need to be established concerning data use.

Big Data and AI are the most used digital applications

Digitization has many application areas in which different technologies are used. This is reflected in the way the EMM's companies use digital technologies in their respective fields. The most popular technologies among those surveyed were Big Data analytics (67 %) and artificial intelligence (58 %). 24 % use 3D printing, 22 % the Internet of Things (IoT), while only 7 % use blockchain technology. Other applications used include electronic data collection and relevant data management as well as Cloud solutions.

Obstacles associated with digitization

The vast majority (89 %) of companies surveyed see digitization as an opportunity. Only 11 % see it primarily as a challenge. When it comes to obstacles associated with digitization, companies identified IT security (71 %) and data protection (58 %) as the primary concerns. Companies' reluctance to accept digitization, as well as a certain scepticism on the part of laboratories, hospitals, and customers concerning the General Data Protection Regulation (GDPR) and/or Cloud solutions, were also mentioned as obstacles.

On the issue of digitization framework conditions in the region, it was also claimed that hospital infrastructure is in some respects not as developed as it should be despite the Future of Hospitals Act („Krankenhauszukunftsgesetz", KHZG). When it comes to balancing interests, data protection is seen as being prioritized far too much over patient benefits, supposedly making innovative (and often international) solutions more difficult. Different interpretations are perceived as being possible within the regulatory framework, but, supposedly, often no attempt to adopt such interpretations is even made. At another point in the survey, the existing framework conditions were generally rated "good". In particular, participants reported great developments in digitizing laboratory environments. However, the use of real-world data from Germany for research purposes is not very well regulated. According to the participants, an improvement in this area would provide an additional boost to research in Germany and benefit many patients. There is

also a desire to see better linking of registry data, and health data should be made more easily available for research purposes.

41 % of companies see the costs of digitization as an obstacle. Additional barriers include the availability of suitably qualified staff (36 %), general levels of expertise in companies and the time investment involved (both factors 35 %). The poor quality of some infrastructure and/or the availability of a sufficiently high-speed internet connection are also problems for some companies when it comes to implementing digital applications.

Requests from scientific research institutions

Research institutions are also expressing their need for better access to clinical healthcare data and real-world data. This would entail, for example, setting up an ecosystem for the safe and transparent sharing of data. In addition to regional and national approaches such as the Leibniz Supercomputing Centre (LRZ) and the National Research Data Infrastructure (NFDI), another highly promising approach is the design and use of the emerging European data infrastructure GAIA-X. In certain respects, better cooperation and mutual understanding on the part of various disciplines is also needed to improve translation, while closer links between experimental research and data science on all levels of research institutions would be beneficial.

Influence of digitization

The majority of companies that took part in the survey share the view that digitization will decisively change the biotechnology and pharmaceutical industry. 17 % strongly agree, 30 % agree to a large extent, and 43 % to a moderate extent. Only 10 % believe that digitization will not change the sector in a major way.

Opinions are split as to whether digitization will also decisively alter processes or products. 51 % do not foresee a decisive change, while 49 % hold the opposite view. The primary influence of digitization is felt in the areas of process optimization, general data collection and processing, and software use and development.

Personalized medicine

Every person is unique. It follows that diseases also often have unique elements in terms of cause and impact on individuals. Personalized medicine is based on identifying relevant differences in the biology and living conditions of individuals with comparable diseases or illnesses and dividing them into patient groups with common traits. Personalized medicine is part of what is known as "P4 medicine" (Predictive, Preventive, Personalized and Participatory), which aims to treat illnesses in a more individual and personalized way. The clear aim of personalized medicine is to offer patients suitable therapy as quickly as possible and thereby also make healthcare more efficient.

Digitization is ascribed a key role in personalized medicine. It offers the chance to improve the availability of health data for identifying relevant biomarkers, and for specific, tailored therapies, thus also helping to reduce side effects and treatment costs. Biomarkers are biological features, changes, and characteristics, for example of surface structures on tumor cells, which define these cells and may also contribute to tumor growth. There are diagnostic, predictive, and prognostic biomarkers, which allow predictions to be made about the likely success of a particular therapy, as well as therapy monitoring. Thorough diagnosis is essential, often combined with omics analysis of the patient, which studies biological data at a molecular level. This may involve analyzing an individual's complete genetic profile and metabolic products (genomics, epigenomics, transcriptomics, proteomics, metabolomics, secretomics, and microbiomics).

45 % of drug authorizations (25 substances) in Germany in 2020 were biopharmaceuticals, i. e. drugs produced by biotechnological means for treating e. g. cancer, infectious diseases and diseases affecting the immune system. The total number of authorized biopharmaceuticals in Germany has risen continuously from 240 in 2015 to 339 at the end of 2020, with total sales of EUR 14.6 billion. Antibodies have been the largest class of authorized biopharmaceuticals since 2018, followed by vaccines. 107 antibodies accounted for almost 32 % of all biopharmaceuticals in 2020, with 71 vaccines accounting for a further 21 %. 93 substances are currently authorized as "personalized" drugs in Germany. For 84 of these, a diagnostic pre-test ("companion diagnostics") is required, while it is recommended ("complementary diagnostics") for an additional nine. (As of 8 August 2021) Diagnostics and therapeutics often go hand-in-hand in personalized medicine.

Many companies in the EMM are key players in the development of personalized therapies and diagnostic systems. For example, Roche and MorphoSys produce highly effective monoclonal antibodies for oncological applications. Immunotherapies such as CAR-T cell therapies (chimeric antigen receptor T cell therapies) are also being successfully developed in the region by Medigene and other companies and are being used at the LMU's and TUM's university hospitals. Optimizing omics analyses is another focal point in the EMM, for example at PreOmics GmbH in Martinsried.

From 2010 to 2015, the Munich-based concept „m4 - Personalized Drug and Targeted Therapies" was funded by the German Federal Ministry of Education and Research (BMBF) as part of the Leading-Edge Cluster. At the core of the m4 projects were targeted therapies, the identification of biomarkers as new targets for drugs and diagnostic systems, the development of innovative technology platforms and new forms of diagnosis, as well as infrastructure projects,

which together boosted Munich's capabilities in the field of innovation. In the Free State of Bavaria, the pilot project "DigiMed Bayern", which runs from 2018 to 2023 and will advance P4 medicine in the Munich Metropolitan Region via research into the common disease atherosclerosis, is also noteworthy.

Changes in authorization, regulation, and reimbursement

Authorization of vaccines

The European Medicines Agency (EMA) has accelerated authorization procedures, analogous to those of the Food and Drug Administration (FDA) in the USA. These accelerated procedures were recently decisive, for example, in the emergency use authorization granted to vaccines against the SARS-CoV-2 virus.

Changes to authorization for in vitro diagnostics and medical devices: IVDR & MDR

Access to EU markets for in vitro diagnostics (IVD) was newly regulated in 2017. The new EU regulations on in vitro diagnostics (IVDR; EU 2017/746) and medical devices (MDR; EU 2017/745) both came into force on 25 May 2017. After the transitional period has expired, they will replace EU Regulation 93/42/EWG as of 26 May 2021 (MVD) and EU Regulations 98/79/EG and 90/385/EWG as of 26 May 2022 (IVDR). By those dates, all IVDs which have been authorized to date must be re-certified.

The IVDR provides a solid, transparent, reliable, and long-term legal framework for in vitro diagnostics. This will ensure high levels of safety and health protection and also promote innovation. The new EU regulation differs in several key points from the expiring EU regulation for IVD. Changes include the introduction of a new classification system. The immediate validity within EU member states ensures a smoothly functioning market within the EU, above all for small- and medium-sized enterprises (SMEs). EU regulations regarding authorization for IVD no longer apply in the United Kingdom following its departure from the EU. Every IVD and medical device must be newly authorized in the UK.

Legal framework for digital health apps: Digital Healthcare Act (Digitale-Versorgung-Gesetz, DVG) & Digital Health Applications Regulation (Digitale Gesundheitsanwendungen-Verordnung, DiGAV)

The number of digital health apps and services for virtual consultations with doctors is rising steadily. With the Digital Healthcare Act (DVG), the Digital Health Applications Regulation (DiGAV), and the guidelines of the Federal Institute for Drugs and Medical Devices (BfArM) according to Section 139e of the German Social Code (SGB V), the necessary legal framework was created to rapidly make "apps on prescription" a regular feature of healthcare. The DVG, which aims to improve healthcare via digitization and innovation, entered into force on 19 December 2019, while the DiGAV and guideline on the fast-track procedure for health apps (DiGA) followed on 8 April 2020.

As a result, health apps can now be prescribed by doctors and therapists and patients' costs are reimbursed by statutory health insurance providers (gesetzliche Krakenkassen, GKV). The app must have a functional, user-friendly, and transparent directory, and have undergone independent, structured, and reliable tests. The DiGAV clearly defines what requirements apps have to fulfil regarding safety, quality, data protection, and data security to obtain CE marking. As long as they pass the testing procedure, approved apps are included in the DiGA directory on the basis of a fast-track procedure (no later than three months after the application for inclusion). According to the BfArM, since the fast-track procedure was launched on 27 May 2020, 88 applications have been submitted (as of 4 August 2021).

Pharmaceutical Market Reform Act (AMNOG) and reimbursement

Ten years ago, on 1 January 2011, the law to reform the German pharmaceutical market („Arzneimittelmarktneuordnungsgesetz", AMNOG) entered into force. On the one hand, the aim was to curb the rapidly increasing drug expenses facing statutory health insurance providers. On the other hand, it aimed to close the loophole in drug pricing regulation for the early authorization of drugs with additional benefits – giving patients faster access to innovative treatments. Price regulation in the form of reimbursement means doctors can more reliably prescribe drugs and still have early access to new drugs. However, reimbursement is a major problem with respect to personalized medicine. When it comes to the previously mentioned "tandem" of diagnostics and therapies in personalized medicine, authorization for reimbursement is not always as fast. As a result, patients often cannot access the therapy that is best suited to them.

As of 9 November 2020, around 60 % of all new substances reviewed were classified as bringing additional benefits. These were frequently substances from the field of oncology. During this period, relief for statutory health insurance providers in the form of reimbursement rose from EUR 0.4 billion in 2011 to EUR 4.4 billion in 2020. The figure is expected to be EUR six billion in 2021. The annual therapy costs for non-rare diseases (incidence of more than five per 10,000 inhabitants) have remained fairly stable since 2012 at around EUR 50,000. However, innovative drugs to treat particularly rare diseases (known as orphan drugs) have led to major price increases. They have climbed from around EUR 100,000 in 2012 to around EUR 350,000 in 2019.

Law for Greater Safety in the Supply of Drugs (GSAV)

Alongside health apps, biopharmaceuticals are also the subject of increasing focus and are the preferred treatment for many diseases. Analogous to generic drugs, doctors and especially pharmacists can avail of alternative biopharmaceuticals, known as biosimilars, to reduce costs for statutory health insurance providers. However, gaining authorization for biosimilars is more difficult than for generic drugs. The Law for Greater Safety in the Supply of Drugs (GSAV), which was drafted by the Federal Ministry of Health and entered into force on 16 August 2019, aims to make biosimilars more rapidly available and to further improve the quality and safety of drug supply. The GSAV can also help to counteract supply bottlenecks, as the statutory health insurance providers are obliged to consider the diversity of suppliers in the case of discount agreements. From August 2022, an amendment to Section 129 of the German Social Code V (framework agreement on the supply of medicinal products) means that pharmacists will have the right to swap biological reference drugs for biological drugs produced using biotechnology. The amendment is controversial among doctors and the pharmaceutical industry. With respect to new types of therapy such as gene therapy, quality assurance measures will guarantee appropriate use. An additional important milestone in the German health system is the introduction of electronic prescriptions from January 2022, regulated in the GSAV.

Financing

The economic development of pharmaceutical and biotechnology companies in 2020 was greatly impacted by the coronavirus pandemic. However, in contrast to many other industries, the effects were primarily positive. While biotechnology seemed to be losing some momentum in previous years, numerous companies posted record figures in the last few quarters. Many of these companies hope that this positive trend will continue into the future. It needs to be pointed out, however, that not all sectors and companies in the biotechnology industry have benefited equally. Nevertheless, regardless of their particular focus, many companies were in a position to react to the changes the pandemic caused and in some cases to benefit from them.

Generally speaking, the pandemic has improved the fortunes of the biotechnology sector around the world. However, the industry is still completely dominated by the USA, where the available capital is far larger than, for example, in all of Europe combined. Capital raised in the USA has leapt from USD 46.3 billion to USD 99.4 billion. Despite a similarly positive development, Europe still lags far behind at EUR 16.2 billion.

Germany is one of the leading locations within Europe and in 2020 recorded a 36 % increase in sales (EUR 6.5 billion). In terms of capital raised, the 2020 sum of EUR 3.05 billion was almost three times higher than the previous record from 2018. The enormous increase here is again due to the pandemic, and to a large extent just a small number of biotechnology companies dominate the figures. Particularly successful were, for example, the initial public offerings of CureVac and Immatics, which generated EUR 439 million of capital.

Bio^{M} carried out a comprehensive survey to assess the economic situation of biotech companies within the EMM. The majority of respondents have a very positive view of the current situation of the pharmaceutical and biotechnology industry in and around Munich. The sector gained a lot of attention and public awareness of the significance of biotechnology increased. However, some companies stressed that to truly benefit from these positive effects a lot more investment is needed in the future.

Cautious estimates suggest that investment of about EUR 500 million flowed into the EMM in 2020 from various sources (not including EUR 325 million of convertible bonds placed by MorphoSys). ITM AG and Immunic were able to obtain EUR 40 million and EUR 25 million loans respectively from the European Investment Bank (EIB). Also notable was Bavarian Nordic's sale of a priority review voucher with a total value of USD 95 million. CatalYm, Immunic, Formycon, Kaia Health Software, and Tubulis were all able to secure funding in the two-digit million range. There were also a number of companies which secured seed financing in the single-digit million range. In the EMM survey a total of 14 % of companies said they obtained equity financing in 2020. Around 18 % of respondents opted for debt financing.

Networks and networking in biotechnology

The European Metropolitan Region Munich is one of Europe's leading economic regions and a leading global location for start-ups. The EMM's greatest strengths are its concentration of knowledge as a major research centre and a very broad technological base with a variety of innovative industries. The region's biotechnology and pharmaceutical sector boasts a strong and vibrant network. The importance of cooperation and networks is clear from the survey of companies and research institutions located in the region: Around 27 % of respondents said they had benefited enormously from the cooperation between industry, research

institutions, hospitals, and universities. The cooperation between companies and local research institutions was particularly valued.

The Bavarian Biotechnology Cluster, start-up centres, and networks

A vibrant and successful biotechnology scene has established itself at four locations in Bavaria. Munich, Regensburg, Würzburg, and Straubing are among the leading German locations for biotechnology. The Bavarian Biotech Cluster links organizations and centres across the region as part of the "Clusteroffensive Bayern".

Key players in the European Metropolitan Region Munich are the biotech cluster organization Bio^{M} in Martinsried, the Innovation and Start-up Center Biotechnology (IZB) in Martinsried and Freising, as well as the networking agency for industrial biotechnology in Bavaria (IBB Netzwerk GmbH). Three consortia from the biotechnology and pharmaceutical industry, ImmPact Bavaria, the Bavarian Diagnostics Network (Bayerische Diagnostik Netzwerk) and the Tools for Life Sciences Network also contribute to the region's international competitiveness.

The close proximity of scientific institutions, technology parks, and companies, along with support from cluster organizations, creates a perfect environment for both new and existing biotech companies to establish themselves in the region. The organizations have managed to develop a strong network of companies, universities, research institutions, university hospitals, chambers of industry and commerce, as well as associations, investors, consultants, and other stakeholders.

Technology transfer in Munich and Bavaria

There are numerous organizations in the EMM, Germany, and Europe that are committed to transferring knowledge from scientific institutions to business. The most important partners for innovation transfer are Ascenion GmbH, Bayerische Patentallianz GmbH (BayPAT), Max Planck Innovation GmbH, and the Bavarian universities' transfer points (TBH).

Congresses and conferences

The City of Munich makes the EMM an internationally renowned location for congresses, conferences, and symposiums in the Life Sciences. Major conferences such as Analytica, BIO-Europe, and BioVaria have been taking place here for years. The current state of biotechnology research is presented at, for example, the FORUM Science & Health and the DigiMed Bayern Symposium. As a start-up hotspot in Germany, the EMM also offers young start-ups numerous opportunities to learn and apply for funding. Established opportunities include the BioEntrepreneurship Summit, the BioTech Bootcamp, the Grow Roadshow events, as well as workshops, coaching, and networking events organized by the LMU Innovation & Entrepreneurship Center and the Technical University of Munich's UnternehmerTUM GmbH. All these formats held virtual and hybrid events to maintain contact and dialogue during the coronavirus pandemic.

Start-ups

The EMM offers entrepreneurs and young companies ideal conditions and is thus a key hub for technology-oriented start-ups in particular. Close links between science, research, and business create an excellent environment for developing and implementing innovative ideas. The EMM's well-established and renowned research landscape with outstanding teaching at (elite) universities is complemented by relevant start-up networks and centres, as well as access to investors and other funding sources.

Numerous successful start-ups offer evidence of the region's progress, which in turn is increasingly appealing to investors, as demonstrated by established venture capital investors opening new offices here.

Bio^{M} records a total of 56 biotechnology start-ups in the Munich Metropolitan Region since 2015, with a peak of 16 in 2020. The majority are drug and therapy developers (six), followed by manufacturers of devices and reagents (four), and bioinformatics/digital health start-ups (three). Two start-ups work in the field of diagnostics, and one in analytics.

The development of new treatments continues to be a key focus among start-ups. However, since the 2014 study, there has also been a notable increase in bioinformatics and digital health start-ups.

The appeal of Germany and the EMM

Whether companies settle and remain in a region depends on a variety of factors beyond economic ones. These include factors closely related to doing business, such as infrastructure, proximity to customers, and tax conditions, but also soft factors such as culture and leisure opportunities or childcare services. Data from company and research institution surveys on the appeal of Germany and the EMM as locations was recorded and compared for this study. Over 80 % of respondents considered the EMM to be a good or very good location for biotechnology and the pharmaceutical industry, compared to just under 76 % for Germany as a whole. The proportion of those who classified the EMM as very good (28 %) was more than twice as high as for Germany as a whole (13 %).

Strengths and weaknesses of Germany and the EMM

The surveys also included questions on the specific strengths and weaknesses of the two locations. With respect to Germany as a whole, respondents saw the level of technology/expertise as the most important strength (22 %). Strong networks, which in 2013 was still considered Germany's main strength, was mentioned by only 4 % of respondents in 2021. The most important location factors in the EMM were the proximity to research institutions and universities (27 %) and the region's biotechnology cluster, and opportunities to build networks (24 %). All respondents also stated that the EMM's status as a renowned research centre is a major strength.

By some margin, the investment climate was viewed as Germany's biggest weakness by respondents (63 %), followed by bureaucracy (30 %). With respect to the EMM, respondents viewed difficulties surrounding investment and financing, and the shortage of laboratory and office space, as weaknesses (27 % in each case). Research institutions in particular saw the dispersed location of institutions across the region, the cost of premises and the cost of living in general, and the competitive research culture as specific weaknesses in the EMM.

Location factors in Germany and the EMM

The major challenges for the future of the Life Sciences industry in Germany clearly lie in optimizing the raising of capital for biotechnology and pharmaceutical companies (44 %) and in reducing bureaucracy (23 %). Competition from the USA and China have also become more prominent in recent years and cannot be ignored (14 %). Respondents noted with growing concern the fall in the number of suitably qualified staff. The importance of this location factor is reflected in its rise from 5.5 % in 2014 to 12 % in 2021.

The current study inquired for the first time about general safety levels in the EMM. It is easily the region's number one positive factor, with some 90 % of respondents either satisfied or very satisfied. Second place in terms of satisfaction went to contact with research institutions, which rose by 2 % from the last survey to 86 %. Respondents were also highly satisfied with culture and leisure opportunities in the EMM (80 %), closely followed by the general openness to biotechnology (78 %), and the cluster effect (76 %). The lack of skilled employees in Germany was also clearly felt in the region's biotechnology and pharmaceutical sector. Satisfaction with the situation fell from 74 % in 2014 to just 56 % in 2021. The trend is almost identical concerning the availability of laboratory and office space, with a drop in satisfaction levels from 74 % to 57 %. Childcare infrastructure also remains a challenge, with only 37 % of respondents satisfied compared to 40 % previously, though this may have been influenced by the difficult situation caused by the coronavirus pandemic.

The survey participants would like to see municipal policy makers provide solutions for more workspace and expansion of the public transport system, as well as for the problems associated with financing and bureaucracy. The Biotechnology Cluster Organization should take a more active role in representing companies' interests in the political sphere. It is also important to keep improving public appreciation of the industry's importance.

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