The
Federal Government

Strategy Paper

Improving the policy environment for the pharmaceutical sector in Germany

Concepts for action to promote research and production

The current situation:

Medicinal products are essential for human health and a major factor driving medical advances. The pharmaceutical industry is a key sector and a leading industry in the German economy. A pharmaceutical industry that remains strong over the long term is of great importance for the healthcare of Germany's population and the country's economy. In terms of the ratio of internal spending on research and development (R & D) to turnover, the pharmaceutical industry is the most research-intensive sector in Germany – at more than €8 billion, it invests roughly 15% of its sector's turnover in research and development. Germany is one of the world's leading biotech centres. In the European comparison of the pharmaceutical markets, Germany ranks first in terms of turnover (€56.5 billion in 2022), and fourth in terms of size, with a global market share of around 4 percent.

The pharmaceutical sector is also a significant part of critical infrastructure. The pharmaceutical industry is essential for ensuring healthcare and requires special attention in preparing against threats and crisis situations. The COVID-19 pandemic illustrated the strengths that the pharmaceutical industry possesses in translating R & D results into life-saving products, and the substantial value it can add to Germany's economy. However, the pharmaceutical industry also revealed dependencies and supply shortages.

A description of the problem:

The last few years have shown that Germany has become less attractive as a host country for research and development in the international comparison. Whilst the number of applications for authorisation of clinical trials of medicinal products for human use submitted to the Federal Institute for Drugs and Medical Devices (BfArM) and the Paul Ehrlich Institute (PEI) remains at a high level, long-term analyses by the German Association of Research-based Pharmaceutical Companies (vfa) show a negative trend in the clinical studies commissioned by pharmaceutical companies. Germany has become less competitive as a centre for research and development, especially in comparison with other European countries.

Also, the COVID-19 pandemic has revealed supply chain vulnerabilities. Globalisation and intense cost pressures, particularly in the generic products industry, have already resulted in a relocation

away from Germany of the manufacturing of starting materials, active substances and medicinal products - which goes for a large number of active substances and medicinal products and in a concentration to a handful of manufacturing sites, mainly in countries outside the EU (and particularly China and India).

In 2000, around 30% of active substances of authorised medicinal products were manufactured in Asia; by 2020, the figure had risen to more than 60%. This trend involves the risk of strategic dependencies and increases the danger of interruptions to supply chains and thus the risk of supply shortages. This can particularly be observed in the case of generic antibiotics. One consequence of this trend is that experts in paediatrics and adolescent medicine are again predicting some supply shortages for the autumn/winter of 2023/2024.

Objectives:

In order to make Germany a more attractive location for the research, development and manufacturing of medicinal products once more, and to ensure a reliable supply, the Federal Government will be working to improve the policy environment for a strong, sustainable and internationally competitive pharmaceutical industry, particularly in Germany, and also in the EU. The Federal Government will raise the points set out in this strategy with the partners at EU level and define a path to implement specific measures. A central factor driving new investment is a reliable policy environment, i.e. predictable market conditions. Only if this is in place will pharmaceutical and biotechnology companies invest in innovative research, development and manufacturing in Germany.

A good research infrastructure with highly qualified specialists is vital for achieving this, as is close cooperation with relevant research institutions. This enables companies to benefit from a high-revenue and stable investment environment, and public health can benefit from swift access to innovative medicines and medicinal products.

The pharmaceutical sector should be included in considerations about Germany's industrial orientation and the shaping of structural change. This requires long-term and broad-based political support for the sector in the form of a good and reliable policy environment. Also, it is necessary to ensure that both Germany and the EU remain internationally competitive manufacturers of medicinal products in order to reduce strategic dependencies and to ensure the availability of medicinal products.

Alongside improvements at national level, it is also necessary to consider the European level. The European Commission presented a proposal to revise the European pharmaceutical legislation in 2023 (Pharma Package). In tandem with other Member States, Germany called in 2020 on the European Commission to propose specific measures for greater EU autonomy in the safeguarding of the supply of medicinal products, in particular greater transparency and diversification of

supply chains, and European cooperation on the expansion of manufacturing of active substances for critical medicinal products.

All the measures cited in or deriving from the strategy paper form a basis for the setting of financial priorities within ministries, and are subject to the availability of funding and the reservation that the Federation is financially responsible for the measures under constitutional law. In order to further boost the sustainability and take-up of state investment incentives and support, consideration is being given to the question of the extent to which these should be linked to incentives to continue activities at the specific site and to offer employment.

Measures to improve the policy environment for the pharmaceutical sector in Germany

1. Simplifying and accelerating clinical trials of medicinal products for human use

Background: The authorisation procedure for clinical trials of medicinal products for human use is harmonised at European level by Regulation (EU) No 536/2014. However, there is a perception that it is more difficult to conduct clinical trials in Germany than elsewhere. Reasons cited for this include the double application for the radiation protection check, contractual negotiations between the sponsor and the implementing institution, processing periods at the authorities, and the involvement of the ethics committees.

Objective: Measures will be taken to optimise and accelerate the authorisation and implementation of clinical trials in Germany without compromising the safety of the clinical trial participants.

Implementation:

1.1. Establishment of a Federal Ethics Committee

- An interdisciplinary Federal Ethics Committee will be set up with an office at the Federal Institute for Drugs and Medical Devices.
- This is initially to be deployed for certain especially urgent and complex procedures such as studies which are discussed in the Emergency Task Force of the European Medicines Agency (EMA), platform studies, highly complex master protocol studies, and first-in-human studies.
- This will be followed by a pooling of the expertise for these specific study types in an ethics committee specialising in these.
- Talks will take place between the Federal Ministry of Health and the Länder with a view to attaining further harmonisation in the decisions of the ethics committees.

1.2. Shortening of the processing times in mononational clinical trials

- The processing times will be adjusted: the assessment of flawless and complete applications is to take place within 26 days; the decision on the application within 5 days. This will save the industrial research community up to 19 days of time.
- This procedural acceleration will take place via an amendment to the Medicinal Products Act and the Clinical Trial Assessment Procedure Ordinance (KPBV).

1.3. Integration of the radiation protection procedure into the authorisation procedure for clinical trials of medicinal products

- Where possible under EU law, the notification procedure under radiation protection law (approximately 85% of the procedures at the Federal Office for Radiation Protection (BfS)) and the authorisation procedure under radiation protection law (approximately 15% of the procedures at the Federal Office for Radiation Protection) are to be integrated into the authorisation procedure for clinical trials. Both the notifications and the applications for authorisations in the radiation protection procedure are to be submitted to the coordinating licensing authority together with the application for the authorisation of the clinical trial. The applications for authorisation are to be forwarded to the Federal Office for Radiation Protection for assessment; this office will also decide on them. The relevant deadlines will be shortened and aligned with those for the assessment under medicinal products legislation, where this is possible whilst maintaining radiation protection. If no decision is issued within the deadline, it is assumed that authorisation has been granted.
- The requirements to be met in terms of the documentation which must be submitted under radiation protection law will be fleshed out and published in order to improve the quality of the documents and to further accelerate the procedures in the validation phase.
- Overlapping assessments will be reduced, as the assessments in the notification procedure are to be undertaken entirely by the ethics committees.
- It is to be possible to submit applications in English, and to do so online via CTIS.

1.4. Model contractual clauses for clinical trials of medicinal products for human use

- The Federal Ministry of Health will publish a notice covering practical model contractual clauses for contracts between sponsors, the trial site and, where appropriate, also third parties.

1.5. Enabling the conduct of decentralised clinical trials

- The special distribution channel for medicinal products used in clinical trials will be expanded to include the direct supply of medicinal products to the trial participants.

1.6. Simplifications in the labelling of investigational and auxiliary medicinal products

- Labelling exclusively in English will be permitted. This rule will only cover investigational and auxiliary medicinal products which remain exclusively in the hands of the investigator or the members of the team of investigators who are physicians, and which are administered directly to the trial participants.
- So far, the labelling of investigational and auxiliary medicinal products has always had to be made in German as well.
- The safety of the trial participants remains guaranteed.

1.7. Ensuring the functioning of and improving CTIS

- Since 31 January 2023, all applications for the authorisation of clinical trials of medicinal products for human use in the EU have had to be submitted via the Clinical Trials Information System (CTIS). CTIS was developed and is operated by the EMA, and is the central contact point for applications for and authorisations of clinical trials.
- Since the introductory phase was beset by considerable teething troubles, the EMA has increased capacities at the initiative of the Federal Ministry of Health, and has improved the functionality of CTIS. This improvement process is being continued. The Federal Ministry of Health is engaged in close dialogue with the EMA and all the other stakeholders and will take further steps if necessary.

2. Strengthening competent higher federal authorities, creating synergies in supervisory authorities

Background: The two competent higher federal authorities BfArM (Federal Institute for Drugs and Medical Devices) and PEI (Paul Ehrlich Institute) have complex shared responsibilities, in particular with regard to combination therapies and doubled structures for clinical assessments relating to the same indication. This interface between the two competent higher federal authorities, and in particular the parallel process to obtain the opinion of the ethics committee, results in delays and increased expenses for the applicants.

For certain biologicals, e.g. advanced therapy medicinal products and genetically produced medicinal products, the competent Land authority already makes its decision on whether to issue a manufacturing authorisation in consultation with the competent higher federal authority. Despite the involvement of the federal authorities and harmonised EU rules and harmonisation formats as well as national activities, there is an ongoing need for harmonisation, especially in the field of innovative pharmaceuticals like gene and cell therapies and personalised medicinal products.

Objective: It is to be ensured that the pharmaceutical industry in Germany benefits from rapid processing of procedures without a lowering of standards. This will necessitate central project management with well-coordinated and well-equipped agencies, where possible on the basis of corresponding fee-based funding.

Implementation:

2.1. Reorganisation of responsibilities between the BfArM and the PEI licensing authorities

- In future, the BfArM will take over the responsibility for coordination and procedural management of authorisation procedures and applications for clinical trials for all medicinal products, apart from vaccines and blood products. The BfArM will be the central contact point for the pharmaceutical companies, will be responsible for administrative processes, will coordinate the procedures for obtaining the ethics committees' opinion and the radiation protection assessment (cf. point 1.3.), and will serve as the interface to the research data centre and other processes.
- The new coordination and procedural management office at the BfArM will be responsible for the controlling of procedures with a view to acceleration. The outstanding expertise of the two competent higher federal authorities will not be affected, and will be deployed in joint project teams. The research and substantive support relating to biological active substances at the Paul Ehrlich Institute will not be restricted in any way.
- A steering group headed by the Federal Ministry of Health will be set up and subsequently integrated into the BfArM. The steering group will consist of members from the Federal Ministry of Health, the BfArM and the PEI.
- The steering group will organise the cooperation between the BfArM and the PEI, will steer processes, harmonise positions and propose structural measures where necessary.
- The personnel of the BfArM is to be increased, funded by fees.

2.2. Harmonisation of the issuing of manufacturing authorisations and the procedures and interpretations of the authorities for certain groups of medicinal products, especially medicinal products for advanced therapy medicinal products

- With a view to the further harmonisation of the issuing of manufacturing authorisations, the higher federal authorities will be commissioned to produce interpretation aids for technical guidelines, including the requirements to be met by the qualified person (QP).
- A power will be introduced for the competent Land authorities to request an expert opinion from the competent higher federal authority on a question of interpretation with regard to Good Manufacturing Practice (GMP).

2.3. Improved international cooperation between the supervisory authorities

- Germany will urge the European Commission to ensure that GMP certificates can also be recognised for manufacturing sites outside the territories of the contracting parties in the context of mutual recognition agreements (MRAs).

3. Driving forward digitalisation in healthcare

Background: New (bio-)technological developments and the application of new therapies will not work without health data. The availability of health data is of central importance for success in pharmaceutical research, e.g. for the identification of suitable study candidates. This includes standardised processes, an efficient infrastructure, and the use of personalised medicine.

Objective: Digitalisation in healthcare is to be driven forward and health data to be made accessible to the pharmaceutical industry. Data protection supervision for cross-Länder research projects in the healthcare sector will be harmonised and simplified.

Implementation of the Health Data Use Act[1]:

3.1. Further development of the Health Data Lab (HDL) at the BfArM

- When the law comes into force, existing barriers to the use of health data will be further reduced. When applying to use data from the HDL, an exhaustive list of eligible applicants will be waived. Instead, the determining factor will be the intended purpose of the data access. This means that access to the data of the HDL will be open to pharmaceutical research for the first time.
- Efforts will be made in particular to provide a clear definition of requirements for filing and approving applications.

3.2. Reorganising the data infrastructure of the genome sequencing model project for industrial researchers

- The genome sequencing model project (section 64e of German Social Code Book V) collects genomic and clinical data in the field of rare and oncological diseases in a quality-assured and interoperable manner, and makes them accessible for healthcare and research, as the innovative potential of genomic data is immense. However, it can only unfold in an interplay between healthcare and research.

[1] Currently passing through the parliamentary procedure

- The use of the data from the model project will be made possible for private-sector research and thus also for the pharmaceutical industry. In addition, a European link via the European Genomic Data Infrastructure (GDI, currently under construction) and via the European Health Data Space is being prepared.

3.3. Further development of the concept of lead responsibility for data protection supervision for cross-Länder research projects in the healthcare sector in section 5 of the Health Data Use Act (GDNG)

- The lead responsibility for data protection supervision for cross-Länder research projects will be extended to cover all health data, meaning: the supervision under data protection law of cross-Länder research projects in the health sector will be better coordinated in future thanks to a lead Land data protection authority.
- If non-public partners (companies) share joint responsibility under data protection law for cross-Länder research projects, the partners involved can decide that a single data protection supervisory authority is solely responsible.

4. Incentives to attract manufacturing sites to the EU and to diversify supply chains

Background: There is a high level of dependency on manufacturing sites in third countries (China and India) in particular for patent-free medicinal products. The underlying causes are in particular the lower manufacturing costs in third countries, the fact that generic products are in the low-price segment, also in Germany, and targeted subsidies by third countries for the establishment of manufacturing sites in this field.

Objective: This strategic dependency is to be reduced by health and economic policy measures in order to give a sustainable boost to the security of medicinal products supply. For this purpose, measures to diversify the supply chains and raise the attractiveness of the EU as a manufacturing base are regarded as particularly suitable. This will require a medium- to long-term perspective, since it takes several years to build up new sustainable manufacturing capacities for pharmaceutical active substances.

Corresponding measures must be designed in a targeted and product-specific way. The focus is initially to be placed on antibiotics and oncology medicinal products. There are insufficient or no therapeutic alternatives for these medicinal product groups. However, these medicinal product groups are essential for health care and must be available at all times and without delay.

Implementation: According to the coalition agreement entitled "Daring more progress" (*Mehr Fortschritt wagen*)", measures are to be taken in this area to relocate the "manufacture of medicinal products including the manufacturing of active and auxiliary substances to Germany or the EU. This includes the reduction of bureaucracy, the consideration of investment subsidies for manufacturing sites, and the consideration of grants to ensure security of supply."

4.1. Examination of incentive systems for manufacturing sites (focus on antibiotics)

- The establishment of manufacturing sites in Germany is to become more attractive. The Federal Ministry for Economic Affairs and Climate Action and the Federal Ministry of Health will examine, in the context of a joint project structure, targeted funding instruments as an important element for the establishment of new manufacturing sites. The funding instruments must be considered in particular with a view to the establishment of end-to-end production and the financial requirements needed.
- The reduction of strategic dependencies in the field of selected technologies is also an issue at European level. Germany supports the goal of reducing such dependencies and is ready to consider useful initiatives by the European Commission for the pharmaceutical and biotech sectors.

4.2. Further grants to ensure security of supply in the context of price regulation under social law

- In the context of rebate contracts to strengthen the EU as a manufacturing base, the measures taken in the Act to Address Supply Shortages of Off-Patent Medicines and to Improve the Supply of Paediatric Medicines (e.g. rules on rebate contracts initially for generic antibiotics: half of the lots for rebate contracts with manufacturers making active substances in the EU/EEA) will be widened to cover other selected medicinal products, in particular oncological medicinal products.

4.3. Amendment of EU procurement law in terms of the award criteria

- Germany will develop proposals to amend and develop EU procurement law for critical medicinal products in order to increase security of supply and to diversify supply chains, e.g. with a view to EU-based manufacturing, and will champion their implementation (analogous to other critical areas).

4.4. Drafting of a procurement transformation package

- Public procurement is to be simplified, made more professional, digitalised and accelerated, and its economic, social, ecological and innovative orientation strengthened without endangering the legal certainty of award decisions or increasing the access barriers for small and medium-sized enterprises. One focus of the procurement transformation package is to avoid additional bureaucracy.

- Draft legislation is to be presented in the winter of 2023/2024. The pharmaceutical industry will also benefit from the measures.

4.5. Active support for the drafting of an EU Critical Medicines Act

- Following the logic of the Critical Raw Materials Act and the Chips Act, there is a need for a Critical Medicines Act (CMA) from the European Commission, specifically in order to implement economic policy measures for critical medicinal products. Germany is actively supporting the work on the details of this initiative in order to ensure swift implementation. Belgium is taking the lead on this initiative.

5. Creating a regulatory framework to strengthen EU competitiveness

Background: Pharmaceutical law is harmonized at the European level. On 26 April 2023, the European Commission presented the pharmaceutical package to revise the EU law on medicinal products. This revision is a milestone which will shape the legal framework for the coming decades – particularly in terms of the existing procedures and the competitiveness of the EU's pharmaceuticals market.

Objective: Maintaining an attractive EU framework for the research and development of new medicinal products in the EU, securing patients good access to new medicinal products, and upholding the system of intellectual property rights in its entirety.

Implementation:

5.1. EU pharmaceutical package

- Germany champions the regulatory simplification of marketing authorisation procedures (e.g. shortening of processing deadlines, reduction of the number of scientific committees, removing obligatory marketing authorisation renewals) and a highly competitive regulatory environment.
- In particular, Germany rejects a shortening of data protection periods.

5.2. EU patent package and international pandemic agreement

- Germany is working at the European and international level to ensure that the systems protecting intellectual property rights are not weakened. Their balanced architecture is the foundation and precondition for lasting investment in research and development. The Federal Government therefore also continues to oppose TRIPS waivers and mandatory technology transfer. Beyond this, the Federal Government is also working to ensure a level international playing field for the German pharmaceutical industry.

6. Promotion of innovation and research projects

Background: Germany can build on very strong and successful basic research in the pharmaceutical sector. However, the translation of academic research findings into applications, and in particular the transfer into the development of medicinal products by pharmaceutical companies, must be improved further. Startups from scientific institutions and small and medium-sized enterprises (SMEs) are key players in this process. The research and development of new medicinal products is expensive, lengthy and risky.

Startups and SMEs in Germany lack a sufficient supply of outside capital to fund their research, particularly in the growth and maturity phase. In the case of medicinal products where there is a lack of market potential due to low profit expectations (e.g. antibiotics, medicinal products for rare diseases (orphan drugs), vaccines and medicinal products to prevent pandemics), the translation gap that already exists between science and business is even wider. There is therefore a continuing need for special public funding of research and development in this sector.

Objective: There is a need for incentives to mobilise and channel more capital. In this case of medicinal products where there is market failure, additional pull incentives are needed. The tax incentives for research are to be increased, and targeted support for research and development, innovation, transfer and startups is to be further developed.

Implementation:

6.1. Strengthening of research and development in areas in which there is market failure

- The targeted support for research and development of medicinal products where there is market failure (e.g. antibiotics, medicinal products for rare diseases, vaccines and medicinal products to prevent pandemics) will be continued. The focus here is placed on project funding and institutional funding for early development phases and participation in international public-private partnerships, in order also to support late development phases.
- Further pull incentives for medicinal products where there is market failure (especially antibiotics, if necessary medicinal products for rare diseases, vaccines and medicinal products to prevent pandemics) will be considered.

6.2. Expansion of the research allowance in the Growth Opportunities Act

- The Growth Opportunities Act envisages a comprehensive expansion of tax incentives for research (the research allowance) which will also benefit the pharmaceutical companies doing research in Germany. The eligible expenditure will be extended to include (some) material costs, and the ceiling for the assessment basis will be tripled to €12 million. This provision, in particular, will specifically benefit research-based pharmaceutical companies. Also, SMEs are to be able to apply for a funding rate that is 10 percentage points higher. Here, use will be made of scope offered by EU State aids rules.

- Further to this, research and development is to be given a tax break in the form of an extended deduction for losses.
- Consideration will be given to other tax-based support instruments, particularly in comparison to other EU Member States.

6.3. Study on the improvement of existing / already planned sector-neutral growth financing services

- A study on requirements in the field of venture capital will clarify whether and where the existing and already planned sector-neutral growth financing services can be improved not least for sectors like medicine and the bio-economy. The findings of the study are to be available by the end of 2023.
- If a corresponding need is identified, measures will be defined to improve the growth financing services.

6.4. Strengthening of measures to close the translation gap

- Measures are being continued and developed to boost a translation of academic research findings into applications and a transfer of these into the business community (e.g. EXIST – Business startups in science and academia, GO-Bio, GO-Bio initial and KMU-innovative: Biomedicine).
- The planned new edition of GO-Bio will support the preparation and sustainable development of spin-offs in the life sciences by means of sector-specific measures.
- In the field of cell and gene therapy, the Berlin Institute of Health@Charité (BIH) is currently coordinating the development of a National Strategy for Gene and Cell Therapy, which will be published in the summer of 2024. The aim is to design an integrational and viable approach for Germany, strengthening and networking all the links in the translational value chain, irrespective of indication, from basic research through to the clinic.

6.5. Harmonising the enforcement of the Genetic Engineering Act in the field of medicinal products

- Certain enforcement aspects relating to the transport of Advanced Therapy Medicinal Products (ATMPs) from the manufacturer to the user (doctor) will be clarified together with the Länder and will be harmonised and simplified where necessary.

6.6. Improvement of the availability of venture capital for young companies

- Via the RegioInnoGrowth (RIG) future fund module, which launched in mid-August 2023, the Federal Government is enabling the Länder to set up Land-specific funding programmes like InnoGrowth BW. This latter programme launched in mid-October 2023, and addresses e.g. biotechnology firms from Baden-Württemberg. The Länder have a lot of flexibility in the design and implementation of their respective programmes under the RIG umbrella, and can

set the programmes up to meet their needs. The programme launched in November 2023 in Hesse. Further Länder programmes will follow in the near future.

- In order to address large professional private investors like insurance companies, pension funds and foundations, the Federal Ministry for Economic Affairs and Climate Action and KfW Capital have designed a structured fund of funds worth around €1 billion as part of the Future Fund; this fund of funds is entitled "Growth Fund for Germany". The targeted funding amount of a billion euros was reached in November 2023. The fund of funds has already started investing the money, and has pumped around €200 million into German and European venture capital funds.
- The Future Financing Act, which was adopted by the Bundestag on 17 November 2023, improves the possibilities for SMEs, and young companies in particular, in all sectors to obtain equity capital. IPOs in particular are to become more attractive as a result of changes to various national policies. These include the relaxation of prudential rules for IPOs, the relaxation of corporate law for capital increases, the option of multiple-voting shares, and the introduction of an IPO via a shell joint-stock company. Making exits via an IPO easier could make young firms in Germany more attractive for venture capital providers, as the holdings become more liquid.
- The Federal Ministry of Finance will take measures to improve the financing conditions for young companies in Germany in particular and to motivate private institutional investors to invest e.g. in technology firms. In line with the French Tibi Initiative, the Federal Government aims to work with the German financial sector to structure an investment initiative to boost VC/innovation funding and Germany's financial sector. Ideally, this investment programme will be funded entirely by the private sector.

6.7. Flexibilisation of funding via EXIST Business start-ups in science

- Via the new EXIST funding guideline published in April 2023, the Federal Government will facilitate much more financial and operational flexibility for innovative, risky and complex spin-offs from science, e.g. for the development of active substances.

6.8. Sector-specific service by the German Accelerator

- Alongside the sector-neutral service of the German Accelerator, the Life Science Accelerator in Boston will continue to address startups from the life sciences and to deploy experienced coaches and advisors from the sector and the financial world to help them – e.g. at the U.S. Food and Drug Administration on licensing and internationalisation.

6.9. Advice on and review of the suitability of existing funding programmes

The Federal Government offers a wide range of funding programmes open to companies from the pharmaceutical sector.

- The Federation supports companies by providing individual and rapid advice on suitable funding programmes, and these programmes are constantly updated in response to changing needs.
- At present, for example, the "Industrial Bio-Economy" funding guideline is being revised. Representatives of biotech firms in the pharmaceutical industry are involved in the work on the revision.
- Further to this, the Federation helps companies to find appropriate sites for investment via Germany Trade and Invest, and offers specific programmes for structurally weak areas.

7. Financial stability of the statutory health insurance system; here: supply of medicinal products

Background: Germany already offers the pharmaceutical industry a competitive policy environment in terms of market access, full reimbursement, benefit assessment, and the subsequent pricing of new medicinal products. Alongside the availability of highly qualified professionals, rapid authorisation procedures and established supplier structures, these are also a precondition governing decisions by companies in the sector on where to invest.

A key locational factor for new investment is reliability and thus certainty for companies planning investments, so that pharmaceutical and biotechnology firms will want to undertake their innovative investments in research, development and production in Germany.

Germany has so far ranked first in Europe in providing swift and widespread access to new medicinal products. There is ongoing monitoring to detect any impact on this due to the latest changes introduced by the Financial Stabilisation of Statutory Health Insurance System Act.

Objective: A reliable, straightforward and easy-to-implement policy environment for pricing and reimbursement will be ensured, based on the principles of a social market economy, in the interest of good access to new medicinal products. Appropriate consideration will be given to therapeutic improvements. At the same time, it is important to keep an eye on the financial stability of statutory health insurance.

Implementation:

7.1. Re-evaluation of the reform of the Act on the reform of the Market for Medicinal Products in the Statutory Health Insurance

- Until the end of 2023, the Federal Ministry of Health will carry out an evaluation of the reform of the negotiation of reimbursement rates for new medicinal products (reform of the Act on the reform of the Market for Medicinal Products in the Statutory Health Insurance) introduced

by the Financial Stabilisation of Statutory Health Insurance System Act. In particular, consideration will be given to whether the reform is already having an impact on security of supply and, in consensus with the Federal Ministry for Economic Affairs and Climate Action, on manufacturing of medicinal products in Germany. This review process will be continued in 2024 in the form of an external evaluation with the involvement of the stakeholders.

7.2. Facilitating a confidential reimbursement rate

- It will be made possible to replace the publicly listed reimbursement rate by a confidential one in the context of the negotiations on reimbursement rates.
- It is necessary to ensure that confidential reimbursement rates for new medicinal products do not result in additional expenditure or bureaucracy for the German health care system. This will require further follow-up arrangements.
- The confidential reimbursement rates will be taken into account in negotiations on the contractual units costs of retail pharmacist services (Hilfstaxe) and in other negotiations on reimbursement rates.
- To implement the confidential reimbursement rates, the pharmaceutical companies will inform the eligible recipients (e.g. individual health insurance funds, private health insurance companies, providers of government health aids to civil servants, hospitals, prisons) and make up the difference to the price freely set by the pharmaceutical company.

7.3. Safeguarding the future financing of the statutory health insurance system without further increases in the manufacturer's discount

- The Federal Government intends to stabilise the manufacturer's discount for reimbursable medicinal products without a maximum reimbursement rate at the level of 7 percent.

8. Outlook: Further removal of bureaucracy, best practice dialogue

Background: Germany's attractiveness for the sector and investments in Germany are hampered by excessive rules and bureaucracy.

Objective: Bureaucratic requirements and administrative processes should be scaled back (interministerial/cross-sectoral initiative).

Implementation:

8.1. Greater digitalisation of the application processes

- The Federal Government is working towards greater digitisation of the application processes in authorisation procedures.
- As part of these efforts, it has presented a draft law to amend the Online Access Act.

8.2. The Bureaucracy Reduction Act IV

- A draft Bureaucracy Reduction Act IV is being submitted in 2023.
- The Federal Ministry of Health has presented its own proposals to cut bureaucracy. These also take account of the needs of the pharmaceutical sector.

8.3. Establishment of a joint discussion format with industry, best-practice dialogue and networking

- The Federal Ministry of Health and the Federal Ministry for Economic Affairs and Climate Action will discuss with industry representatives and other stakeholders (e.g. self-governing bodies, federal agencies) the need for action and potential improvements, particularly with a view to current and future developments like new forms of therapy. This is based on a best-practice approach.
- The Federal Government promotes the networking of the stakeholders in the biotech sector. For example, the Federal Government has published a map with model regions of the industrial bio-economy. This also shows the regions in which the pharmaceutical industry is represented. It indicates, for example, a medicines region in central Germany.