Project Summary

Ensuring Patient Access to Medicines in Austria and the EU by improving the Pharmaceutical Value Chain

Technical Support Instrument

Supporting reforms in 27 Member States

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1. INTRODUCTION TO THE PROJECT

Sustainable access to medicines is a topical issue in Austria and other European states (including EU member states), that has become increasingly important in recent years. Patients are confronted with situations in which medicines are not available in pharmacies or no treatment options for their (rare) diseases are available. Policy makers in the healthcare system are faced with the challenge of providing access to potentially innovative medicines while at the same time securing the financing of the solidarity systems in the long term.

The project "Ensuring Patient Access to Medicines in Austria and the EU by Improving the Pharmaceutical Value Chain" (in short: Patient Access to Medicines) aimed to develop proposed solutions to ensure sustainable patient access to medicines in Austria. This involved strengthening the resilience and attractiveness of the pharmaceutical value chain. The project ran from fall 2021 to fall 2023 and was financed via the EU "Technical Support Instrument" (TSI). It was initiated by the European Commission's Directorate-General for Structural Reform Support (DG REFORM) on behalf of the Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection (BMSGPK) and supported by the Austrian Federal Ministry of Labour and Economy (BMAW).

The focus of the project was on the development of recommendations for policy measures to improve access to medicines, which were made available to policy makers in Austria. This was intended to support them in making decisions about measures and investments to be made and to accompany them in the implementation of selected policy measures in Austria.

In the first phase of the project, the strengths and weaknesses of the pharmaceutical value chain were analyzed from different perspectives (political, economic, socio-cultural, technological, ecological, legal and ethical) in terms of its contribution to patient access to medicines in Austria. Based on this, seven topic areas (hot topics) were identified in which levers can be applied to improve patient access to medicines. Subsequently, potential policy measures to strengthen sustainable patient access to medicines in Austria were proposed. These were assessed and prioritized on the basis of a decision matrix developed in the project and with evaluation criteria based on public health objectives. Further recommendations for possible implementation were developed for the prioritised measures.

The following measures were prioritized: strengthening registry research, increasing flexibility and transparency to strengthen the security of supply of essential medicines, joint procurement of medicines for public hospitals, piloting outcome-based managed entry agreements in the community-based sector, additional funding for innovative medicines and strengthening production. Due to the high relevance of the issue of supply bottlenecks, a particular focus was placed on recommendations for action in this area.

Project team

The project was carried out by an international consortium with expertise in public health, health economics, medical research, pharmaceutical regulation and legislation, innovation, economic analysis, policy analysis, strategy and implementation support with in-depth knowledge of the Austrian and European system.

Project Governance

In addition, the following committees were set up to advise the consortium:

Operational Working Group (OWG)

The OWG was made up of representatives from the following organizations:

- Consortium
- Directorate-General for Structural Reform Support of the European Commission (DG REFORM)
- Federal Ministry of Social Affairs, Health, Care and Consumer Protection (BMSGPK) and Gesundheit Österreich GmbH (GÖG)
- Federal Ministry of Labor and Economic Affairs (BMAW)

The OWG monitored the operational implementation of the project throughout the entire duration of the project, including at bi-weekly meetings. Among other things, this committee had the task of preparing decisions, managing the operational implementation and reviewing the technical and methodological implementation.

Steering Committee

A steering committee was set up to ensure strategic coordination and participation. It's task was to make important decisions in the project, advise on procedures and introduce political positions.

Advisory Board

To ensure the quality of the results, an independent scientific advisory board was set up. The advisory board consisted of national and international experts with broad specialist knowledge and excellent methodological expertise.

Sounding Board

A sounding board was set up to exchange ideas with central actors. This board included representatives from the social insurance institutions, the federal states and the industry.

Representatives of the Advisory Board and the Sounding Board also provided input on the evaluation and prioritization of policy measures.

Stakeholder participation

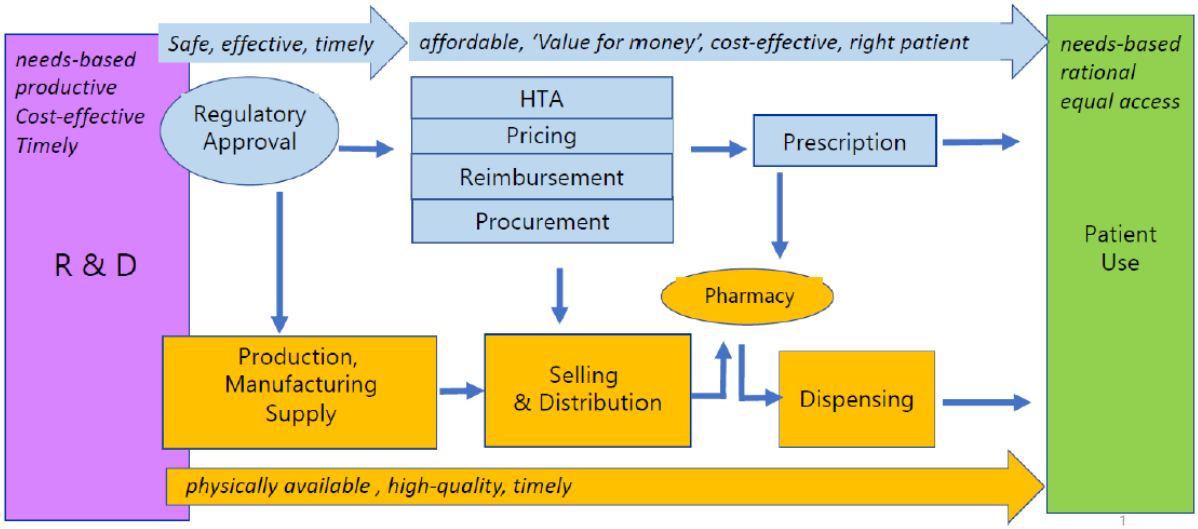
Throughout the project, stakeholders from the public and private sectors who play a role in the supply of medicines were consulted.

2. ANALYSIS OF THE PHARMACEUTICAL VALUE CHAIN AND FUNING INSTRUMENTS IN AUSTRIA (INCL. EU LEVEL)

The first phase of the project focused on analyzing the pharmaceutical value chain and funding instruments.

Analysis of the pharmaceutical value chain

To structure the analysis of the pharmaceutical value chain, an analytical framework was created to illustrate the breakdown. In the subsequent figure it is demonstrated how the different areas relate to the different dimensions of patient access to medicines:



Analytical framework of the pharmaceutical value chain in relation to the dimensions of patient access to medicines

Comprehensive information was collected as part of a literature review, which was supplemented by interviews with stakeholders and information from experts from various fields. A PESTELE analysis was carried out on the basis of this information.

Analysis of funding instruments in Austria (incl. EU level)

As part of the analysis of funding instruments in Austria (incl. EU level), existing funding instruments for research and development (R&D) and the production of medicines were identified, analyzed and assessed with the support of an evaluation system with regard to their direct and indirect effectiveness. Subsequently, so-called "hot topics" were derived from the results of the analysis.

Hot Topics

The barriers and opportunities for improving patient access to medicines identified in the analysis were assigned to the following hot topics:

- Real World Evidence
- Research and development - selection and performance
- Market resilience and supply bottlenecks
- Regionalism and system fragmentation
- Approaches to Health Technology Assessment (HTA)
- Pricing, reimbursement and procurement
- Rational use of medicines

In order to address the identified barriers and exploit opportunities, 20 proposals for possible policy measures were developed and prioritized on the basis of evaluation criteria.

Evaluation criteria

In addition to analyzing the pharmaceutical value chain, evaluation criteria were developed to assess the impact of potential policy measures on patient access to medicines on public health. Based on the following evaluation criteria, the ministries had the opportunity to evaluate and prioritize the 20 proposed measures as part of a rating process. Analyses were also carried out by the Advisory Board and Sounding Board.

Public Health Assessment Criteria:

- Coverage of pharmaceuticals
- Quality
- Availability and affordability of medicines
- Safety of medicinal products

Political Evaluation Criteria:

- Feasibility
- Realizability
- Operation

Economic Evaluation – Production:

- Production costs
- Production capacities
- Availability of labor
- (European) production networks

Economic evaluation - RTI (Research, Technology & Innovation)

- Financing research, technology & innovation
- Infrastructure for research, technology & innovation
- Research, technology & innovation - Human capital
- Network structures for research, technology & innovation

Legal evaluation criteria

- Legal feasibility

3. PROPOSALS FOR POLICY MEASURES

In the second phase of the project, 10 proposals for policy measures were selected using a decision matrix. An action plan with further recommendations for action was drawn up to serve as a basis for potential subsequent implementation.

Measures to prevent delivery and supply bottlenecks:

In July 2023, a wide variety of measures were presented in the Council of Ministers report "Immediate measures healthcare reform package – social health insurance care units, psychosocial care, prevention and digitalization", which are intended to help ensure the supply of medicines for the 2023/2024 winter season. In addition to the storage of critical active ingredients, the report also mentioned increasing transparency with regard to supply bottlenecks and improving the framework conditions for alternative procurement options. Some recommendations for possible policy measures that were developed in this project are based on the content of the Council of Ministers' report and are described in more detail below.

Creating more flexible national framework conditions for the dispensing of medicines by pharmacies and the import of medicines that are not available or only available to a limited extent in Austria:

The aim of the proposed measure is to reduce the effort for patients between the prescription of an (unavailable) medicine by a doctor and the dispensing of this medicine or a therapeutic alternative, while at the same time maintaining a sufficient level of safety for patients. This could mitigate or avoid the negative effects of drug shortages on patients' health. This is because prescribing medicines that are not available due to supply bottlenecks leads to time and costs on the part of pharmacies and to uncertainty and time expenditure on the part of patients. Measures such as the dispensing of selected (supply-critical) prescription-only specialty medicinal products "aut idem" by pharmacies, the production and dispensing of magistral preparations on the basis of a prescription for an unavailable prescription-only specialty medicinal product, as well as measures to accelerate the parallel import of medicines could help to achieve this goal.

Transparency database:

The Federal Office for Safety in Health Care (BASG) already offers the distribution restriction register on its website, which lists all reported distribution restrictions and thus ensures transparency. The register can be accessed via the public internet or integrated as an interface into the practice software of registered doctors. The register is intended to help ensure that registered doctors are informed about current supply restrictions at the time of prescribing medicines and take these into account when prescribing.

Medicines listed in the BASG distribution restriction register are no longer available in some public pharmacies, while other pharmacies still have remaining stocks. A transparency database could enable registered doctors to obtain an overview of the availability of a medicine listed in the distribution restriction register when prescribing it, so that they can pass this information on to their patients. The possibility of picking up the medication from a pharmacy with stock could save patients unnecessary trips and waiting times for their medication.

Establishment of raw material warehouses:

Due to problems in the supply chain of raw materials, production restrictions in the pharmaceutical industry occur repeatedly. These production restrictions can result in distribution restrictions and delays in the supply of finished medicinal products. By setting up raw material warehouses for pharmaceutical manufacturers (e.g. at EU level), they could be enabled to continue production even in the event of problems in the supply chain for pharmaceutical raw materials, thereby cushioning supply bottlenecks over a certain period of time. A list of critical pharmaceuticals and critical pharmaceutical raw materials with an estimate of the required quantities at EU level would be suitable as a basis for determining requirements, procuring and stockpiling raw materials. However, a prerequisite for the establishment of raw material warehouses is the clarification of financing and the conclusion of agreements with marketing authorization holders/manufacturers on the modalities of raw material storage. Raw material warehouses at EU level or national raw material warehouses can represent an important alternative option for pharmacies, but are associated with high financial and bureaucratic costs.

Measure for joint procurement of pharmaceuticals

In the Austrian healthcare system, the responsibilities for financing are divided among different players, and this also applies to pharmaceuticals. This is an important explanation for observed differences in the availability of and access to medicines in the respective provinces or at the level of individual hospitals, which may pay different prices for medicines in the inpatient sector (details are often not known due to confidential agreements). An expansion of the joint procurement of pharmaceuticals and participation in cross-provincial purchasing networks could strengthen the negotiating position of hospitals. Joint procurement could also improve the availability of generics and biosimilars (including their patent-expired original preparations) due to the higher quantities in demand.

In the case of potentially innovative medicinal products, joint procurement could contribute to uniform access throughout Austria in the inpatient sector on the basis of clear guidelines. In addition, joint procurement (e.g. as part of a public tender) could be used as a mechanism if no price agreement can be reached between an individual hospital or a hospital purchasing group and a pharmaceutical company. The establishment of a central body representing all hospitals in Austria in procurement would therefore be recommended.

Measure „Outcome-Based Managed Entry Agreements" (OBMEAs) for controlled access for new, personalized medicines and medicines for rare diseases

New, personalized medicines and medicines for rare diseases are often approved with little evidence of efficacy and clinical (additional) benefit, i.e. the cost-benefit ratio of these medicines is highly uncertain at the time of application for reimbursement. OBMEAs, in which reimbursement is linked to clinical outcomes, could offer a solution to enable patients in the outpatient sector to access these drugs. Piloting OBMEAs in the outpatient sector, embedding them in the HTA process and aligning documentation requirements with the inpatient sector are seen as important steps towards implementation. In practice, however, OBMEAs have certain limitations. It would therefore be important to evaluate whether OBMEAs are feasible in the outpatient sector and whether they can contribute to improving access to medicines in Austria.

Measure to improve the financing of selected innovative medicinal products via the 15a B-VG mechanism (or health target control):

High-priced drugs for rare diseases and in personalized medicine tend to pose challenges for their financing. In order to counter the limits of funding from the limited budgets of hospital operators, this measure proposes an increase in funding for medicines used in hospitals. This would require an amendment or supplement to the agreement pursuant to Art. 15a B-VG on the organization and financing of the healthcare system - Section 8, Art. 32. The same applies to the inclusion of operational regulations in the agreement pursuant to Art. 15a B-VG on health target management or in the target management agreement at federal level.

Measures to optimize the collection, quality and use of health data:

Health data holds great potential for improving healthcare. By using health data, research, industry, regulatory authorities and policy makers can gain insights that subsequently contribute to improved medicines and care delivery as well as the development new health apps (digital health applications). The prevention of diseases can also be improved through data-supported detection of abnormalities as part of preventive medical check-ups. In order to make optimal use of health data, there is a need to improve data collection, data quality and data linkage, which is addressed by the following proposals for policy measures:

Improved data collection could, for example, help to promote the evidence-based or rational use of antibiotics in the community setting.

The misuse (excessive or incorrect use) of antibiotics leads to unnecessary costs for the healthcare system and increases the risk of antibiotic resistance. To this end, it would be useful to evaluate the potential to collect better data on the prescription and use of antibiotics in the community setting. This could serve as a basis to promote evidence-based and rational use.

Assessment of the potential for improving data quality in the Austrian healthcare system:

In comparison with other European countries, there is a need for optimization of the existing data quality in the Austrian healthcare system. In order to improve the quality of documentation and the data to be recorded, incentives for service providers, e.g. in the sense of a pay-for-performance model (P4P), could have an effect. An assessment of the use of such models in Austria could be achieved through a corresponding review. The results of this review could serve as basis for decision for or against the introduction of certain incentive measures.

Registry research:

The Austrian healthcare system has large amounts of data, some of which are not accessible and not linked to each other. In order to make all relevant registers in the public healthcare system accessible for research via the Austrian Micro Data Center (AMDC) and thus enable registry research, it would be necessary to issue a corresponding ordinance in accordance with Section 38b Z1 FOG and Section 2d Para. 2Z 3 FOG. Registry research made possible in this way could make a significant contribution to gaining knowledge for the improvement of healthcare.

Measure to strengthen Austria/EU as a production location:

Reducing dependenies on imports from Asian countries could make a significant contribution to strengthening the security of supply of medicines in EU countries. The strategic expansion of pharmaceutical production in Europe is a long-term project, and therefore short and medium-term measures are required in the meantime to strengthen resilience to supply shortages and promote the competitiveness of pharmaceutical manufacturers in the EU. Diversification of supply chains by expanding the supplier base for raw materials and finished medicinal products or the approval of second suppliers or the joint procurement of medicinal products by several EU states could contribute to strengthening resilience, for example. Among others, measures in the area of pricing and reimbursement policy, a reduction of bureaucracy or the targeted promotion of the training of specialists could strengthen the competitiveness of pharmaceutical production in the EU. The involvement of all stakeholders in a stakeholder dialog is recommended.

Measure to improve cooperation at EU level:

The continuation and expansion of Austria's cooperation with other member states at EU level is an essential part of efforts to improve the security of supply of medicines. In this regard, the proposal published by the EU Commission in spring 2023 to revise the general EU pharmaceutical legislation was examined and the effects and requirements for Austria analyzed. The proposal comprises two interlinked legislative proposals aimed at improving security of supply and eliminating bottlenecks, among others. Legal reviews relating to the

monitoring and reporting of shortages, the prevention of shortages and transparency of information, the identification of critical medicines and cooperation with the EMA and the MSSG (Executive Steering Group on Shortages and Safety of Medicinal Products) have identified possible legal and organizational adaptation measures for the Austrian authorities.

Outlook

The proposals for policy measures and the associated recommendations for action could help to ensure sustainable access to medicines for patients in Austria.

One of the main challenges in the potential implementation of the policy proposals is to involve and motivate the various stakeholders to work together towards the goal of improving the supply of medicines for Austria and the EU. It is no less important to inform the population and sensitize them to the sensible use of medicines. Following project completion, it is up to the ministries to establish political commitment for the implementation of these measures and subsequently to plan, carry out and evaluate their concrete implementation.

4. DELIVERABLES

The project comprised a total of ten deliverables, which are subsequently summarized for an overview:

Deliverable 1: Report on project implementation

This Deliverable covers the most important content and framework conditions of the project work. This includes, in particular, the methodological approach and content-related questions.

Deliverable 2: Analysis of the resilience and attractiveness of the pharmaceutical value chain in Austria and in the EU context

This Deliverable includes the results of the analysis. The focus was on prescription drugs with and without competition, with and without patent protection, which are used in both inpatient and outpatient settings.

Deliverable 3: Evaluation of existing funding instruments to support the research, development and production of medicinal products in Austria and the European Union

This Deliverable identifies and analyses existing support instruments for research and development (R&D) and the production of medicines in Austria (including at EU level).

Deliverable 4: Decision matrix of policy measures

This Deliverable documents the process and result of prioritizing policy measures. The proposed 20 policy measures were evaluated in the Foresight Strategy Cockpit, using the previously developed evaluation criteria, by a defined group of participants from the ministries involved and members of the Advisory Board, including input from representatives of the Sounding Board. Taking into account the available evaluation results, the Steering Committee selected ten of the proposed measures for further work.

Deliverable 5: Action plan

This Deliverable contains an action plan that was drawn up for the previously selected ten proposals for policy measures, with further recommendations for action on the respective measures for potential implementation.

Deliverable 6: Policy Brief

This Deliverable represents an accompanying strategy paper for national actors in Austria. The dossier contains a brief description of the project context as well as a content related summary of the prioritsed policy measures.

Deliverable 7: Report on the implementation support provided and the experience gained

This Deliverable reports on implementation support which was provided for some of the prioritized measures. In particular, proposals for the revision of the general EU pharmaceutical legislation were examined with regard to the need to adapt Austrian law.

Deliverable 8: A use case for Europe - sharing knowledge and experience

This Deliverable reports on the results of activities aimed at enhancing the transferability of project results. Select project outputs were translated into English. In addition, and to present initial results on key topics, a panel on "Security of supply for medicinal products: measures for Austria" including a panel discussion took place at the Austrian Health Forum in Gastein from September 25-26, 2023. In addition to a representative of the project team, the expert panel included representatives from the following institutions: European Commission, Federal Ministry of Social Affairs, Health, Care and Consumer Protection, Austrian Chamber of Pharmacists, Austrian Self-Help Association and Austrian Generics Association.

Deliverable 9: Communication strategy & materials

This Deliverable includes communication materials such as project logo, project descriptions as well as infographics, factsheets and a PR & communication strategy.

Deliverable 10: Final report

This Deliverable outlines an overview of the project, the key findings from the project implementation, an analysis of the potential application in other EU member states and a roadmap for potential future activities.

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