

Market access in the German healthcare system

*National and subnational structures
to help navigate complexity*



Market access in Germany requires insights on strategic key decisions at the national, subnational and local levels.

Quintiles understands the unique market access challenges of the German healthcare system and can help smooth the path when entering Europe's biggest pharma market.

Pharmaceutical success rests on a simple principle: prove the value of your treatments, or risk losing the chance to gain market access for your product. Healthcare costs are climbing, regulators around the globe are requiring more information – and both providers and payers have higher expectations for a medical treatment's proof of value before prescribing or paying for those treatments.

Germany in particular has a set of very specific regulatory requirements that make market access different than in other countries. The legislation in the German healthcare environment especially contributes to a complex market access strategy. There are also different stakeholder groups with distinctive needs that must be met. Rely on Quintiles to help you navigate the challenges and successfully launch in the German market.

Quintiles helped develop or commercialize

98 of the Top 100

best-selling products of 2014.

The German healthcare market: characterized by continuous change

The Act on the Reform of the Market for Medicinal Products (AMNOG), implemented in January 2011, introduced a compulsory early benefit assessment of innovative pharmaceuticals for the first time in Germany. As a result, there is a complex regulatory environment of stakeholders involved in market access, at the national and subnational level.

Market access activities in Germany need to be built on a robust strategy on operationalization, depending on product and product category, reimbursement and engagement with stakeholders at the national and subnational level. This will establish a solid base for sustainable marketing of all new as well as in-market products. A company must have an interdisciplinary team – as well as experts skilled in helping meet the requirements of drug development and commercialization today. Quintiles' market access team in Germany can help create an optimal market entry strategy, with flexible and integrated solutions for both new and established products.



Why choose Quintiles?

Successful market access requires **insight and know-how on key strategic decisions** made at the national level – as well as a superior understanding of subnational and local specifics.

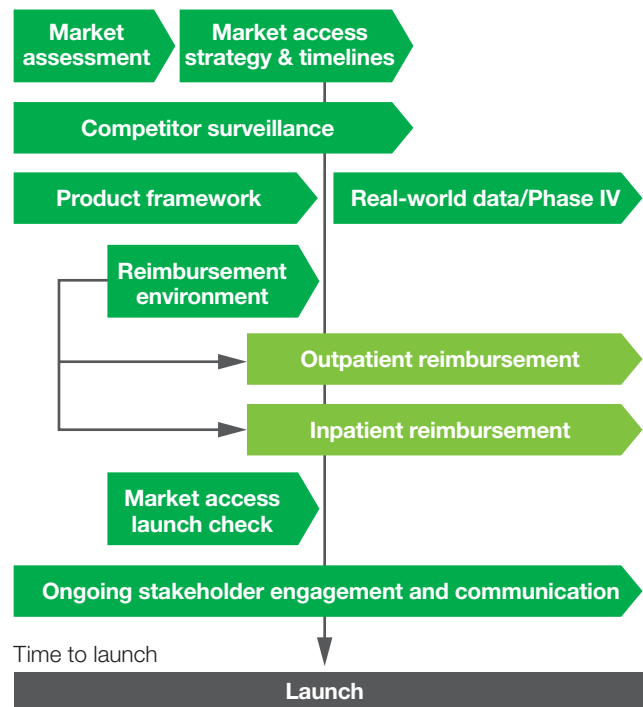
Quintiles offers:

- Strategic recommendations on navigating the German healthcare landscape
- Design and implementation of an integrated market access strategy covering all relevant reimbursement processes and related activities
- Development of a solution-specific roadmap to guide you through the marketing, reimbursement and product positioning process, taking into account all relevant stakeholders
- Access to detailed knowledge of subnational supply structures and regulatory, stakeholder, medical and payer needs – for optimal and efficient use of marketing and sales resources

By partnering with Quintiles, an experienced provider of market access solutions, you could achieve and sustain peak commercialization faster, leveraging the industry's largest integrated service infrastructure.

The Quintiles market access roadmap

The German healthcare market represents a significant opportunity for biopharma, medical devices and diagnostics. Tackling the challenges of sustainable market access requires a roadmap that can guide you through marketing, reimbursement and product positioning with numerous stakeholders. Quintiles knows that every situation is different – and can help you **draft and execute your unique strategy** efficiently.



Identifying and dealing with subnational structures makes all the difference for success

Germany is a fragmented market with multiple stakeholder groups. Successful market access requires understanding the subnational stakeholder landscape and how established contacts are necessary for gaining access. Quintiles' subnational market access team in Germany is organized into several regions to help you reach your objectives.

Subnational market access expertise	Project examples
<ul style="list-style-type: none">• Market access and key account management with focus on national and subnational physician associations, statutory health insurance funds and private health insurances• Deep insights into the Rx market with respect to prescription and regulation• Contract negotiation according to Social Security Code (SGB V)• Individual contracts with stakeholders of the German health care system• Support of tender business for drugs and medical devices• Close contacts and broad network in the relevant target groups• Continuous monitoring of the change of regulatory instruments for drug regulation	<ul style="list-style-type: none">• Negotiation of contracts (cost share, risk share, capitation, rebate) with statutory health insurance funds and private health insurances to secure market share before and after loss of exclusivity (LoE); e.g. rebate contracts with 128 sick funds reg. CNS product as bridging during LoE phase• Work out strategies for integrated care in physician networks in collaboration with sick funds• Training of Key Account Managers on the German healthcare system

Europe: More complex than you might think

The EU is not a single monolithic entity – each nation has its own regulatory landscape to understand. For successful market access in Europe, you need a partner who understands the process on the national, subnational and local levels.

Realize the potential of your product in Germany

Establish your product's value with Quintiles' tailored market access strategies, roadmaps and tactics to support entry and commercialization. Our subnational teams support you every step of the way, analyzing your unique situation to craft a product-specific, integrated solution and support execution. Gain access to leading insights to improve your probability of success™ in Germany.

Contact us today to find out more about how we can help with market access for your product.

Contact us

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