MAIS – Market Access Intelligence System

The MAIS-database contains all relevant information on the AMNOG procedures and links them for comprehensive precedent analyses and a clear presentation.

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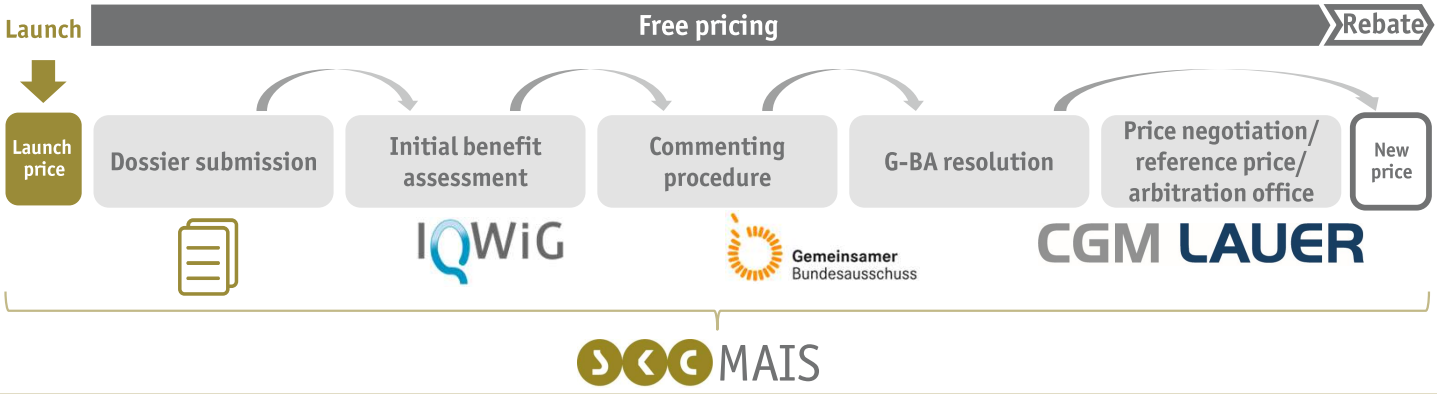
What is the purpose of the MAIS-database?

Market access in Germany is a multi-layered and complex process with various obstacles and high requirements. A deep understanding of the market and precedent analyses are essential for an optimal strategy. The MAIS-database serves as a hub for the information of all important stages of the AMNOG system.

What does the MAIS-database contain?

The database contains the most important aspects of all stations of the AMNOG:
General: overview of procedures/active substances, label, reason for submission, indication, document/patent protection, orphan status, status of procedure
Dossier: studies, study arms, endpoints, patient populations, added benefit claim
Benefit assessment: patient populations as well as associated studies and accepted endpoints, recommended added benefit
Resolution: patient populations as well as associated studies and approved endpoints, added benefit, annual therapy costs and appropriate comparison therapy
Price negotiation: annual therapy costs, rebate on pack level and annual therapy cost level
Arbitration office: arbitral verdicts, rebate on pack level and reimbursement amounts



What functions does the MAIS-database offer?

Overview: Quick overview of all procedures, basic search and sorting
Fact sheet: Overview of individual procedures, information from dossier, benefit assessment and resolution, patient populations, assessment of presented evidence, added benefit, costs, rebates and arbitral verdicts
Advanced search: Programmable search with seven levels of results and combination options for all parameters of the data set, Excel export for further analysis of the data
Automatic analyses: automatic visualization of added benefits, rebates, budget impact, history of costs and rebates, etc.

Exemplary analysis: single arm studies in orphan-procedures

All orphan procedures with added benefit

To date, there are **185**/223* (**82.96%**) orphan procedures for which an added benefit has been granted by the G-BA. This added benefit was derived from either single-arm or randomized trials.

Procedures with single arm studies have received a non quantifiable added benefit

A total of **111** orphan procedures were assigned a non quantifiable added benefit, 39 (**35%**) of which were based solely on single-arm studies.

For 39 orphan procedures, the evaluation was based exclusively on single arm studies

In **39** (**17,49%**) orphan procedures, the pivotal studies were only single arm studies.

Data cut-off: 04.08.2022

* The 38 orphan procedures without added benefit either exceeded the 50 million threshold or are drugs that have a new indication in the orphan spectrum.