



AMNOG

Early Benefit Assessment

An IGES + CSG Training Program

Focus: Additional Benefits

On January 1, 2011, the Act on the Reorganization of the Pharmaceutical Market (AMNOG) became effective. For pharmaceutical companies, the means of obtaining cost reimbursements from statutory and now also private health insurances have changed significantly: The prices for most pharmaceuticals with new active ingredients which the health insurances reimburse will now be fixed during the first year after their approval: Either through their immediate classification into a specific reference price group, or through negotiations with the National Association of Statutory Health Insurance Funds (GKV), or – in the case that these negotiations fail – through the regulation of a responsible arbitration board.

Any specification of the reimbursement price shall be based on the benefit assessment of a new drug. That is why an early benefit assessment assumes a key role in this.

Pharmaceutical companies have ascertained and demonstrated the benefits of their drugs for many years now. As a consequence they have adjusted their prices accordingly as, for example, studies of the IGES Institut demonstrate. But the new legal situation requires an adjustment of these procedures both before as well as after the approval of a drug. This calls for strategic decisions. On the one hand, the access to markets might be reduced while, on the other hand, new opportunities might open up.

For 30 years now, the IGES Institut has been working in the sectors benefit assessment, pharmaceutical market analyses, health economics, and health policy. The most visible indicator is the IGES Arzneimittel-Atlas ("Drug Atlas") which analyzes the pharmaceutical market for the statutory health insurance. Since 1998, IGES has been active in clinical research together with its subsidiary CSG. CSG specializes in late phase clinical studies, non-interventional studies as well as specific issues revolving around "patient reported outcomes."

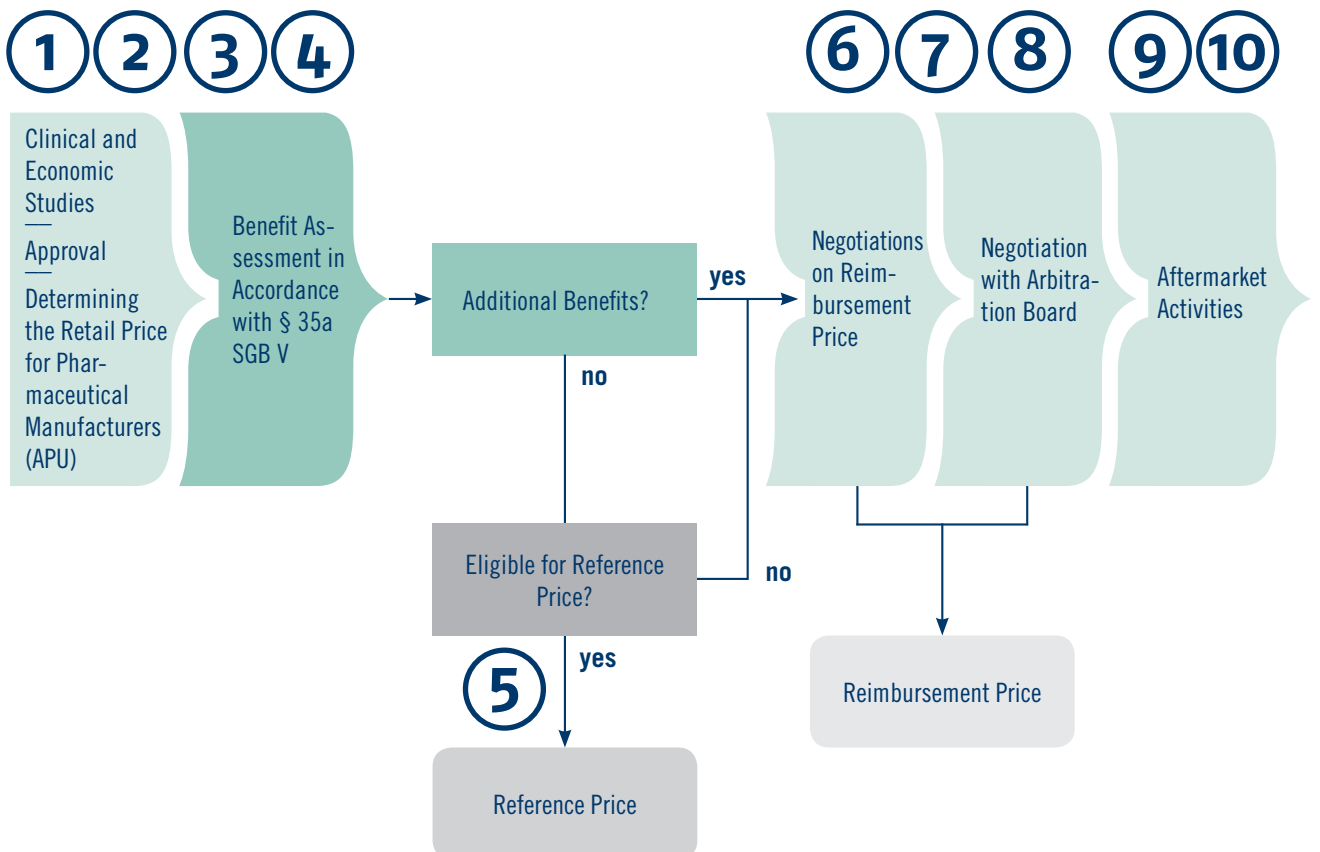
Against this backdrop, the IGES Institut and CSG offer a curriculum which will assist you both in your general preparations for the AMNOG and in addressing concrete questions.

The essential changes are outlined and expounded in ten separate training modules. The training concept closely follows the processes and procedures which need to be observed when obtaining cost reimbursements.

We'll advise you on how to ...

1. Prepare studies which take into account the new requirements
2. Benefit from meetings with the Federal Joint Committee (G-BA) on the compilation of studies (such meetings have now become possible in accordance with § 35a Section 7)
3. Prepare a "Dossier of the Pharmaceutical Manufacturer," and what needs to be considered in doing so
4. Ascertain the budget impact for your product from different perspectives because the budget impact will play a decisive role in the future
5. React prior to and/or after classification into a specific reference price group
6. Prepare yourself for negotiations with the National Association of Statutory Health Insurance Funds (GKV) on the reimbursement price in accordance with § 130b
7. Evaluate the strategies of your negotiating partners from the National Association of Statutory Health Insurance Funds (GKV) and the arbitration board
8. Prepare a summary of the "retail prices in other European countries" for the arbitration board
9. Negotiate value-added contracts in order to improve the placement of your product
10. Monitor your portfolio and assess its future development against the background of numerous external factors

Training Modules 1 – 10 focus on the procedures designed to ascertain the reimbursement price:



| Module | Main Focus | Contents |
|--|--|--|
| 1 CONCEPTUAL DESIGN OF STUDIES | Preparing studies to substantiate the additional benefits and economic advantages against the background of negotiating the reimbursement price | <ul style="list-style-type: none"> → Which conceptual design is most appropriate? → Can an appropriate comparator therapy already be considered? → Which parameters in clinical studies support the assessment of additional benefits? → Which economic parameters encompass the consumption of resources under everyday conditions? → How can economic advantages be quantified for negotiations on the reimbursement price? |
| 2 MEETING WITH THE FEDERAL JOINT COMMITTEE (G-BA) | Preparing oneself for a meeting with the G-BA on the methodological requirements regarding the verification of benefits for a future study | <ul style="list-style-type: none"> → What is relevant when preparing for such a meeting? → What are the relevant aspects of the legal regulations and procedural rules for the assessment of additional benefits? → What are the reasons for the soloist status? → Which methods and innovative approaches can be used to verify additional benefits? |
| 3 DOSSIER | Preparing the dossier | <ul style="list-style-type: none"> → What has to be included in the dossier? → What formal aspects and deadlines exist? → How can a “appropriate comparator therapy” be ascertained? → How can additional benefits be substantiated and categorized? → How can those patient groups be quantified for whom there is a therapeutically relevant additional benefit? |
| 4 BUDGET IMPACT | Assessing the budget impact as the basis for negotiating the reimbursement price | <ul style="list-style-type: none"> → Ascertaining the prevalence of ailments → Differentiating according to such patient characteristics as need for treatment and treatment phase, severity level, response, etc. → Ascertaining the expenditures for a therapy compared to previous therapies → Strategies for expanding the indications or any other reasons for exceeding the agreed-upon budget |
| 5 REFERENCE PRICE | Strategies for fixing a reference price | <ul style="list-style-type: none"> → What options exist to verify the additional benefits compared to the reference price group? → What are the economic scenarios resulting from the potential options of fixing a reference price? → What accompanying measures are suitable if the fixed price exceeds the reference price? |

| Module | Main Focus | Contents |
|--|--|--|
| 6 NEGOTIATING THE REIMBURSEMENT PRICE I | Preparing oneself for negotiations with the National Association of Statutory Health Insurance Funds (GKV) on the reimbursement price | <ul style="list-style-type: none"> → Which treatment need exists in the target indication? → What is the patient-relevant benefit and additional benefit of the pharmaceutical? → Which patient groups benefit in particular? → How can the additional benefit be monetized with regard to health economics? |
| 7 NEGOTIATING THE REIMBURSEMENT PRICE II | Strategies for negotiations with the National Association of Statutory Health Insurance Funds (GKV) and the arbitration board | <ul style="list-style-type: none"> → What is the logic behind the payers' decision making? → What convinces the payers, and what does not? → How can therapeutic references be designed and compiled? → How can a position be presented at the arbitration board? |
| 8 EUROPEAN PRICE LEVEL | A European comparison of prices and strategies for their market launch | <ul style="list-style-type: none"> → What countries are included in a comparison? → What country-specific criteria can be applied? → What negotiation strategies can be developed? |
| 9 VALUE-ADDED CONTRACTS | Design and implementation of value-added contracts | <ul style="list-style-type: none"> → What are the impediments and success factors of existing contracts? → What type of contract fits what product? → How should instructions for therapies be designed? → How can the payer be convinced? → How can contracts be managed successfully together with the contractual partner? |
| 10 PORTFOLIO MONITORING | Monitoring and analyzing portfolios | <ul style="list-style-type: none"> → How do prescriptions and sales develop? → What are the potentials and risks of the product when considering the entire therapeutic sector? → What role does the health policy environment play for the portfolio? |

Training Team

Benefit assessment, health technology assessment, health economics, and outcomes research have been the key topics of the IGES Institut and CSG for many years now. This training program is, thus, based on both the scientific as well as the business strategic experiences gained by both institutes.

The training team consists of specialists who have gained renown in the relevant scientific and applied fields:

Hans-Holger Bleß, Pharmacist

- Conceptual design of individual contractual strategies as well as development, negotiation, and evaluation of selective contractual models at a large health insurance company
- Experience in dealing with the relevant committees of the GKV
- Development, implementation, and evaluation of cost management measures in the GKV
- Advanced development and implementation of cost effectiveness audits in accordance with § 106 SGB V
- Pharmacological and pharmacoeconomic assessment of therapies

Prof Dr Bertram Häussler, Physician

- Health services research
- Treatment epidemiology
- Benefit assessment
- Economics of the pharmaceutical market
- Professor of “Economics of the Pharmaceutical Industry”

Dr Ariane Höer, Specialist Physician for Pharmacology and Toxicology

- Analyses and prognoses of drug prescription and sales trends in the GKV market (IGES Arzneimittel-Atlas)
- Drug evaluation
- Health services research based on claims data analysis

Dr Peter K. Schädlich, Pharmacist

- Conceptual design of clinical and non-interventional studies with economic parameters
- Health economic evaluation through models and/or primary data
- Positioning of pharmaceuticals with health economic arguments

Training Details

- Every module encompasses half a day of training.
- Modules may be booked separately.
- Several modules may be combined individually.
- The training sessions can be held either in your company or at the IGES Institut in Berlin.
- The training sessions can also be held at a location of your choice.
- The participation fee for each module amounts to EUR 2,500.00 plus VAT for up to five participants.
- The cost for additional participants is EUR 500.00 plus VAT per person per module.
- Comprehensive training materials are included in the price for each participant.
- The training agenda will specifically address your individual questions.
- Sufficient time will be allotted to the interaction among the participants and with the instructors.

Please contact us if you wish to combine a number of different modules and/or a larger number of participants is intended.

If you have specific requests or questions regarding the content of the modules, please contact:

Hans-Holger Bleß
Phone + 49 30 230 809 348

at any time.

You can also send us an email to Schulung@iges.de and/or use the enclosed fax response form.

Fax Reservation

Please send to + 49 30 230 809 11

I would like to make a binding reservation for:

| Please Select | Module | Preferred Date | Number of Participants |
|-----------------------|--|----------------|------------------------|
| <input type="radio"/> | 1 CONCEPTUAL DESIGN OF STUDIES | | |
| <input type="radio"/> | 2 MEETING WITH THE FEDERAL JOINT COMMITTEE (G-BA) | | |
| <input type="radio"/> | 3 DOSSIER | | |
| <input type="radio"/> | 4 BUDGET IMPACT | | |
| <input type="radio"/> | 5 REFERENCE PRICE | | |
| <input type="radio"/> | 6 NEGOTIATING THE REIMBURSEMENT PRICE I | | |
| <input type="radio"/> | 7 NEGOTIATING THE REIMBURSEMENT PRICE II | | |
| <input type="radio"/> | 8 EUROPEAN PRICE LEVEL | | |
| <input type="radio"/> | 9 VALUE-ADDED CONTRACTS | | |
| <input type="radio"/> | 10 PORTFOLIO MONITORING | | |

Fax Reservation

Please send to + 49 30 230 809 11

CONTACT INFORMATION

Company _____

Title _____

First Name(s) _____

Last Name(s) _____

Your Responsibilities _____

Street / No. _____

Postal Code / City _____

Phone _____

E-Email _____

Date/Company Stamp/Signature

TRAINING LOCATION

- In your company (plus travel expenses for trainer(s))
- At the IGES Institut, Berlin
- At an another location (plus location fees, travel expenses for trainer(s))

Please select the desired location

YOUR ADDITIONAL COMMENTS



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CSG

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Companies of the IGES Group.

