Are vaccinations really different to pharmaceuticals with respect to market access in Germany?

A systematic analysis of the German vaccine market access route

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Federal Joint Committee (G-BA)
- The legislator provides the framework for the regulation in obligatory health insurance. The legal principle for the work of the Federal Joint Committee (G-BA) is to define how preventive or therapeutic interventions are actually reimbursed. Under the Vaccination Directive (§ 130 b SGB V), the G-BA determines the reimbursement prices for vaccinations.
- The Federal Joint Committee (G-BA) provides the basis of the G-BA’s obligation to render services in its vaccination directive.

Social Health Insurances (GKV regional level)
- Within the framework set by G-BA the G-BA’s obligation to render services according to the vaccination directive.
- Further and beyond the health insurance funds can offer additional vaccination services, not specified by the G-BA, on optional benefits according to their standards.
- The cooperation of the public health services and the SHIs and the reimbursement of the material costs by the SHIs is defined in § 23d SGB V.
- For the purpose of provision and reimbursement of vaccinations the regional SHIs contract with the public health authorities.
- Some particular agreements, depending on the individual states, are negotiated with municipal public health authorities if framework level at state level is not applied.

State Ministries of Health (Landesminister-Amt für Gesundheit)
- The State Ministries can use public health offices at municipality to provide specific vaccination services at no cost, defined by §47 Abs. 1 No. 16 AMG
- According to §47 Abs. 1 No. 16 AMG they can procure these vaccinations directly by the manufacturer or wholesalers that are forecast as preventive care for free of charge according to §38 Abs. 5 GKV-DSG.
- In liaison with the local Association of SHI physicans they assure comprehensive vaccination provision.

ABMOG vs. Market access for vaccinations
- The AMBMO process intends to proof the eligibility for reimbursement of a new medicinal product.
- Within ABMOG as an early benefit assessment is conducted by GBA and approved by the G-BA.
- Following the process the G-BA’s approval establishes the reimbursement price.
- During the time of appraisal and negotiation the price is not public as outcome of the process will be replaced by the reimbursement price agreed.
- The Market access of vaccinations is a two-tier process distinguishing between the appraisal at a national level and the proof of eligibility for reimbursement of a regional level.
- The STIKO conducts the approval and general recommendations, the G-BA updates and includes the vaccination directive by specifying the details of the G-BA’s obligation to render services of the type of scope of the vaccinations.
- For the regional approval of the supply with vaccines the regional health insurance negotiate and contract based on the manufacturers prices less discounts and rebates and including the agreements with different public health authorities on state and municipality level.

Figure 1: Stakeholders, processes and responsibilities for vaccination services in Germany (Source: Own representation following ISPOR institute at 4/16)

Federal Ministry of Health (Bundesministerium für Gesundheit)
- The Ministry gives general directives and delegates the implementation and Surveillance to the bodies.
- Generally the Ministry decides which vaccinations have to be connected to the SHIs, other can be provided by the public health offices [2].

The Standing Committee on Immunization (STIKO)
- The National immunization schedule is developed by STIKO, and an updated version is usually published once a year (usually in July) in the Epidemiological Bulletin of the Robert-Koch-Institute [2].
- Besides the routine immunization schedule (see Figure 2 below), STIKO also recommends vaccinations for special targets or particular groups.
- When developing a new vaccination recommendation, STIKO usually needs to address a set of key questions. These questions fall within the five categories:
  1. pathogenesis and the disease; pathogens of the target disease;
  2. characteristics of the target disease;
  3. vaccine characteristics (efficacy/safety, immunogenicity);
  4. implementation of the recommendation (possible obstacles, potential reactions of the vaccine in the population, operational issues, reimbursement; if a final evaluation is available cost-effectiveness of vaccination);[7]
  5. following that a risk-benefit assessment is conducted by STIKO and the overall public interest in the vaccination is considered.
- Besides epidemiological risk assessment, STIKO considers extra safety and efficacy on the population level.
- Further STIKO can take into account a health economics evaluation (HEE) in the decision-making process according to the standard operating procedures of the STIKO as it is routinely considered in immunization introduction decision-making processes in many industrialised countries[8].
- However, there is currently neither a guideline stating the criterion requirements for HEE to be accepted for STIKO nor have results of HEE should be considered in decision-making process of STIKO.

Figure 2: Vaccination schedule Germany (Source: ISPOR [3] & STIKO [6])

Figure 3: Differences between ABMOG for regular pharmaceuticals and market access for vaccinations (Source: Own representation following ISPOR [3], 2015)

METHODS:
- We reviewed systematically the regulatory and general information of relevant German authorities – e.g. G-BA, STIKO (Standing Immunization Advisory Committee), Robert-Koch-Institute, SHI (Social Health Insurances/Health Insurers), Head Association of Statutory Health Insurance Funds (GKV-Spitzenverband), different Associations of the Statutory Health Insurers (Kassenärztliche Vereinigungen), IQWiG (Institute for Quality and Cost-effectiveness in Healthcare), Germany, German Health Care Commission (Bundesseelsorgerkammer), Advisory Council on the Assessment of Developments in the Health Care System (Gesundheitsausschuss), Head association of drug manufacturers (Bundesverband der Arzneimittelhersteller e.V.)
- We evaluated publications on the public health and vaccine market in Germany, interesting for our analysis.

RESULTS:
- Based on the results of the systematic analysis we could ascertain specifics for the vaccination market. For an overview see Figure 1.1.

CONCLUSION:
- The systematic analysis revealed a clear access market access route, stakeholder complex and important strategic implications for the pharmaceutical companies with respect to the ABMOG.
- The Referred benefits to the ABMOG are varying allocations at different levels and responsibilities of those. Pricing might be more feasible with vaccinations even though final decision might apply.

Reference: