# IMPLEMENTATION AND APPLICATION OF THE PHYSICIAN INFORMATION SYSTEM (ARZTINFORMATIONSSYSTEM, AIS) IN GERMANY



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## **OBJECTIVES**

Since July 2020, detailed information on German benefit assessments of medicinal products provided by the physician information system (Arztinformationssystem, AIS) must be included in practice management softwares. In the Electronic Physician Information Ordinance (Elektronische Arztinformationen-Verordnung), the German Federal Ministry of Health (BMG) obliged the Federal Joint Committee (G-BA) to provide a machine-readable version of its decisions available as data set on its website. The information must be implemented in the AIS allowing easy access on authorised indications, individual patient groups, results for mortality, morbidity, health-related quality of life, safety and the decision on the additional benefit of the medicinal product. For this purpose, the G-BA publishes a machine-readable version of the decisions available as a regularly updated XML file twice a month. The objective of this analysis was to present the content of the XML file and possible applications of this data for the AIS and other purposes.

### PHYSICIAN INFORMATION SYSTEM

A physician information system is generally referred to as software that supports the management, organization and operation of medical practices or the medical profession. The main tasks of this software include appointment management, documentation of diagnosis and laboratory values, document management and medication management. The aim of the statutory introduced AIS is to enable physicians to obtain information on the additional benefits of a new drug quickly and easily when prescribing it. An exemplary implementation of the information of the machine-readable XML file in an AIS is shown in Fig. 1.

# **METHODS**

After extraction and implementation of the data from the XML file in the IQVIA Insights Builder, we use the example of orphan drugs to show which information can be visualized and combined for a comfortable access of the information.

### **RESULTS**

Of 865 benefit assessments completed to date (15.09.2022), 183 are of orphan drugs<sup>2</sup>. To date, not all benefit assessments by the G-BA have been recorded in the XML file. The XML file published by the G-BA contains to date (15.09.2022) 521 benefit assessments in total, including 110 assessments of orphan drugs (Fig. 2, Fig. 3). Until 1st April 2023, all published assessments on the G-BA website will be included in the XML file with regular updates. In order to identify the justification for the decision of a quantifiable additional benefit with regards to outcomes, the related benefit assessments were analyzed in detail. For this purpose, the period from 01.01.2020 till 13.03.2022 was examined in more detail. 17 orphan dossiers achieved a quantifiable additional benefit in this period. The analysis revealed that the justification was based on superiority versus the study comparator (independent of appropriate comparator therapy) exclusively on primary endpoints (4 cases), exclusively on secondary endpoints (7 cases) and on primary and secondary endpoints (6 cases). In one case the safety profile was sufficient to achieve a quantifiable additional benefit (Fig. 4)<sup>2</sup>.

# CONCLUSION

The implementation of the AIS in Germany helps physicians to access information from the benefit assessment procedures efficiently and improves the possibility of supporting the individual decision of the physicians in the treatment of patients with evidence-based information. However, the AIS, or the information on which it is based, is a valuable pool of information that can be easily accessed. Analyses for benefit assessments of any kind are conceivable with the data set. In this analysis we show in which way the information can be visualized and combined for a convenient access.

Abbreviations:

AIS: Arztinformationssystem; BMG: German Federal Ministry of Health; G-BA: Federal Joint Committee.

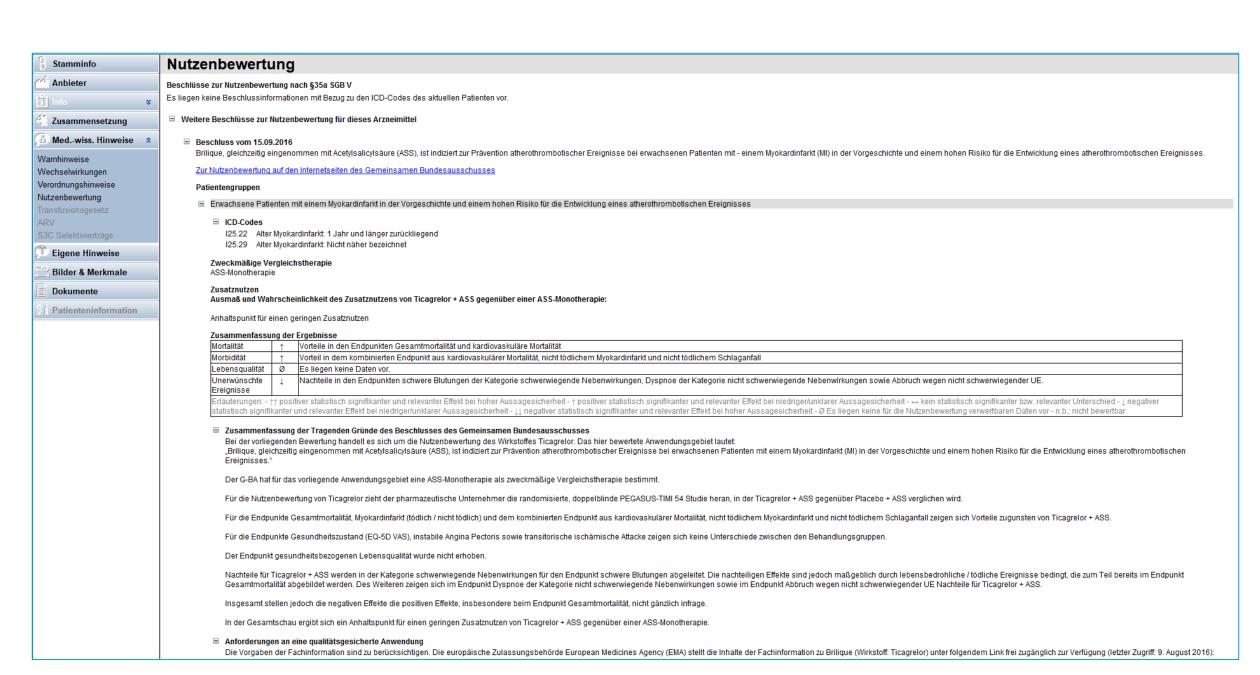


Figure 1: Example of the implemented information of the machine-readable XML file in a physician information system<sup>1</sup>.

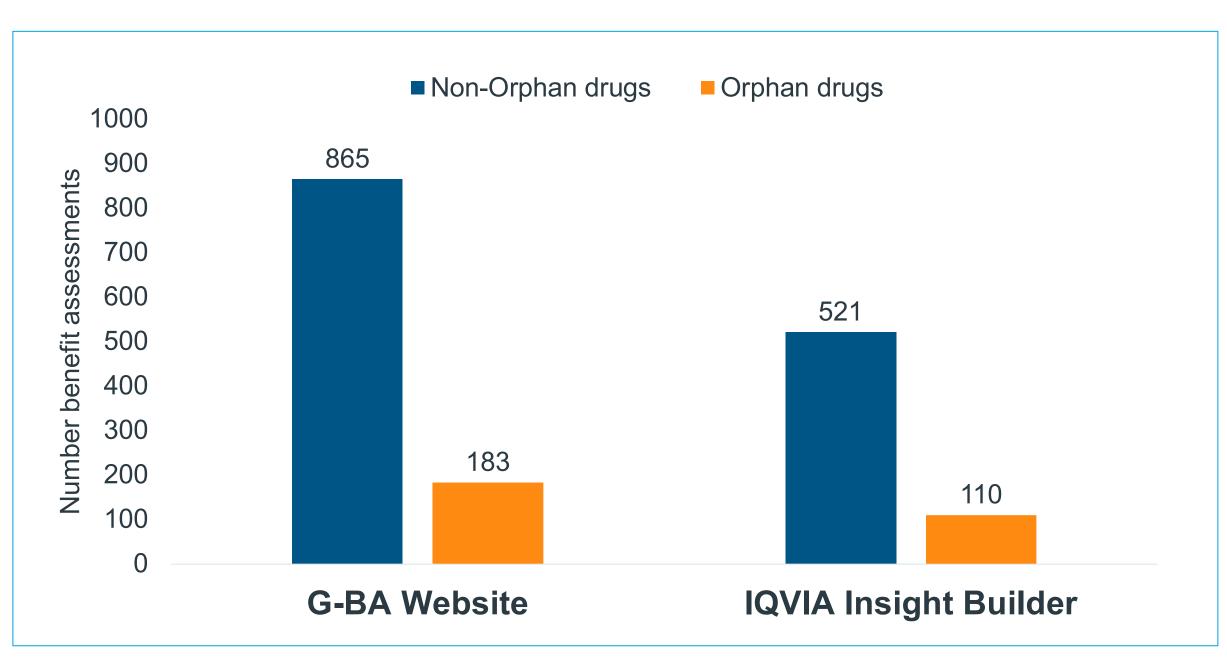


Figure 2: Amount of completed benefit assessments in total and for orphan drugs by the G-BA available on the G-BA website and available in the IQVIA Insights Builder (date 15.09.2022)<sup>2, 3</sup>.

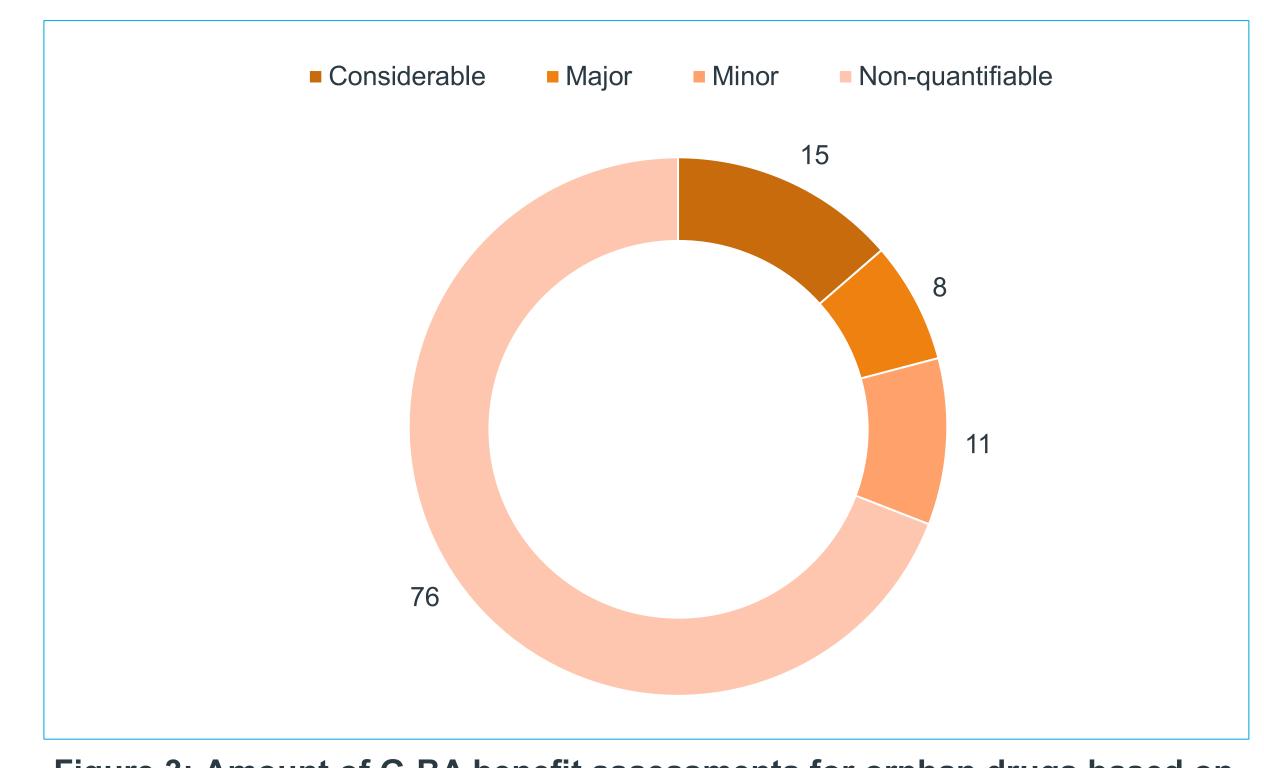


Figure 3: Amount of G-BA benefit assessments for orphan drugs based on the published G-BA XML file data implemented in the IQVIA Insights Builder (date 15.09.2022)<sup>3</sup> split according to benefit rating.

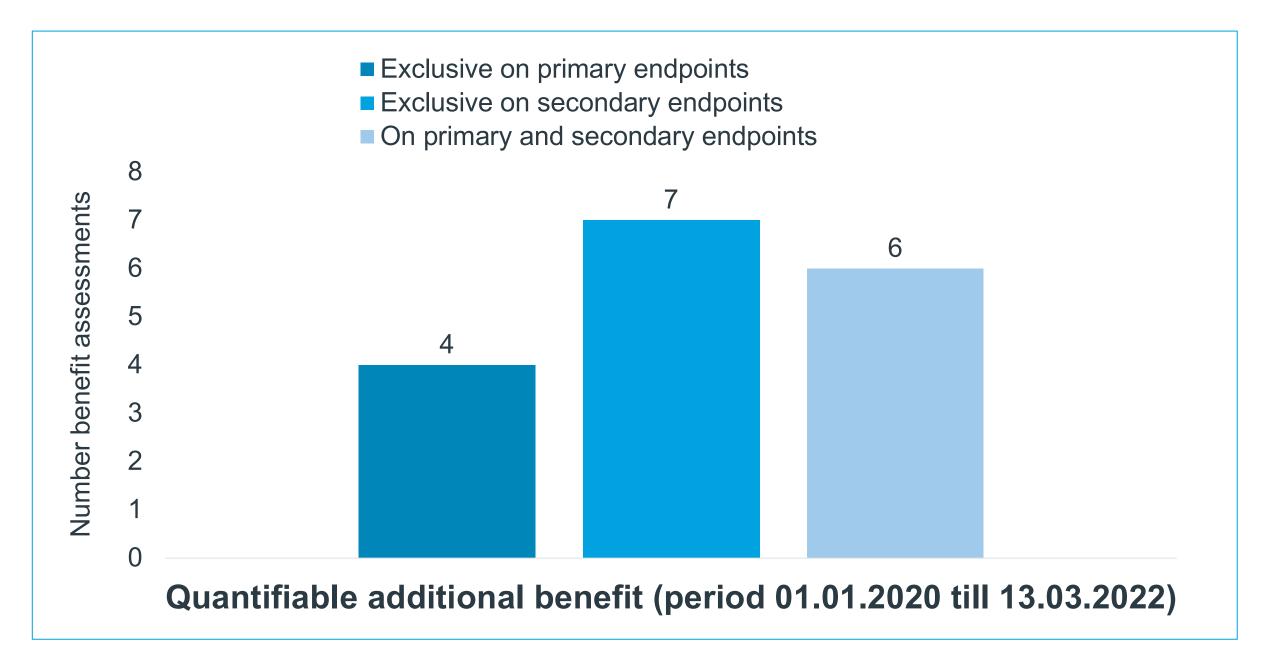


Figure 4: Amount of G-BA benefit assessments for orphan drugs with a quantifiable additional benefit in the period from 01.01.2020 till 13.03.2022 based on the published G-BA XML file data implemented in the IQVIA Insights Builder (date 15.09.2022)<sup>2, 3</sup>.

### References:

- 1. Software ifap praxisCENTER®
- 2. www.G-BA.de (15.09.2022).
- 3. IQVIA Insight Builder (15.09.2022).

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