Press release

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Medicinal products

2nd Joint Meeting on ‘Innovations in Healthcare’ – virtual symposium brings together EU pharmaceutical experts

Berlin, 18 September 2020 – How can methodological and scientific advice to manufacturers of medicinal products be further optimised at European level in order to generate more relevant scientific evidence before and after the authorisation of a product? This question will be addressed at the 2nd Joint Meeting ‘Innovations in Healthcare’ (INNO Meeting) at the beginning of October. The virtual symposium is being organised by the Federal Joint Committee (G-BA) and the Institute for Quality and Efficiency in Health Care (IQWiG). The INNO Meeting will take place between 1-2 October 2020 and is part of the German Federal Ministry of Health’s associated programme under the German EU Council Presidency 2020.

Participating organisations include the Scientific Advice Working Party (SAWP), the EU Innovation Network (EU-IN), the Clinical Trials Facilitation and Coordination Group (CTFG), the European Network for Health Technology Assessment (EUnetHTA), the Innovation Task Force (ITF) and the SME Office of the European Medicines Agency (EMA). The guiding concept of the event is to collect relevant data that can be used for both marketing authorisation and HTA assessment through efficient cooperation between European marketing authorisation authorities and HTA organisations when advising the industry. The main topics include how to work with innovations, such as advanced therapy medicinal products (ATMPs), and the collection of registry data and their applicability in Europe.

‘I am very pleased that the G-BA and IQWiG will be jointly hosting and supporting the second INNO Meeting. In recent years, there has been a trend towards authorising new medicinal products faster than ever, sometimes on the basis of data that is still inconclusive. This means that timely cooperation between the European regulatory authorities and HTA organisations in providing scientific advice to the pharmaceutical industry is vital. The common goal should be to generate meaningful data via clinical trials for both authorisation and HTA evaluation’, said Professor Josef Hecken, impartial Chair of the G-BA and Chair of the Subcommittee on Pharmaceuticals.

‘All study data must meet the requirements for evaluating new drugs of the respective Member States of the European Union. Scientific issues,

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such as clinical trial requirements, methodology, endpoints or surrogate parameters, should be addressed as uniformly as possible according to the standards of evidence-based medicine', added IQWiG Director Professor Dr. Jürgen Windeler. 'It is essential to have an exchange of information between the European partners.'

The most important outcomes of this invitation-only event will be announced in a press release shortly afterwards. Comprehensive documentation of the outcomes will then be posted later on the G-BA website.

Background

Both the G-BA and IQWiG are partner organisations in the European Network for Health Technology Assessment (EUnetHTA). Since 2007, IQWiG has been the Lead Partner of EUnetHTA's JA3 Work Package 6 – Quality Management, Scientific Guidance and Tools; as such, it is largely responsible for developing the quality framework of EUnetHTA products. The Federal Joint Committee has been Co-Lead Partner of EUnetHTA's JA3 Work Package 5A – Early Dialogues since 2016; thus playing a major role in jointly advising the industry on trial design by HTA organisations at European level, together with the additional participation of the European Medicines Agency (EMA).

The 1st Joint INNO Meeting took place in Helsinki in 2019 under the Finnish Presidency of the EU Council. It was agreed to continue this exchange once a year under the aegis of the rotating EU Council Presidency.

The **Federal Joint Committee (G-BA)** is the highest decision-making body of the joint self-government of physicians, dentists, psychotherapists, hospitals, and health insurance funds in Germany. It issues directives for the benefit catalogue of the statutory health insurance funds (SHI) for more approx. 70 million insured persons. The G-BA specifies which services in medical care are reimbursed by the SHI. The legal basis for the work of the G-BA is the German Social Code, Book Five (SGB V). In accordance with the Patient Involvement Act, patient representatives take part in the consultations of the G-BA in an advisory capacity and have the right of petition.

The health policy framework for medical care in Germany is set by the parliament in the form of laws. It is the task of the G-BA to adopt uniform guidelines for practical implementation within this framework. The guidelines adopted by it have the character of subordinate standards and are binding for all stakeholders of the SHI.

In making its decisions, the G-BA takes into account the generally accepted state of medical knowledge and examines the diagnostic or therapeutic benefits, medical necessity, and the principle of economic efficiency of a benefit from the compulsory catalogue of health insurance funds. The G-BA also has other important tasks in the area of quality management and quality assurance in outpatient and inpatient care.

For more information, see **www.g-ba.de**

Quality and efficiency – these are two crucial factors in a good and effective healthcare system. To achieve and maintain this goal, it is important to assess medical interventions using objective methods. This is precisely the task of the **German Institute for Quality and Efficiency in Health Care (IQWiG)**.

As an independent scientific institute, IQWiG examines the advantages and disadvantages of medical interventions. In our reports we draw conclusions on what is beneficial from a diagnostic and therapeutic point of view and what is superfluous or even harmful. IQWiG produces reports on drugs, medical devices, surgical procedures, diagnostic and screening tests, clinical practice guidelines, and disease management programmes. We also produce easily understandable health information on our reports and on further topics for the general public as well as decision aids to inform them about the advantages and disadvantages of screening tests.

According to the law, only two institutions can directly commission IQWiG: the Federal Joint Committee (G-BA) or the Federal Ministry of Health. In addition, since 2016 the general public can propose diagnostic and therapeutic topics to be assessed within IQWiG's "ThemenCheck Medizin" ("Topic Check Medicine", website available only in German).

For more information, see **www.iqwig.de/en**