Statement of the Federal Republic of Germany

in the consultation on an Inception Impact Assessment

"Strengthening of the EU cooperation on Health Technology Assessment (HTA)"

of 14 September 2016

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I. Context: The status and utilisation of HTA in Germany

Health insurance in Germany is made up of two different systems: statutory health insurance and private health insurance. Almost 90 percent of the population have statutory health insurance. Statutory health insurance operates on the basis of the solidarity principle. Earnings-related premiums paid by both employers and employees, supplemented by a tax-funded federal subsidy, as well as supplementary contributions specific to each health insurance fund, guarantee that the system is soundly funded. Regardless of the amount of contributions which they pay, all insured persons receive the medically-necessary services and are entitled to the same services. The principle of self-government applies in statutory health insurance: The State creates the statutory framework and defines the mandate. The organisations of the insured persons and contributors, and of the healthcare providers, are accountable for providing healthcare. These include the statutory health insurance funds (all of which are represented in the National Association of Statutory Health Insurance Funds [*GKV-Spitzenverband*]) and the regional Associations of Statutory Health Insurance Physicians and Statutory Health Insurance Dentists (each represented in the National Association of Statutory Health Insurance Physicians or the National Association of Statutory Health Insurance Dentists (KBV/KZBV)). Together, the National Association of Statutory Health Insurance Funds, the National Association of Statutory Health Insurance Physicians, the National Association of Statutory Health Insurance Dentists and the German Hospital Federation form the Federal Joint Committee (*Gemeinsamer Bundesausschuss* – G-BA). The latter is the highest decision-making body of joint self-government in the healthcare system. The Federal Joint Committee hands down legally binding guidelines which have the status of sub-statutory regulations.

The guidelines regulate the supply of medicinal products, remedies and medical aids, as well as the provision of medical services and diagnostic and treatment methods. They are binding on all insured persons, health insurance funds and healthcare providers who are involved in care. The procedures for guideline creation and decision-making, which are set out in the Rules of Procedure of the Federal Joint Committee, differ widely in some instances. This is because the various fields (such as medicinal products, medical devices,

diagnostic and treatment methods, etc.) cannot be assessed by uniform procedures. The procedures are intended to facilitate transparent, legally-certain decisions which correspond to the generally-recognised state of medical knowledge.

The medical and technical evaluations carried out by the Federal Joint Committee in the guideline creation and decision-making procedure are covered by the term Health Technology Assessment (HTA).

Consequently, HTA is highly significant in Germany overall, and it has become very well established. The requirements made as to the quality of HTA reports, as well as the standards applicable to the evidence on which they are based, the processes by which they are drawn up and the public hearing procedures on the reports, are set out in law, and are tried and tested. Their central role as a basis for decisions in the German healthcare system is widely recognised. It is primarily the Institute for Quality and Efficiency in Health Care (IQWiG) which carries out the scientific evaluation on behalf of the Federal Joint Committee, whilst the Federal Joint Committee, as the normative institution, implements further consultation procedures which are stipulated by law, takes care-related aspects into account and is responsible for adopting the normative guidelines. The same legal and methodical standards are binding for evaluation by the Federal Joint Committee as those with which the IQWiG must comply when drawing up the reports. Both institutions work within a framework which is set in law, and which is largely centred on the all-embracing entitlement of insured persons to services which are sufficient, necessary and economical.

It is this service entitlement on which the evaluation procedures are centred. This will be explained below for a variety of technologies.

When it comes to **technologies** which do not constitute medicinal products, they aim to ensure that, as a matter of principle, only those services are covered by solidarity-based statutory health insurance where the diagnostic or therapeutic benefit has been adequately proven. Here, the evaluation forms the basis for the decision as to whether a service is listed among the benefits funded by statutory health insurance. The Federal Joint Committee reviews new diagnostic or treatment methods at the request of an eligible organisation y. The evaluation procedure is generally to be completed within three years at most. In the further procedure, the decision of the Federal Joint Committee must factor in the

statements of the respective Scientific Medical Societies, as well as of the medical device manufacturers affected and their associations, based on the scientific method assessment. If the Federal Joint Committee concludes that a new method does offer potential for a necessary alternative treatment, but that the evidence that is currently available is still insufficient to prove its benefit, it may initiate scientific trials of the new method (Erprobung). The health insurance funds meet the cost of providing the new method being trialled, and the medical device manufacturers involved pay for the research and evaluation to a reasonable degree. As a matter of principle, the diagnostic or treatment method remains providable and billable on an in-patient basis until the results of these trials are available.

A special procedure has applied since 2016 to new methods where the technical application is fundamentally dependent on the deployment of a **high-risk-class medical device** and is to be provided on an in-patient basis for the first time. This obligatory evaluation procedure is carried out by the Federal Joint Committee within a total period of roughly five months after the first documents have been submitted, with the involvement of affected hospitals and medical device manufacturers. This therefore ensures the timely funding of any additional costs that are incurred for methods the benefit of which is already considered as having been proven, or which at least show potential for a necessary alternative treatment. For methods which show potential, the testing (Erprobung) is carried out by the Federal Joint Committee as a matter of principle. Hospitals which would like to provide the method applying the high-risk-class medical device at the expense of statutory health insurance are obliged to take part in the trials.

Market access for **medical devices** – and thus benefiting from the principle of free movement of goods –requires the confirmation of conformity with the relevant general safety and performance requirements, including the evaluation of acceptability of the benefit/risk ratio on the basis of adequate clinical data.

The efficacy of **medicinal products** is already confirmed by virtue of their marketing authorisation. They are billable as a matter of principle on the basis of the marketing authorisation under the law on medicinal products. The Federal Joint Committee evaluates the additional therapy-relevant benefit obtained from medicinal products vis-à-vis the

standard therapy that is applicable in Germany. This evaluation forms the basis for the subsequent price negotiations. To this end, the additional benefit of newly-launched medicinal products with new active agents vis-à-vis the standard therapy that is applicable in Germany has been evaluated since 2011. The Federal Joint Committee evaluates the additional benefit of the medicinal product within three months of its market launch as part of the benefit assessment. The manufacturer must submit to the Federal Joint Committee a dossier containing the documents required for this. As a rule, the Federal Joint Committee commissions the IQWiG with carrying out the evaluation. Once the result of the scientific evaluation has been published, the manufacturers, associations and experts have an opportunity to issue opinions. After another three months, the Federal Joint Committee hands down a resolution on the basis of the benefit assessment and of the opinions. The resolution establishes amongst other things the extent and probability of the additional benefit, broken down according to patient populations, requirements as to quality-assured application, as well as therapy costs. If an additional benefit is proven, the National Association of Statutory Health Insurance Funds and the manufacturer negotiate a reimbursement amount within six months. If no additional benefit is proven, and if it is not possible to attribute the medicinal product to an existing maximum reimbursement amount (Festbetrag), a reimbursement amount is also agreed on. In this case, the reimbursement amount may not lead to higher annual therapy costs than the price of the appropriate comparator. If no agreement is reached, an arbitration tribunal is called on, which sets the amount.

Details on all the procedures, as well as reports and resolutions, can be retrieved from the website of the Federal Joint Committee (www.g-ba.de) (including detailed information in English on past benefit assessments of medicinal products).

These evaluation procedures provide a motivation for real innovations in evidence-based patient care. For instance, calculating the additional benefit of medicinal products enables higher prices to be achieved for real innovations. Other technologies are not included in the list of benefits until they have been positively evaluated.

II. European cooperation on HTA

II.1. The "State of Play"

The Member States are increasingly using HTA procedures as the basis for decisions on the reimbursement and pricing of healthcare technologies. The different procedures for implementing HTA and the concrete questions which HTA is used to answer reflect the heterogeneity of the Member States' healthcare systems. Depending on the Member State, but also on the technology, HTA is used as a basis for preparing decisions on reimbursement per se, the concrete group of patients for which a service is to be reimbursed, for determining structural or factual preconditions related to reimbursement, or for pricing.

HTA is a policy-advice tool. Policy-makers use the HTA procedures to prepare for decisions, for instance on reimbursement or pricing for healthcare technologies. The specific details of the HTA procedures in the Member States are however inevitably based on varying political value decisions

In other words, HTA procedures are used to facilitate or prevent the reimbursement of new healthcare technologies, to fine-tune them or, where they are reimbursed, to find a reasonable price. In each case, the specific form is determined by fundamental aspects of the respective health insurance system. For Germany, for instance, the all-embracing service entitlement of insured persons in statutory health insurance, described above, is included in this.

These diverse goals and questions are reflected in different structures and responsibilities, as well as in the course of the procedures, and in the selection of the products for which an HTA is implemented.

The political and structural framework impacts the application of the scientific foundations, regardless of the fact that these foundations of the applied scientific methods are the same across borders. Depending on the goal and question, different end points may for instance be accepted in individual cases. In addition, the comparator may for instance be different depending on the national care standard. It may differ for historical or

structural reasons; it may be based on available evidence or on the actual care standard. Finally, the degree to which the scientific assessment is binding for the final decision also influences the requirements made of the scientific assessment. Further structural questions impacting the form of the procedure include whether the two processes are organised separately, and how consistently the separation is actually made, who finally takes the decision (minister, subordinate authority, self-government corporation) and how great their latitude really is in political and legal terms.

This list is intended to exemplify the fact that there are a number of political and structural conditions which differ from one Member State to another, and which implicitly or explicitly influence the decision of a Member State as to how and for what HTA procedures are to be implemented.

The above applies in equal measure, if not more so, to the evaluation of economic aspects.

All Member States have in common that they face the challenge of needing to take appropriate decisions for their respective national contexts that exert a direct impact on healthcare, and at the same time need to bear in mind the sound long-term funding of their healthcare systems. Many Member States have opted to use HTAs in order to carry out this task.

In this situation, the two completed EUnetHTA Joint Actions 1 and 2 offered the Member States' HTA authorities a platform for an exchange which proved itself to be helpful and supportive. The fact that the procedures are carried out differently in each State by no means constituted an obstacle to this exchange.

The considerable diversity of procedures developed in the Member States makes it possible for us to learn from one another and to obtain valuable input for our own work.

A considerable additional benefit of the cooperation activities to date has been the increased acceptance of HTA, including outside the institutions in the scientific and political arenas which are involved in implementation in the strict sense. The fundamental political decision to base concrete decisions in healthcare on a scientific assessment of the available evidence can only be as successful as the level of acceptance of the assessment procedures that are used and the confidence that they are suited to perform an adequate

evaluation. The two completed EUnetHTA Joint Actions have made a rather considerable contribution towards achieving this.

Particularly the creation of joint standards in the shape of guidelines for various elements of the evaluation procedure adds to the value of cooperation, even if they can be applied by every HTA authority in accordance with its national regulations.

II.2. Future cooperation in the EU after 2020

In addition to the positive results of the cooperation to date that have been described above, and which make it worthwhile to continue the cooperation, further areas of work can already be identified for future cooperation after 2020. Some of them are already addressed in EUnetHTA Joint Action 3, so that the results of the respective activity packages will form a major basis for cooperation after 2020. This will be explored in greater detail below.

The paper which the Commission has published on the Inception Impact Assessment demonstrates a very broad spectrum with regard to potential future cooperation, the possible legal framework, its authoritativeness, as well as the breadth and depth of the form which it could take. The options which it discusses exhaustively cover the bandwidth of possibilities. It would however be extremely helpful for the further discussion to detach itself from the packages which have been put together there. In the interest of the clarity and transparency of the discussion, it would be desirable to individually explore the various dimensions. For instance, as the number of possible areas for cooperation increases, their authoritativeness does not necessarily have to increase as well.

What is more, the need for a legislative procedure is not necessarily associated with individual options such as those which are detailed in the abovementioned paper. It would be extremely helpful to first of all discuss the nature of future cooperation, independently of the question related to the need for a legislative procedure, so that an added value is also created in future for all Member States. The next step would then be to examine whether and, if so, what legal amendments are needed for this.

The same equally applies to the structure and to funding.

II.2.1. The legal framework

Responsibility for the definition of health policy and for the organisation and delivery of health services and medical care, including funding, lies with the Member States (Art. 168 (7) TFEU). This includes the decision regarding the inclusion of benefits in the national health insurance systems and on the price, as well as the procedures applied in decision-making,

and the values, criteria and standards underlying such decisions. Accordingly, the HTA network is intended to be a **voluntary association** in accordance with Article 15 of the Patient Mobility Directive. In this regard, the goal of reducing unnecessary duplicate effort and differences in national approaches can only be related to developing common standards making it possible to build on work that has already been done when drawing up HTA reports (Core Model), or voluntarily coordinating procedural steps such that they enable synergies to be generated, without however restricting the Member States with regard to the form of their healthcare systems in terms of their latitude for action and decision-making.

The differences in the healthcare systems are also one reason why Article 168 TFEU only grants competences to the Community to legislate in narrowly-defined cases in healthcare, and hence the original competence to legislate for the healthcare systems remains with the Member States.

According to our evaluation of European law, cooperation between the Member States on HTA can therefore only take place within areas of voluntary cooperation.

II.2.2. The goals and potentials of cooperation after 2020

Cooperation at European level must serve the goal of supporting the Member States in meeting the above challenge, and must generate an added value in this sense. It is most likely to be successful in future if it is able to achieve the highest possible level of acceptance. The added value which the Member States derive from the concrete results of cooperation will be vital to the acceptance of the procedure. It should be taken into account here that Member States may have diverging interests as regards cooperation, depending on the importance already attaching to HTA procedures in national decision-making. Moreover, a flexible structural form is important, allowing changing needs to be taken into account.

In the light of the above, it goes without saying that future cooperation must not be aimed at standardising the national and regional HTA procedures to the greatest possible degree. This would be completely unrealistic in any case. It is a matter of creating a lasting structure

enabling exchange and cooperation at scientific and technical levels. The results of the current EUnetHTA Joint Action 3 will also be relevant for this.

The voluntary nature of cooperation is a major precondition for acceptance here, and hence for future success. It is insufficient for the degree of voluntariness to be restricted to the possibility to voluntarily subject oneself to a further obligation, or indeed not. In the final analysis, it is solely the quality of the results of the joint work which will determine whether and to what degree they are used in decision-making processes in the Member States.

The goal per se can therefore not be to ensure a maximum of re-use. The goal must be for the result of the cooperation as such to be so good that it supports Member States and their HTA authorities in their own HTA procedures, thus generating their interest in using it. This can take place for instance by virtue of their own work being supported through the joint progress that is made in methodical questions. It can also take place through reports or parts of reports which are drawn up in one Member State being made available to others in a transparent, reusable manner. Similarly, individual elements of the HTA procedure, from early dialogues through to the drawing up of parts of reports, can be jointly compiled and integrated by the Member States into their respective procedures. In the end, each authority will be glad to adopt the groundwork that is suited to support and facilitate its own work.

As described above, a major added value of the cooperation to date lies in disseminating and strengthening the acceptance of HTA, including by institutions from the scientific and political arenas, also beyond those involved in its implementation in the narrow sense of the word. It was not necessary for this to be binding, for instance for the application of jointly-drafted quality standards.

Cooperation on HTA in the EU must continue to be voluntary. This is necessary not only as a result of the competence that the Treaty allots to the Member States for determining the form of their healthcare systems, but it is also imperative against the background of the diversity of the healthcare systems. Regardless of this, we consider the voluntariness and flexibility of the acceptance of HTA results as constituting a major precondition for continued successful cooperation.

Regardless of the above legal assessment, a more binding nature of cooperation on HTA is also not expedient given the heterogeneity of the Member States' healthcare systems. It is to

be feared that mandatory cooperation would constitute inappropriate constraints on the Member States' actual latitude for action and decision-making, without taking the real needs, requirements and particularities of the systems into consideration. It also does not appear to make sense for cooperation to be mandatory for this reason.

We particularly disagree with the presumption that the regulations proposed in the paper on the Inception Impact Assessment do not affect pricing in the Member States as a matter of principle. For instance, HTA is primarily concerned with pricing in Germany with regard to medicinal products. The legal and political context differs widely between some of the Member States, so that even where technologies are identical, a considerable degree of variability between HTA evaluations can be justifiably observed, both with regard to the procedures and to the results.

Germany therefore disapproves of imposing a mandatory regulation on the drafting and utilisation of HTA reports at EU level. Germany is highly interested in stepping up the generation of knowledge and improving the exchange of knowledge that is already available since as a rule the evidence is generated and researched via studies at international level. It should however be considered that the methodical approach to drawing up HTAs and the evaluation of the evidence is based on social, cultural and political regulatory and value decisions, and that differences in the organisation of the healthcare systems do not permit the HTA information to be applied uniformly for de facto and legal reasons. The drafting of HTA reports and their subsequent use within appraisal goes a long way towards determining the decision on reimbursement and pricing.

II.2.3. Areas in which cooperation shows a potential added value

Several areas will be outlined below in which we anticipate future cooperation to yield an added value. We have however not limited ourselves here to the time after 2020. Cooperation after 2020 largely depends on the results of what is developed in the EUnetHTA between now and then. Cooperation will thus also benefit many areas before 2020.

- **Joint method discussion/drawing up guidelines**

A major foundation for scientific and technical cooperation consists of the joint discussions being held on methods and requirements. This is reflected in the drawing up of and consensus finding on joint guidelines. This work makes a major contribution towards increasing acceptance of HTA per se and of the results which have been generated. This fundamental component of the cooperation therefore needs to be continued.

- **Generating evidence**

a) **Refining the joint scientific advice by medicinal product authorisation agencies and HTA authorities within early dialogues**

The establishment of joint early advice by medicinal product authorisation agencies and HTA authorities makes it possible to coordinate diverging requirements in the trilateral talks as far as possible, but at least to create complete transparency regarding the respective requirements, see also the "SEED" model project, which has been promoted by the EUnetHTA because of the good experience in Joint Action 2. This applies both with regard to different requirements between marketing authorisation and HTA, as well as between different HTA authorities, depending on national stipulations. In Germany, the authorities responsible for authorising medicinal products have already reached an agreement with the Federal Joint Committee on structured cooperation in order to work together on common issues as early as possible in a close, structured manner. This increases planning certainty for the companies, at the same time as reducing the effort involved.

The Federal Joint Committee has taken on the lead role for creating appropriate structures in EUnetHTA JA3, together with the French HTA authority HAS. There are prospects for joint discussions on HTA at EU level to replace the national deliberations under certain preconditions.

b) **Generation of evidence subsequent to marketing authorisation**

The procedure is also applicable to subsequent evidence generation (post-authorisation-studies, observatory data). A coordinated formulation of evidentiary requirements by the various HTA institutions, as well as by HTA and medicinal product authorisation

authorities, increases the motivation for companies to carry out EU-wide studies (post-marketing authorisation) where appropriate. If this evidence is of high quality, the efforts of the EMA to bring about faster marketing authorisations will also become more important in future for the HTA authorities.

- **Refining the "Core Model" and the "POP database"**
  We consider it to be promising to invest in refining these two tools, which were developed within the EUnetHTA.

  a) Refining the "Core Model"

  The "Core Model" as a methodical framework for generating and exchanging HTA reports or parts thereof forms the technical foundation for fruitful cooperation, depending on the needs of the individual Member State. A system incentivising constructive, active cooperation on the Core Model, as well as the utilisation of the individual parts, is currently being developed within the EUnetHTA. These results are to be awaited and put to good use in future cooperation.

  b) The "POP database" as an alternative to the joint drafting of reports:

  It would be desirable to gradually include the results of the HTA in the next stage of the expansion, as well as the information regarding the state of procedure of evaluations of the HTA organisations involved. This would for instance make it possible to start summarising the results. The work done according to the Core Model could be added later. This would make all the reports drawn up in the Member States easily accessible to and useable for all the HTA organisations involved. A larger number and greater bandwidth of topics would hence be available than in case of jointly-drafted HTA reports. It would clearly benefit Member States which do not have experienced, well-equipped HTA authorities. A greater degree of re-use and less duplication appears to be better achievable by these means than by using binding, joint HTA reports, since based on the experience in the EUnetHTA it is predictable that the agreement processes towards creating a joint HTA report are

highly time-consuming, and the results do not necessarily meet the Member States' needs.

- **Joint evidence-processing standards**

  The Member States apply different methods when it comes to processing and compiling evidence for the HTA reports ("dossiers"). There are prospects here to avoid duplication of work by developing joint standards for the requirements as to dossiers.

  The basis of evidence which is used for drafting HTA reports is generally found in the English-language scientific reference material. On the path towards standardising the stipulations for the dossiers, possibilities should be discussed as to how the effort for translations into different European languages could be reduced.

II.2.4. Structural and financial aspects of future cooperation

- **The administrative structure of cooperation**

Lower priority should be attached in the discussions to debating the administrative structure of future cooperation, and in particular as to whether a separate secretariat is to be established and how this might be equipped, than to the content of the cooperation. At any rate, such a secretariat can only take on a coordinating administrative role.

It would be conceivable to **create a new institution in one of the experienced Member States** which is already highly engaged in the EUnetHTA. The roadmap for increasing cooperation allows such a secretariat or coordinating agency to be established and expanded gradually. It would also be conceivable to have a rotating procedure between different HTA authorities or to divide the tasks between several HTA authorities.

A coordinating agency should not be allocated to any field of technology. The danger otherwise exists that any different requirements as to methods or procedures, in particular between medicinal products and other technologies, would cease to apply. It must furthermore be independent of the upstream procedures relating to market access (marketing authorisation of medicinal products and conformity assessment procedures

with regard to medical devices). This rules out the EMA and the designated conformity assessment bodies (so called notified bodies), in the field of medical devices. .

We do not favour it being established at the Commission because it is a joint institution of the Member States, and not a field that is assigned to the Commission.

We also do not favour establishing the secretariat within an existing EU institution. In the German view, it is vital for the HTA evaluation to be corralled off from marketing authorisation. Whilst, for instance, the EMA is an institution related to medicinal products that is designated for marketing authorisation, establishing the secretariat for HTA cooperation within the EMA would however send out the wrong signals. It is important, particularly vis-à-vis companies, to distinguish between the conditions for marketing authorisation for the national/European market and those for a reimbursement and/or pricing in national healthcare systems. This would also give rise to fears that the coordination of HTA cooperation would be very much dominated by medicinal products and that the particularities of the other important healthcare services such as medical devices, diagnostic and treatment methods would not be adequately prominent.

- **The financial foundation for cooperation**

The initiative towards increased cooperation on HTA is very much typified by the fact that support for the necessary scientific and technical cooperation currently ongoing within the EUnetHTA needs to be clarified after 2020. Even if a need remains to discuss the funding-related issues regarding the necessary structures, the current considerations are to be put forward below from a German point of view.

As in the Joint Actions, there is a fundamental need to clarify how tomorrow's funding is to be distributed between the Commission and the Member States. In particular, the HTA authorities could contribute towards funding by bringing in staff and providing benefits in kind by releasing employees. Industry could also be called on to provide financial contributions in certain areas.