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Impact assessment regarding the revision of the regulations covering medicinal products for paediatric and rare diseases

Statement from the German Social Insurance from 17 December 2020

The German Federal Pension Insurance, the German Social Accident Insurance, the National Association of Statutory Health Insurance Funds and the national associations for statutory health and long-term care insurance have joined together because of their common European policy interests to form the "German Social Insurance - European working group".

This association represents the interests of its members vis-à-vis the EU bodies and other European institutions and it will advise the relevant actors with regard to the context of current legislative projects and initiatives.

Being part of Germany's statutory security system, the health and long-term care insurance, pension insurance and accident insurance organisations all provide effective protection against the consequences of major life risks.

I. Preliminary remarks

The leading organisations involved in German Social Insurance welcome the plan to revise the existing incentive systems for medicinal products that will be used with paediatric and rare diseases.

The German Social Insurance agrees with the EU Commission that the objective of this revision must be:

1. to target support in areas where the regulations have not had the desired effect

2. to end support for areas where it is not deemed to be necessary

3. to link support to market availability throughout the EU

4. to provide options for member states to achieve sustainable and fair prices with regard to the real profitability of the medicinal products covered.

II. Comments

Realigning the incentives requires a medical needs definition that should be based on societal perspectives. Such a definition should be as specific as possible in order to target previously neglected therapeutic areas. Whether decoupling research and development (R&D) from sales can be realised through increased public research funding should also be studied.

It remains unclear whether a need to extend PRIME[1] also exists. Its objective of promoting medicinal products that might have a major therapeutic benefit or those that are being developed for patients without existing therapeutic options, already conforms with the objectives described here. The German Social Insurance takes a critical view of an extension.

For medicinal products for paediatric and rare diseases the German Social Insurance advocates orientating towards the proposed 4th option. Vouchers provided under this context should only relate to regulatory processes. Any transferable vouchers to be used for extending the protection periods, which has been proposed by individuals, should be rejected because of the risk of overcompensation.

The 2018 Copenhagen economics study clearly showed that a Supplementary Protection Certificate (SPC)[2] is not sufficiently targeted as an incentive for paediatric medicinal products. Therefore, it seems logical to abandon extending SPC and switch over to an alternative reward that is more targeted instead. A voucher for regulatory processes seems to be a sensible option here.
However, it is also important to ensure that there is no undue delay even in areas where compliance with a Paediatric Investigation Plan (PIP)[3] is not linked to the incentive. Any sanction mechanisms required for this should be studied.

[1] PRIME is an EMA (European Medicines Agency) programme that supports the development of medicinal products that address unmet medical needs.
[2] Additional SPCs enable the patent protection duration to be extended.
[3] A PIP is a development plan designed to ensure that the necessary data is generated through studies in children to support the marketing authorisation of a paediatric medicinal product.

In the case of rare diseases, the move away from the previous system of market exclusivity in favour of a selectively awarded voucher appears more likely to correct misaligned incentives under the previous system. In particular, we support the objective of making the prevalence for a rare disease designation being dependent on the overall prevalence across all authorised area of applications and this should counteract "slicing" being based on biological markers. The strong role of stratified medicinal products during the past decade and foreseeable developments in the biological medicines sector, which includes medicinal products for novel therapies, call for such measures.

At the same time, the German Social Insurance opposes abolishing the possibility of a medicinal product being designated a rare disease product on the grounds of insufficient profitability. The designation criterion should be maintained. The regulation should be corrected so that a medicinal product that has received a designation based on prevalence, can also have it withdrawn based on the profits that it has made. Profitability should be operationalised (e.g. sales within the EEA), through the use of fixed annual review dates in order to avoid continued support being given to products that are already highly profitable.