Justification

Gemeinsamer Bundesausschuss

of the resolution of the Federal Joint Committee (G-BA) on the initiation of benefit assessments of pharmaceuticals on the existing market in accordance with the German Social Code, Book Five (SGB V), section 35a, paragraph 6 in connection with the G-BA Rules of Procedure (VerfO), chapter 5, section 16

from 18 April 2013

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1. Legal basis

In accordance with the German Social Code, Book Five (SGB V), section 35a, paragraph 6, in connection with the Federal Joint Committee (G-BA) Rules of Procedure (VerfO), chapter 5, section 16, the G-BA can initiate a benefit assessment of pharmaceuticals already authorized and marketed upon request of its members or the organizations and institutions named in SGB V, section 139b, paragraph 1, sentence 2.

Priority is given to assessing pharmaceuticals significant for healthcare or those in competition with a pharmaceutical for which a benefit assessment in accordance with SGB V, section 35a, paragraph 3 already exists. In the present resolution, the G-BA substantiates the criteria and the procedure (hereinafter: decision principles) for identifying pharmaceuticals on the existing market that are significant for healthcare (hereinafter: healthcare-relevant pharmaceuticals), in order to conduct a benefit assessment of these pharmaceuticals in accordance with SGB V, section 35a, paragraph 1. By applying the decision principles, the G-BA has identified the active ingredients named in the resolution as healthcare-relevant pharmaceuticals in the sense of SGB V, section 35a, paragraph 6, sentence 1. The benefit assessments of these active ingredients will begin at the points in time determined in the resolution.

2. Basic points of the decision

A. Pharmaceuticals covered by the scope of application of SGB V, section 35a, paragraph 6

The scope of application of the existing market benefit assessments extends to all reimbursable pharmaceuticals with new active ingredients in the sense of the Rules of Procedure, chapter 5, section 2, paragraph 1. These are active ingredients first marketed before 1 January 2011 which are still covered by data exclusivity for newly authorized pharmaceuticals at the time the reimbursable price negotiated in accordance with SGB V, section 130b took effect. If a pharmaceutical contains more than one active ingredient (combination pharmaceuticals), at least one of the individual active ingredients must be authorized as a pharmaceutical still covered by the data exclusivity of the initial authorization.

Active ingredients with pharmaceuticals are not affected, if

- The Federal Joint Committee has identified them as appropriate comparators for benefit assessment
- They are subject to reference price regulation
- They are excluded from prescription

Based on the wording and the intent and purpose of the norm, and under consideration of rationale deliberations by lawmakers on SGB V, section 35a, paragraph 6, in particular the number of patients treated with the pharmaceutical, the costs for statutory health insurance (SHI), and the quality of healthcare must be considered in the question of whether pharmaceuticals are significant for healthcare (cf. Bundestag document 17/2413, page 22). From that can be derived that the indefinite criterion "significance for healthcare" as a premise for identifying healthcare-relevant pharmaceuticals demands an appraisal of both the economic and the therapeutic relevance of the active ingredient for the healthcare of persons insured by SHI. Based on this, the G-BA selected the following criteria for determining the significance of an active ingredient for healthcare: the revenue a pharmaceutical generates from the SHI as an expression of its economic weight, and the number of pharmaceutical packs prescribed as an inclusion criterion for appraising the extent of therapeutic significance of the pharmaceutical for healthcare of insured persons in the therapeutic indications authorized. To ensure objective selection decisions on pharmaceuticals for an existing market benefit assessment, it is necessary, as part of a normative substantiation and, building on that, operationalization of the selection criterion "significance for healthcare", to bring both components of meaning into appropriate relation to one another, oriented to the intent and

purpose of the regulation in SGB V, section 35a, paragraph 6. The procedure for determining the healthcare-relevance of pharmaceuticals on the existing market described in sections B. to E. serves this purpose. Both revenue and frequency of prescription can be ascertained from existing data sources for the entirety of preparations available on the market, including formulations (source: Galaxy Datenbank Insight Health).

B. Necessity of prognostic view

The revenue (basis for calculation: pharmacy retail price including VAT) and the frequency of prescription of an active ingredient at any given time do not sufficiently indicate the typical course of market development of a pharmaceutical. Active ingredients with pharmaceuticals that come into consideration for the existing market are in different stages of their product lifecycles. This implicates that market developments until the estimated end of data exclusivity, and not current revenue, be considered. That is taken into account by determining the projected revenue and the projected number of packs prescribed at the expense of the SHI (hereinafter: number of packs prescribed) of the initial active ingredients that fulfil the primary inclusion criterion of healthcare relevance.

C. Determining the projected revenue and the projected number of packs prescribed of the initial active ingredient

The starting point for determining the projected revenue and prescription development of an active ingredient is the calculation of current revenue and the current number of packs of the active ingredient. This is based on its revenue and prescription development in the 12 calendar months preceding the initiation of an existing market benefit assessment following a resolution in accordance with the Rules of Procedure, chapter 5, section 16, paragraph 1. Based on that, the projected revenue and projected number of packs prescribed are calculated on an exact monthly basis by means of typed revenue and prescription developments until the estimated end of data exclusivity. The typification of this progression is conducted based on real revenue and number of packs prescribed growth rates of a selection of 188 active ingredients.

In this context, the 2012 Pharmaceuticals Prescription Report (Arzneimittelverordnungsreport) observed that 892 new active ingredients and active ingredient combinations were launched on the market between 1986 and 2011 (cf. Schwabe Paffrath, Arzneiverordnungsreport 2012, p. 189f). Those taken off the market prematurely, e.g. due to grave shortcomings, as well as those still protected by patent, were removed. In the final result, 188 active ingredients were available to the authors as the basis for determining a typed gross revenue and prescription development over the product lifecycle. For the projection, these lifecycle progressions formed the basis for the revenue and prescription development assumed for active ingredients available on the existing market. The growth rates typed on this basis for revenue and packs prescribed are shown in the following chart.

Chart: Typed growth rates of revenue and packs prescribed

Year	Gross revenue in €m per patent	Revenue growth from previous to current year in per cent	Packs prescribed in thousands per patent	Prescription growth from previous to current year in per cent
1	3.02		67.3	
2	11.82	291%	227.22	238%
3	18.13	53%	352.79	55%
4	23.67	31%	412.49	17%
5	27.1	14%	446.78	8%
6	32.55	20%	505.18	13%
7	34.99	7%	527.75	4%
8	38.43	10%	552.2	5%
9	41.07	7%	566.43	3%
10	43.77	7%	557.58	-2%
11	45.17	3%	573.2	3%
12	45.71	1%	550.4	-4%
13	43.32	-5%	505.75	-8%
14	40.1	-7%	463.67	-8%
15	35.01	-13%	423.42	-9%
16	31.91	-9%	404.54	-4%

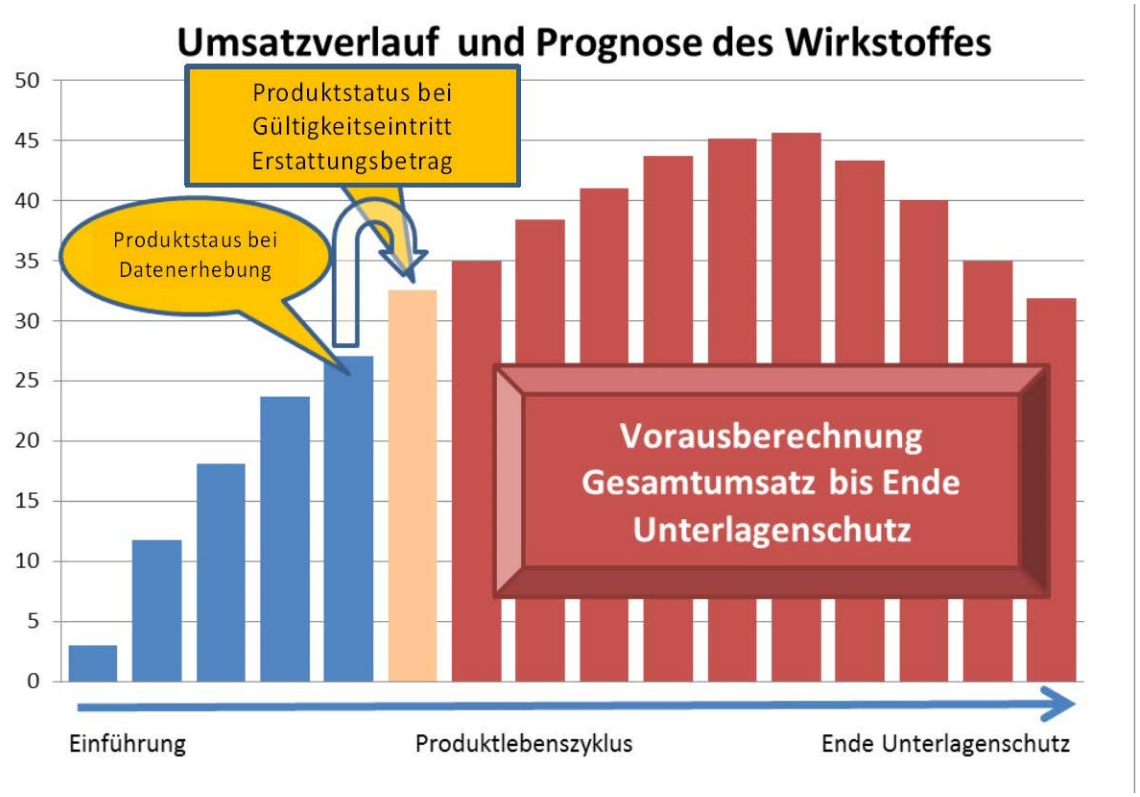
The projection applies these growth rates to illustrate the revenue and prescription development on the basis of the current status in the product lifecycle of the active ingredient, starting with market launch. For the projection, market launch serves as the beginning of data exclusivity. Starting with the market launch of each pharmaceutical, its revenue and prescription development is illustrated for the duration of its data exclusivity. The time period observed for the projection starts here at the point in time the reimbursable price agreement in accordance with SGB V, section 130b (hereinafter: start of validity of the reimbursable price in accordance with SGB V, section 130b) for a pharmaceutical took effect, and finishes with the estimated end of data exclusivity.

To determine the projected revenue and prescription development of active ingredients affected by the resolution, the cumulative revenue and the cumulative number of packs prescribed were calculated at the starting point according to active ingredient on the basis of the prescription survey in the period from November 2011 to November 2012 (source: Insight Health; product status November 2012). Prescription data available at the time of data collection for the existing market were taken into account. This method is justified because the price moratorium in accordance with section 130a, paragraph 3a is currently in effect; the price component is thus static, and the prescription development is illustrated by the projection calculation.

In the first step, the status of the active ingredient in its product lifecycle is determined for the projection. For this purpose the number of days from the beginning of data exclusivity until the date of data collection for the existing market are calculated.

The year and month in which the product finds itself in its lifecycle is then calculated based on a "360-day year" by dividing the number of days by 360. The month of the lifecycle was calculated in the same manner, and rounded up or down to full months.

On this basis, and with the help of the typed growth rates (see chart above: Typed growth rates of revenue and packs prescribed), the revenue and number of packs prescribed in the month the validity of the reimbursable price in accordance with SGB V, section 130b took effect are projected on an exact monthly basis. Beginning with the start of validity of the reimbursable price in accordance with SGB V, section 130b, the same typed growth rates are used to determine projected overall revenue and the projected number of packs prescribed for the remaining time of data exclusivity. Calculations for partial years were conducted using 1/12 of the typed annual growth rates.



Thus the product lifecycle of an active ingredient on the existing market is illustrated continuously from its product launch to the end of data exclusivity.

D. Ranking of the active ingredients on the existing market

The legal mandate calls for those pharmaceuticals that are "significant for healthcare" to be prioritized for an existing market selection. To be able to illustrate the significance of an active ingredient for healthcare on the pharmaceuticals market, with regard to both the extent of therapeutic significance for the patient collectives affected and its economic weight, an overall ranking in descending order is compiled after the projected revenue and prescription development for each active ingredient is determined. This overall rank of an active ingredient is calculated by adding the rank of the active ingredient's projected revenue (hereinafter: revenue rank) and the rank of the active ingredient's projected number of packs prescribed (hereinafter: prescription rank).

This approach considers both the overall revenue of a pharmaceutical by active ingredient and its number of packs prescribed as criteria. Revenue is reflected insofar as it represents, as a product of the number of packs sold and the price per pack, a dimension of frequency of prescription as well as the economic burden on the SHI community of solidarity for treating patients with this active ingredient. The number of packs prescribed stands for the market prevalence of a pharmaceutical, and implicitly for the prevalence of a disease as well. It therefore reflects the extent of therapeutic significance of an active ingredient for treating insured persons in the therapeutic indications authorized.

Taking only the projected revenue or the number of packs prescribed into account as the inclusion criterion is not sufficient for determining the healthcare-relevance of a pharmaceutical. If only the projected revenue (pharmacy retail price including VAT [hereinafter: pharmacy retail price] x number of packs prescribed at the expense of the SHI, adjusted to typed market developments) were applied, pharmaceuticals with a very high pharmacy retail price but low number of packs prescribed would be classified as equally healthcare-relevant as pharmaceuticals with a high number of packs prescribed but a comparatively low pharmacy retail price. In addition, pharmaceuticals that have a very high pharmacy retail price, but are prescribed to few patients, can also be ranked highly.

If only the number of packs prescribed is taken as a criterion, pharmaceuticals prescribed particularly often for healthcare of the population receive greater significance. But then the economic significance of the price component for the SHI community of solidarity is not accounted for at all. To ensure that the revenue and prescription rank together can be added together in appropriate relation to one another in the overall ranking, the G-BA has determined a weighting ratio of these summands. The overall value from the sum of the revenue rank (basis is the projected revenue for the remaining time of data exclusivity) is weighted with a proportion of 80 per cent, and the prescription rank (basis is the projected number of packs prescribed for the remaining time of data exclusivity) with a proportion of 20 per cent.

In detail:

The projected overall revenue of an active ingredient is calculated by multiplying the pharmacy retail price with the corresponding number of packs prescribed. Both factors are weighted equally in this equation to calculate revenue. In the revenue rank, the revenue and number of packs prescribed are reflected in equal weighting. The prescription rank is formed based only on the number of packs prescribed. If an overall ranking were formed based on these revenue and prescription ranks by combining the revenue and prescription ranks without weighting them, the prescription part would dominate the overall ranking. That is because it would influence the overall result both through the revenue rank, which, as shown, is determined from the pharmacy retail price and the number of packs prescribed, and – as the sole criterion – through the prescription rank. To prevent the overall ranking, as the sum of revenue and prescription rank, from being disproportionately determined by the frequency of prescription, the weighting proportion of the prescription rank is ascertained after which a clear change compared to the revenue rank occurs when including all active ingredients on the existing market. The Federal Joint Committee has iteratively ascertained this value of a clear change. Starting with a prescription rank proportion of 0 per cent, at 10 per cent prescription rank proportion the change compared to the revenue rank was negligible. On the other hand, increasing the prescription rank weighting to 20 per cent showed a clear change in the ranking of active ingredients compared to the revenue rank; the ranking compared to the revenue rank changed for the first time for some active ingredients by more than 10 positions.

The result is that the revenue rank, which is determined by price and quantity, is weighted with 80 per cent in the overall results, and the prescription rank, which is determined by quantity alone, is weighted with 20 per cent. Because the amount component is already contained in the revenue, the weighting factors selected counteract an excessive dominance of the amount component and lead to a balanced weighting.

The overall values ascertained on the basis of this calculation are then assigned to the overall ranking in descending order. This approach of weighted ranking prevents active ingredients that are very expensive but relevant for few patients from being selected.

E. Initiation of a benefit assessment for additional pharmaceuticals on the existing market in healthcare-relevant therapeutic indications

Based on the weighted overall ranking comprising revenue and prescription frequency thus ascertained, the Federal Joint Committee determines the initial active ingredients to be selected from the existing market. These initial active ingredients represent the therapeutic indications relevant for healthcare. In order to be able to extensively assess the relevant therapeutic indication on the existing market, those active ingredients with pharmaceuticals corresponding to the relevant active ingredients according to rank in at least one therapeutic indication are selected in addition to the active ingredients identified according to the system described above. This corresponds to the intended purpose of SGB V, section 35a, paragraph 6, sentence 1, according to which the benefit assessment under consideration of the criterion "significant for healthcare" targets initiation of a benefit assessment for healthcare-relevant pharmaceuticals in a therapeutic indication (cf. Bundestag document 17/2413, page 23).

The dossiers must be submitted to the Federal Joint Committee by the deadline indicated in the resolution at the latest. In accordance with the Rules of Procedure, chapter 5, section 7, the Federal Joint Committee offers consultation for the pharmaceutical companies affected before the deadline.

3. Bureaucracy costs

No information obligations for care providers in the sense of the Rules of Procedure, chapter 1, appendix II arise through the regulations contained in the resolution. Therefore there are no bureaucracy costs.

4. Procedure

The pharmaceuticals subcommittee discussed the method in its meetings on 26 February 2013, 12 March 2013, 26 March 2013, and 9 April 2013.

Berlin, 18 April 2013

The Federal Joint Committee
in accordance with SGB V,
section 91
The Chair

Hecken