DECISIONS

COMMISSION DECISION (EU) 2015/1300

of 27 March 2015

on the aid scheme — aid to German pharmaceutical companies in financial difficulties through the exemptions from mandatory rebates SA.34881 (2013/C) (ex 2013/NN) (ex 2012/CP) — implemented by Germany

(notified under document C(2015) 1975)

(Only the German text is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular the first subparagraph of Article 108(2) thereof,

Having regard to the Agreement on the European Economic Area, and in particular Article 62(1)(a) thereof,

Having called on interested parties to submit their comments pursuant to the provisions cited above ([1]), and having regard to their comments,

Whereas:

1. PROCEDURE

(1) On 24 May 2012, the Commission received a complaint from a German pharmaceutical company that alleges that the exemption from the manufacturer's rebate for pharmaceuticals granted to its competitors under German law constitutes State aid.

(2) On 8 June 2012, the Commission submitted a non-confidential version of the complaint to the German authorities, asked for comments on the complaint and requested additional information.

(3) By letter dated 27 July 2012, Germany provided comments on the complaint and submitted the additional information requested. On 31 July 2012 Germany submitted a non-confidential version of this reply. On 24 August 2012, the Commission sent this non-confidential version to the complainant, inquiring if the complainant wanted to pursue the matter in the light of the explanations provided by Germany.

(4) The complainant maintained his allegations. By letter dated 26 September 2012, he provided comments on Germany's arguments. On 21 November 2012, the Commission submitted the complainant's reply to Germany, on which the German authorities commented by letter dated 13 December 2012.

(5) A meeting with the complainant took place on 6 December 2012.

(6) On 30 January 2013 and 5 April 2013 the complainant submitted additional information.

(7) By letter dated 24 July 2013 the Commission informed Germany that it had decided to initiate the procedure laid down in Article 108(2) of the TFEU in respect of the aid.

(8) The Commission decision to initiate the procedure was published in the *Official Journal of the European Union* ([2]). The Commission invited interested parties to submit their comments on the measure.

(9) By letter dated 30 September 2013 Germany submitted comments on the decision to initiate the formal investigation procedure. Furthermore, the Commission received several comments by interested third parties as well as by the complainant.

([1]) OJ C 297, 12.10.2013, p. 76.
([2]) See footnote 1.

(10) On 6 January non-confidential versions of these observations were forwarded to Germany, which was given the opportunity to react. Germany's comments were received by letter dated 14 February 2014.

2. THE COMPLAINT

(11) The complainant, *Allergopharma Joachim Ganzer KG*, based in Reinbek near Hamburg, is engaged and specialised in research, manufacturing and distribution of products for diagnosis and therapy of allergic diseases.

(12) The complainant alleges that the exemption from the manufacturer's rebate for pharmaceuticals granted to its competitors under Section 130a of Book V of the German Social Security Code constitutes State aid.

(13) Furthermore, the complainant alleges that the beneficiaries of the exemption are companies in difficulty. According to the complainant the measure has to be considered as illegal operating aid since the aid does not meet the legal requirements of the Community guidelines on State aid for rescuing and restructuring firms in difficulty ([3]) (hereinafter 'R&R Guidelines').

3. DESCRIPTION OF THE MEASURE

(14) The measure under scrutiny consists of a German scheme on the exemption from a mandatory rebate on certain pharmaceutical products.

3.1. Health insurance system in Germany

(15) Germany has a universal multi-payer system with two main types of health insurance: Public sickness funds (*Gesetzliche Krankenversicherung*) and private health insurance (*Private Krankenversicherung*).

(16) *Public sickness funds*: 85-90 % of the population in Germany is covered by public sickness funds. The public health insurance system is financed by a combination of contributions by members on the one hand and funds from the State's general budget on the other hand. Every individual member and his/her employer pay a percentage of that person's gross monthly salary as contribution. The percentage is determined by law and applies equally to all public providers. In addition, the State contributes a certain amount for so-called non-insurance-related expenses. The contributions of all members of the public system and the State contributions are pooled in the central 'health fund' (*Gesundheitsfonds*), administered by the Federal Insurance Authority (*Bundesversicherungsamt*). The 'health fund' then pays each provider a lump-sum per member, with the amount per member depending on the members' age, gender and health condition.

(17) *Private health insurance*: 10-15 % of the population opt for private health insurance. This private system is financed exclusively by the premiums paid by its members which are based on individual agreements with the insurance company defining the set of covered services and the percentage of coverage, which depend on the amount of services chosen and the person's risk and age of entry into the private system and which are also used to build up savings for the rising health costs at higher age as required by law.

3.2. Exemption from the manufacturer's rebate on pharmaceutical products under German law

(18) Between August 2010 and December 2013 pharmaceutical undertakings in Germany were generally obliged to grant rebates of 16 % of the price of patented prescription medicines outside the fixed-price system to all health insurances, i.e. to public sickness funds as well as private health insurance companies. Between 1 January 2014 and 31 March 2014 this mandatory rebate was lowered to 6 %, from 1 April 2014 onwards the rebate was

([3]) OJ C 244, 1.10.2004, p. 2 ('2004-Guidelines'). The validity of these Guidelines was initially set until 9 October 2009. However, the Commission decided to extend their validity first until 9 October 2012 (Commission Communication concerning the prolongation of the Community Guidelines on State aid for Rescuing and Restructuring Firms in Difficulty (OJ C 156, 9.7.2009, p. 3)) and then, in the context of the State aid modernisation (SAM) initiative, until such time as the R&R Guidelines are replaced by new rules on State aid for rescuing and restructuring firms in difficulty (Commission communication concerning the prolongation of the application of the Community guidelines on State aid for rescuing and restructuring firms in difficulty of 1 October 2004 (OJ C 296, 2.10.2012, p. 3)). On 1 August 2014 the new Guidelines on State aid for rescuing and restructuring non-financial undertakings in difficulty (OJ C 249, 31.7.2014, p. 1) entered into force ('2014-Guidelines'). However, according to point 137-138 of these new Guidelines, in cases where aid was granted before the publication of the Guidelines in the *Official Journal of the European Union*, it must be assessed on the basis of the Guidelines applicable at the time the aid was granted. Germany confirmed that no new exemptions would be granted under the national scheme after the adoption of the decision to initiate the formal investigation procedure (on 24 July 2013), until a final decision on the matter is adopted by the Commission. As such, the applicable Guidelines are the 2004-Guidelines.

slightly increased to 7 % (with the exception of generic drugs, for which the rebate remains 6 % also after 1 April 2014). At the same time, pharmaceutical undertakings are, until 31 December 2017, obliged to keep their prices at the level as of 1 August 2009 (*Preismoratorium*).

(19) Both, the mandatory rebates (regardless of the exact percentage) as well as the *Preismoratorium*, constitute a 'price freeze' in the meaning of Article 4(1) of Directive 89/105 ([4]). Article 4(2) of that Directive lays down that in exceptional circumstances any holder of a marketing authorisation for medical products has the right to apply for a derogation from such a price freeze if justified by 'particular reasons'. According to the Court of Justice, Member States are, on the basis of this Article, obliged to provide, in all cases, a possibility to apply for such a derogation ([5]). German law foresees that pharmaceutical undertakings can apply for an exemption ([6]) from the mandatory rebate and that a federal authority, the Federal Office of Economics and Export Control (*Bundesamt für Wirtschaft und Ausfuhrkontrolle*, hereinafter 'BAFA'), decides whether to grant this exemption on a case-by-case basis.

(20) More specifically, under section 130a paragraph 4 of Book V of the German Social Security Code, and as further clarified by an information sheet published by BAFA concerning its decision making process ([7]), 'particular reasons' are given if the price freeze puts an unacceptable financial burden on the affected business group (or individual undertaking but only if said undertaking does not belong to a business group). A financial burden is assumed to be unacceptable if the affected undertaking is unable to avoid illiquidity through its own resources, contributions of its shareholders or other measures.

(21) According the information sheet published by BAFA, the decisive elements taken into account by it for establishing whether an exemption is to be granted are the following:

(a) Operating earnings before tax of the previous three business years;

(b) A demonstration by the applicant for an exemption of the development of its earnings and liquidity during the previous three years on the basis of its key business indicators (e.g. its EBIT margin, return on equity, equity and debt ratio, liquidity and debt ratio) and an explanation of the effects of the price freeze on these indicators;

(c) A demonstration by the applicant of the additional burden introduced on the business group/undertaking by the price freeze on the basis of a proof of the actual amount of the rebates already paid;

(d) An assessment of the overall financial and economic situation of the applicant which takes, in addition to the revenue/profit situation, in particular also its assets and liquidity into account. To this end a retrospective cash flow statement as well as a prospective cash flow statement (financial pan), as well as a liquidity plan for the coming three years and a short-term financial plan for the coming 12 months have to be submitted by the applicant.

(22) Applicants for an exemption have to prove a direct causal link between the price freeze and their financial difficulties. It must, in particular, be shown that there are no structural causes for the financial difficulties and if there are any business measures suited for avoiding or limiting the financial difficulties still available, these must primarily be taken. Any business measures already taken to that end need to be described by the affected undertaking in its application.

(23) The applicant has to prove the fulfilment of all eligibility criteria for an exemption on the basis of an expert opinion by a certified accountant. This expert opinion must expressly confirm the direct causal link between the price freeze and the financial difficulties of the applicant and must provide reasons.

(24) To this end the accountant must analyse the financial statements of the previous three years as well as the liquidity plan of the coming three years with regard to the effect of the rebates on the financial situation of the applicant. The accountant must verify the calculations and submissions concerning the key business indicators

([4]) Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ L 40, 11.2.1989, p. 8).
([5]) Joined Cases C-352/07 to C-356/07, C-365/07 to C-367/07 and C-400/07 A. *Menarini and Others* [2009] EU:C:2009:217, para. 58.
([6]) Exemptions either being a full exemption from the mandatory rebate or a reduction of the rebate. The latter means that, for the period between August 2010 and December 2013, during which the mandatory rebate was 16 %, the BAFA could grant a reduction of 10 % points of the rebate, after which the affected companies were obliged to only grant a 6 % rebate instead of the full 16 %.
([7]) See http://www.bafa.de/bafa/de/weitere_aufgaben/herstellerabschlaege/publikationen/merkblatt.pdf

and the revenue and liquidity situation. Against this background the accountant must assess whether the additional burden introduced by the price freeze is so significant that the financial capacities of the undertaking are in danger in the short to medium term.

(25) Applications for exemptions have to be based on the audited financial statements of the previous year (*year n-1*). If the conditions for an exemption are fulfilled, the BAFA grants a 'preliminary exemption' for the current business year (*year n*) plus 180 days. The applicant is obliged to provide the updated data for the current year (*year n*) within 120 days after the end of the business year. If this updated information is not provided within the 120 days deadline, the BAFA automatically hands down a final negative decision, which repeals the previous preliminary decision. If the updated data shows that the conditions for an exemption were actually fulfilled during *year n*, the BAFA hands down a final positive decision ('final exemption'). If, however, the data shows that the conditions were not fulfilled during *year n*, the BAFA hands down a final negative decision, which repeals the previous preliminary decision.

(26) Based on information provided by the German authorities, nine companies were granted preliminary or final exemptions between August 2010 and December 2013 for different periods (no company was granted an exemption for the whole period 2010-2013). In addition, two companies were first granted a preliminary exemption, which was however repealed by a final negative decision.

(27) Out of all the exemptions, in 2013 five preliminary exemptions were granted (by decision of the BAFA taken before July 2013), two of them until the end of the year. In accordance with the standstill obligation enshrined in Article 108(3) TFEU, the BAFA, until a final decision by the Commission on the matter is adopted, does not take any final decisions concerning these preliminary exemptions and also does not take any decision concerning five additional applications for preliminary exemption filed after the date of the decision initiating the formal investigation procedure (July 2013).

(28) According to the German authorities, the total amount of final exemptions granted until 31 December 2013 is EUR 6,268 million, of which the biggest beneficiary received EUR 5,037 million. Germany estimates that the additional amount resulting from preliminary exemptions granted for 2013 is around EUR 6 million. Thus, the total amount of exemptions granted (either final or preliminary) is, according to the German submissions, around EUR 12-13 million.

3.3. **Grounds for initiating the procedure**

(29) On 24 July 2013 the Commission decided to open the formal investigation procedure in accordance with Article 108(2) TFEU (hereinafter 'opening decision').

(30) The Commission preliminarily concluded that the measure involves State resources, in particular due to the finding that German legislation lays down the prices that insurance funds (public and private) have to pay for pharmaceutical products and that the BAFA, a State authority, by granting exemptions from the mandatory rebates, ensures that these funds pay a higher price for the products in question.

(31) As the notion of 'particular reasons' is not defined sufficiently clear and precise in Directive 89/105, but leaves the Member States discretion in how to define it, the Commission considered that the measure is imputable to Germany.

(32) The Commission, furthermore, due to a lack of a clearly defined entrustment act for each exemption rejected the argument that the measure could be regarded as a measure of general economic interest but rather considered it to constitute a selective advantage in favour of certain pharmaceutical companies active in the production of certain goods.

(33) Lastly, the Commission considered that it is likely that the measure distorts competition and affects trade between Member States.

(34) Against this background the Commission preliminarily considered that the measure constitutes State aid.

(35) The Commission raised serious doubts as to the compatibility of the aid with the internal market. It observed that the beneficiaries under the scheme have to be considered as firms in difficulty in the meaning of the R&R Guidelines and that those Guidelines should, therefore, be the legal basis on which to assess the compatibility of the aid. As the measure does not seem to fulfil the conditions under these Guidelines for rescue or restructuring aid, the Commission came to the preliminary conclusion that the aid is not compatible with the internal market.

4. COMMENTS FROM INTERESTED PARTIES

(36) In the course of the formal investigation procedure the Commission received comments from the complainant as well as from several interested parties, amongst them a substantial submission by the *Bundesverband der Pharmazeutischen Industrie* (hereinafter 'BPI') and submissions by pharmaceutical companies that were either granted an exemption under the scheme or had applied for such an exemption.

(37) The complainant upheld its arguments that the measure constitutes incompatible State aid. In particular it stressed that the measure is imputable to Germany, as Directive 89/105 merely lays down a procedural requirement to foresee the possibility to apply for exemptions but leaves the decision whether to ever grant such exemptions to the Member States.

(38) The BPI stressed that the opening decision did not take into account that applicants for exemptions from the price freeze must prove a causal link between their financial difficulties and said price freeze, meaning that the successful applicants would not have been in financial difficulties if it were not for the price freeze. It, furthermore, argued that no State resources are involved as both private and public health insurances should be regarded as being independent from the State. It submitted, in analogy to similar case law by the Court concerning general tax measures, that the measure is not selective but constitutes a general measure as the German constitution requires the legislature to foresee hardship clauses to prevent excessive interferences into the rights of private parties. Furthermore, the BPI argued that the measure is not imputable to Germany, as the German implementation of Article 4(2) of Directive 89/105 is directly required by EU primary law, namely Articles 15, 16 and 52 of the Charter of Fundamental Rights ([8]). In case the Commission, nevertheless, concludes that the measure constitutes State aid, the BPI submits that the R&R Guidelines pursue different aims (restructuring of firms in difficulties) than the measure (hardship clause preventing German legislation from forcing otherwise healthy undertakings into bankruptcy) and should, therefore, not be applicable. Thus, the compatibility should rather be assessed directly on the basis of the Treaty. In particular, the BPI points out that Article 168(7) TFEU states that the EU must respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care, including the allocation of the resources assigned to health services and medical care.

(39) As stated above, in addition to the submissions by the complainant and the BPI, the Commission received comments by 9 pharmaceutical companies. All these companies are either beneficiaries under the scheme or had unsuccessfully applied for an exemption. Due to partly overlapping arguments, the submissions by these 9 interested parties are summarised together below.

(40) According to these submissions the measure merely constitutes a price regulation and, due to the lack of a transfer of resources from the State to the beneficiaries, does not involve State resources. The money involved is rather money that is exclusively attributable to the beneficiaries. Furthermore, it is also questioned whether the money is ever under the control of the State, as it is argued that the health insurance funds are bodies independent from the State and as such their financial means should not be regarded as State resources.

(41) In addition, several of the third parties submit that their products are amongst the cheapest on the market. This is in particular true for parallel-importers, who offer the imported products at a price considerably lower than their producers. The third parties argue that without the exemptions to the price freeze they will be forced into bankruptcy. As this will mean that they will have to leave the market, only the more expensive products remain available. Thus, by granting exemptions and keeping them in the market, the measure actually reduces the costs for the health insurances, meaning that without the measure the costs and the transfers of public funds to pharmaceutical companies will increase.

(42) Furthermore, it is argued that the measure is not imputable to Germany, as the foreseen exemptions are merely a mandatory implementation of Article 4(2) of Directive 89/105.

(43) The interested parties further submit that the mandatory rebate of 16 % of the turnover forces mainly small and medium sized firms into bankruptcy, which were healthy firms before the introduction of the rebate, but whose profit margins are not big enough to be able to bear its additional costs. In this regard the third parties in particular point to the fact that the combination of the mandatory price freeze with the *Preismoratorium* prevents firms from compensating the additional costs of the former through an increase in prices. It is, therefore, argued

([8]) Charter of Fundamental Rights of the European Union (OJ C 326, 26.10.2012, p. 391). Hereinafter 'the Charter'.

that the possibility of granting exemptions does not lead to a selective advantage, but rather prevents discrimination of smaller undertakings with small profit margins. In this sense, the measure must be seen as a hardship clause, reducing the impact of the price freezes to a proportionate level. It is argued that the price freezes would be in breach of the freedom to conduct a business, as laid down in Article 16 of the Charter, without such a hardship clause. In this regard all beneficiaries point to the fact that they would not be firms in financial difficulties if it were not for the price freezes. In light of this direct causal link between the legislation introducing the price freezes and their financial difficulties, the beneficiaries underline the importance of a hardship clause.

(44) Several of the third parties in addition explain that the price freezes were introduced only shortly after stricter conditions concerning certification of several of their products, significantly increasing their costs, entered into force. The legislation laying down these stricter conditions recognised the fact that it will lead to additional costs. Yet, due to the *Preismoratorium* in combination with the mandatory rebate, the affected companies were not able to compensate these additional costs. They, therefore, argue that the measure is not selective as it applies to all undertakings subject to this double burden.

(45) Lastly, due to the small amounts involved the third parties submit that there is no distortion of competition. Several beneficiaries, furthermore, submit that there is no effect on trade between the Member States, as they only operate within Germany and only with products that are certified in Germany.

5. **COMMENTS FROM GERMANY**

(46) Germany maintained its position that the measure does not constitute State aid.

(47) According to the German authorities the measure merely constitutes part of a general framework regulating the price levels for pharmaceuticals. Germany points out that there are several different mechanisms regulating prices for certain medical products or certain producers, the measure at stake in the present case merely being one of them. In this regard Germany argues that the decision by the BAFA to grant exemptions does not *directly and in itself* lead to any transfer of funds from the health insurances to the eligible undertakings, but merely sets a certain price for a specific product. Such transfer of funds only occurs once a doctor prescribes a certain medicine and is, therefore, not directly linked to any action by a State authority or any public or private body set up by the State to administer the funds.

(48) In this regard Germany, in addition, submits that the measure is not imputable, as it is merely an implementation of Article 4(2) of Directive 89/105. Germany submits that this Article lays down an obligation to foresee a possibility to apply for an exemption from a price freeze. Even though it leaves the precise meaning of the term 'particular reasons' open, an interpretation that would generally and *ex ante* make the grant of an exemption impossible would not be in accordance with the obligation to implement the Directive. The BAFA carries out case-by-case assessments of applications and, amongst other possible grounds, grants exemptions from the price freeze if the applicant is in financial difficulties because of the price freeze. Germany considers that no other interpretation of Article 4(2) of Directive 89/105 than to grant exemptions to undertakings that could not carry the financial burden of a price freeze would be appropriate, as exempting companies that can carry the burden themselves (or companies that are in difficulties even without the price freeze) is not necessary.

(49) In this regard Germany additionally argues that it follows from the opening decision that the Commission came to the preliminary conclusion that *any* exemption from a price freeze constitutes a selective advantage and therefore State aid, irrespective of the grounds on which it is granted. However, Article 4(2) of Directive 89/105 forces Member States to decide upon applications for such exemptions. Thus, it is unclear to Germany whether the exemption foreseen in Article 4(2) of Directive 89/105 can ever be granted without constituting State aid and if so how this could be done in conformity with State aid law.

(50) Furthermore, Germany asserts that EU institutions must avoid inconsistencies that might arise in the implementation of various provisions of Union law, especially in circumstances as the present case, where the rules on State aid as well as Directive 89/105 pursue a common objective. It must, thus, be presumed that the European legislature has already assessed that exemptions from price freezes do not distort competition and that there is,

therefore, no room for a subsequent assessment under the State aid rules. To conclude that such exemptions constitute State aid would deprive Article 4(2) of Directive 89/105 of any content.

(51) Finally, in case the Commission comes to the conclusion that the measure constitutes incompatible aid, Germany asks that the decision should exceptionally not order recovery of the aid. It argues that this would be justified by the particular circumstances of the case, in particular since Article 4(2) of Directive 89/105 requires Member States to foresee exemptions from prices freezes while there is neither any indication in the Directive nor jurisprudence of the Court that such exemptions could constitute State aid. In this regard Germany also points to the fact that the Commission has never argued before the opening decision that exemptions based on Article 4(2) of Directive 89/105 constitute State aid and also did not raise any concerns relating to a possible conflict of that Article with the rules on State aid in the ongoing revision of Directive 89/105.

6. **ASSESSMENT**

6.1. **Existence of aid**

(52) According to Article 107(1) TFEU any aid granted by a Member State or through State resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods shall, in so far as it affects trade between Member States, be incompatible with the internal market. It follows that, for a State measure to be qualified as State aid within the meaning of Article 107(1) TFEU, the following cumulative criteria have to be fulfilled: involvement of State resources; imputability to the State; selective advantage to an undertaking; and (potential) distortive effects on competition and intra-Union trade.

Involvement of State resources

(53) For advantages to be capable of being categorised as aid within the meaning of Article 107 TFEU, they must be granted directly or indirectly through State resources. The distinction made between 'aid granted by a Member State' and aid granted 'through State resources' does not mean that all advantages granted by a State, whether financed through State resources or not, constitute aid, but is merely intended to bring within the definition of State aid both, advantages which are granted directly by the State and those granted by a public or private body designated or established by the State to administer the advantages ([9]).

(54) The fact that a measure granting an advantage is not financed directly by the State, but by a public or private body established or appointed by the State to administer the aid does not exclude that that measure is financed through State resources ([10]).

(55) In the case at hand the relevant German legislation (through the price moratorium and the manufacturer's rebate) lays down the price that the insurance funds have to pay for pharmaceutical products. By granting the exemptions under assessment, the BAFA (a federal authority) ensures that these funds pay a higher price for the products in question, namely products of companies deemed to be in sufficient financial difficulty to justify an exception to the generally applicable fixed price.

(56) As indicated above (recital 16), 85-90 % of the population in Germany is covered by public sickness funds, while just a residual part of the population opt for private health insurance. This means that it is mainly public sickness funds that have to pay higher prices due to the exemptions in questions. The present measure therefore creates additional costs for public sickness funds, thereby involving a loss of State resources ([11]).

(57) Thus, the present case is different from the situation in *PreussenElektra* ([12]), where the Court only examined whether an 'obligation imposed on private electricity supply undertakings to purchase electricity produced from renewable energy sources at fixed minimum prices' involved 'any direct or indirect transfer of State resources to undertakings which produce that type of electricity' ([13]).

(58) In the light of the above, the Commission concludes that the measure involves state resources.

([9]) Case C-379/98 *PreussenElektra* EU:C:2001:160, paragraph 58.
([10]) Case C-78/76 *Steinike & Weinling* v *Germany* EU:C:1977:52, para. 21.
([11]) See, by analogy, Case C-200/97 *Ecotrade* EU:C:1998:579, paragraphs 38 and 41, and
([12]) Case C-379/98 *PreussenElektra* [2001] EU:C:2001:160.
([13]) Paragraph 59 of the judgment, emphasis added. See also paragraphs 55 and 56 of the judgment, where the Court clarified the scope of the question referred to it.

Imputability to the State

(59) In order to fall within the definition of State aid in the meaning of Article 107(1) TFEU, the measure must be imputable to the State ([14]).

(60) As stated above, Germany argues that the measure is not imputable to it, as it is merely an implementation of an obligation to foresee exemptions to price freezes laid down in Article 4(2) of Directive 89/105. While Germany admits that the term 'particular reasons' is rather broad, it asserts that the reason for this broad formulation is to make it possible for Member States to react to changing market conditions. However, according to Germany, this does not change the fact that Article 4(2) of Directive 89/105 lays down an obligation to grant exemptions on the basis of particular reasons and as such does not give Member States discretion on whether to grant exemptions or not.

(61) The Commission notes that in situations in which Member States merely transpose a clear and precise obligation put on them by a provision of Union legislation into national law, they are indeed only fulfilling their obligation under the Treaty to implement EU law into national law and that such implementation is, therefore, not imputable to them. In this regard, the General Court held, for example, in *Deutsche Bahn* v *Commission* that the implementation by Germany of a clear and precise obligation not to levy the harmonised excise duty on fuel used for the purpose of commercial air navigation laid down in Directive 92/81 ([15]) was, as an implementation of this obligation into national law, not imputable to Germany but in fact stemmed from an act of the Union legislature ([16]).

(62) However, as regards the present case, recital 6 of the preamble of Directive 89/105 clarifies that requirements under that Directive neither affect Member States' policies for determining prices for medicinal products nor national policies on price setting or the determination of social security schemes, except in so far as it is necessary to attain transparency for the purposes of the Directive. As confirmed by the Court in *Menarini and Others*, it follows that the underlying principle of Directive 89/105 is the idea of minimum interference in the organisation by Member States of their domestic social security policies ([17]).

(63) In accordance with this underlying idea, Article 4(2) of Directive 89/105 is formulated in a very wide manner and, in particular, does not define the meaning of the term 'particular reasons'. In this regard the Court clarified that, while Article 4(2) of Directive 89/105 requires Member States to provide for the possibility to apply for an exemption from a price freeze, this '*possibility is without prejudice to the ascertainment, by the competent authorities of the Member States, that it is an exceptional case and that there are particular reasons, within the meaning of that provision.*' ([18])

(64) It follows that it is for the Member States to establish when particular reasons are given and that they, therefore, have considerable discretion in defining under what conditions to grant exemptions. Thus, the term 'particular reasons' laid down in Article 4(2) of Directive 89/105 is not sufficiently clear and precise enough to be able to reach the same conclusion as in *Deutsche Bahn*, i.e. that the national measure does nothing more than to give form in the national legal order to an obligation imposed by the Union legislature.

(65) In *Deutsche Bahn* the relevant provision of Union law, namely Article 8(1)(b) of Directive 92/81, laid down a clear and precise obligation not to levy the harmonised excise duty on fuel used for the purpose of commercial air navigation. This Article left the Member States only certain discretion as to the wording of the conditions implementing this exemption ([19]), as it provided that exemptions from the excise duty are to be granted by Member States 'under conditions which they shall lay down for the purpose of ensuring the correct and straightforward application of such exemptions and of preventing any evasion, avoidance or abuse'.

([14]) See, e.g., Case C-482/99 *France* v *Commission (Stardust Marine)* [2002] EU:C:2002:294, paragraph 24; Case C-677/11 *Doux Elevage* [2013] EU:C:2013:348, paragraph 27.
([15]) Council Directive 92/81/EEC of 19 October 1992 on the harmonization of the structures of excise duties on mineral oils (OJ L 316, 31.10.1992, p. 12).
([16]) Case T-351/02 *Deutsche Bahn* v *Commission* [2006] EU:T:2006:104, paragraph 102.
([17]) Joined Cases C-352/07 to C-356/07, C-365/07 to C-367/07 and C-400/07 *A. Menarini and Others* [2009] EU:C:2009:217, paragraph 36.
([18]) Ibid, paragraph 58.
([19]) Case T-351/02 *Deutsche Bahn* v *Commission* [2006] EU:T:2006:104, paragraph 105.

(66) However, in the present case, Article 4(2) of Directive 89/105 does not define the term 'particular reasons' and, thereby, gives Member States a wide margin of discretion under what conditions to grant exemptions from price freezes. This discretion goes beyond a mere discretion as to the wording of the implementing measures but rather leaves it for the Member States to decide under what conditions to grant exemptions ([20]). Thus, while in *Deutsche Bahn* the relevant Directive clearly identified when exemptions are to be granted, namely with regard to fuel used for commercial air navigation, in the present case Article 4(2) of Directive 89/105 leaves the decision when to grant exemptions to the Member States.

(67) It follows that under Article 4(2) of Directive 89/105 Member States enjoy discretion as to the *substance* of the scope of exemptions. As stated above, this makes it impossible to draw the same conclusions as in *Deutsche Bahn*.

(68) The Commission, therefore, concludes that the measure is imputable to Germany.

Selective advantage to an undertaking

(69) At the outset the Commission observes that the eligible beneficiaries are pharmaceutical undertakings that are clearly engaged in an economic activity. As such, the beneficiaries are to be regarded as undertakings in the meaning of Article 107(1) TFEU.

(70) Furthermore, the Commission notes that the grant of an exemption from the price freeze leads to increased turnover and income for the undertakings benefitting from it. The exemption must, therefore, be seen as granting an advantage to the beneficiaries as compared to their competitors.

(71) As to the selectivity of the measure, it is clear that, following an application process, a case-by-case assessment and a decision by the BAFA only a limited number of undertakings operating in a specific sector (for pharmaceutical products) and fulfilling specific criteria (of being in financial difficulties) benefit from the measure. In this sense, it cannot be seen as a mere price regulation, as it leads to prices beneficial for certain companies in deviation of the general price regulation in form of the price freeze. The measure must, therefore, be seen as selective.

(72) In this regard the arguments put forth by the BPI, according to which the condition of selectivity is not fulfilled as the measure must be seen as a general measure under German (constitutional) law cannot be upheld. To support this argument the BPI points at case law in which the Court held that a measure granting an exception to the application of the general tax system of a Member State is not selective and, thus, does not constitute aid even though conferring an advantage on an undertaking, if that measure '*results directly from the basic or guiding principles*' of said '*tax system*' ([21]). In the present case, the BPI essentially argues that the advantage conferred to the beneficiary undertakings results directly from the basic or guiding principles of the German constitution.

(73) In this regard, the Commission observes that the point of reference to establish whether the exceptions in question grant a selective advantage to certain undertakings is the price freeze system, from which they derogate, and not the general principles of the German constitution. However, the BPI did not argue, nor *a fortiori* show, that the exceptions in question result directly from the basic or guiding principles of the price freeze system.

(74) In any event, in the judgment invoked by the BPI the Court ruled that exemptions from tax measures subject to an authorisation procedure are only regarded as not being selective if the latitude of the competent national authorities is limited to verifying that certain conditions laid down by law are fulfilled ([22]). However, in the present case the German constitution does not define in any way when exemptions are to be granted. As such, it does not define any conditions for granting exemptions to price freezes and does not limit BAFA's discretion to merely verifying that these conditions are fulfilled.

(75) In the light of the above the Commission concludes that the measure grants a selective advantage to undertakings.

Distortion of competition and intra-Union trade

(76) Lastly, in order to fall under the definition of State aid in the meaning of Article 107(1) TFEU, the measure must distort or threaten to distort competition and affect trade between the Member States.

([20]) See also, as stated above, Joined Cases C-352/07 to C-356/07, C-365/07 to C-367/07 and C-400/07 *A. Menarini and Others* [2009] EU:C:2009:217, paragraph 58.
([21]) See, e.g., Case C-6/12 *P Oy* [2013] EU:C:2013:525, para. 22.
([22]) Ibid, paras. 23-25.

(77) In this regard the Commission notes that the beneficiaries under the scheme trade with pharmaceutical products and that there is strong competition among market participants in the pharmaceutical sector. As such, the advantage granted to the beneficiaries under the scheme is likely to distort competition.

(78) In addition, according to the Court, when an advantage granted by a Member State strengthens the position of an undertaking compared with that of other undertakings competing in intra-Union trade, the latter must be regarded as affected by that aid ([23]). It is sufficient that the recipient of the advantage competes with other undertakings on markets open to competition. In this regard the Commission observes that pharmaceutical products are widely traded between Member States and that the pharmaceutical market is open to competition.

(79) Hence, the Commission concludes that the measure at least threatens to distort competition and to affect trade between Member States.

Conclusion on the existence of aid

(80) In light of the above the Commission concludes that exemptions from price freezes granted under the scheme at stake constitute State aid in the meaning of Article 107(1) TFEU.

6.2. **Compatibility with the internal market**

(81) Since the measure constitutes State aid it is necessary to examine its compatibility with the internal market.

(82) As stated above, the exemptions from the price freeze are granted if an undertaking is, due to the mandatory rebate, subject to an unacceptable financial burden. A financial burden is assumed to be unacceptable if the company in question is unable to avoid illiquidity through its own resources, contributions of its shareholders or other measures.

(83) This concept of an unacceptable financial burden is similar to the definition of firms in difficulty under the R&R Guidelines, which provide that a firm is regarded as being in difficulty if 'it is unable, whether through its own resources or with the funds it is able to obtain from its owner/shareholders or creditors, to stem losses which, without outside intervention by the public authorities, will almost certainly condemn it to going out of business in the short or medium term.' ([24])

(84) Thus, by applying the definition of unacceptable burden laid down in the scheme it is likely that firms in difficulty in the meaning of the R&R Guidelines will be eligible for an exemption, which would, in principle, make it necessary to assess the aid under these Guidelines.

(85) However, the Commission takes note of the unique circumstances of the present case.

(86) Under Directive 89/105 Member States are allowed to introduce price freezes if all conditions under said Directive are fulfilled. As stated above, Article 4(2) of the Directive provides that undertakings affected by a price freeze may, in exceptional cases, apply for a derogation if this is justified by particular reasons.

(87) In its judgment in *Menarini and Others* the Court clarified that Article 4(2) of Directive 89/105 must be interpreted as meaning that: Member States must, in all cases, provide for the possibility for an undertaking, which is concerned by a measure freezing or reducing the prices of all, or of certain categories of, medicinal products, of applying for a derogation from the price imposed pursuant to such measure ([25]).

(88) Thus, Article 4(2) of Directive 89/105 lays down an obligation for Member States to provide for a possibility to apply for a derogation from a price freeze (even if, as noted above, such obligation is not clear and precise enough to come to the conclusion that its implementation is not imputable to the State). Germany introduced the scheme under assessment in implementation of this obligation.

(89) In this regard the Commission, in particular, points to the fact, which was also emphasised by the submissions received by interested parties and by Germany in the course of the formal investigation procedure, that only

([23]) See, in particular, Case 730/79 *Philip Morris* v *Commission* [1980] EU:C:1980:209, para. 11; Case C-53/00 *Ferring* [2001] EU:C:2001:627, para. 21.
([24]) See point 9 of the R&R Guidelines.
([25]) Joined Cases C-352/07 to C-356/07, C-365/07 to C-367/07 and C-400/07 *Menarini and Others* [2009] EU:C:2009:217, para. 58.

undertakings that can prove a direct causal link between their financial difficulties and the price freeze introduced by German legislation are eligible for aid under the scheme. In other words, without the price freeze the beneficiaries under the scheme would not be firms in difficulty, meaning that without the exemption, the price freeze, and thus German legislation, would force otherwise healthy undertakings into bankruptcy.

(90) The guiding principle of the R&R Guidelines is to ensure that inefficient firms are not artificially kept on the market. As such, the Guidelines are based on the premise that the exit of inefficient firms is a normal part of the operation of the market and must, as such, remain the norm, whereas rescuing or restructuring such firms must remain the exception ([26]).

(91) Inefficient firms cannot survive (i.e. cover their costs and a sufficient profit margin) on the basis of market prices. However, in the present case and given the direct and strict causal link between the difficulties of the beneficiaries and the price freeze, these beneficiaries cannot be regarded as inefficient firms. Their survival on the market is not threatened by their inability to cover their costs on the basis of market prices but rather by the State intervention in the form of the price freeze, which prevents them from charging such market prices. As such, the exemptions from the price freeze introduced by the scheme under assessment therefore do not aim at keeping inefficient firms artificially on the market and thus do not run counter to the underlying principles of the R&R Guidelines.

(92) In the light of the above and under the specific circumstances of the present case the Commission considers it, therefore, exceptionally appropriate to assess the compatibility of the aid directly under the Treaty. This decision, therefore, assesses the compatibility of the particular exemptions, as defined in the German scheme under assessment in the present case, with the internal market on the basis of Article 107(3)(c) TFEU.

(93) Article 107(3)(c) TFEU provides for the authorisation of aid to facilitate the development of certain economic activities or of certain economic areas, where such aid does not adversely affect trading conditions to an extent contrary to the common interest.

(94) In order to be compatible under Article 107(3)(c) TFEU, an aid measure must meet a clearly defined objective of common interest, must be well designed to deliver said objective and must not affect competition and intra-EU trade to an extent contrary to the common interest.

Well-defined objective of common interest

(95) Recital 3 of Directive 89/105 recognises the promotion of public health by ensuring the availability of adequate supplies of medicinal products at a reasonable cost as the primary objective of price freezes. The need for sustainable health systems, especially in the economic climate in Europe during the recent years, has also been stressed by the Council of Health Ministers in December 2013 ([27]) and the 2014 Annual Growth Survey ([28]), which emphasised the need to improve financial sustainability of healthcare systems.

(96) Thus, price freezes, such as the ones introduced by Germany, are intended to maintain a sustainable level of costs in the public health system to promote public health. However, price freezes introduce a distortion of the free market ([29]) and it can, therefore, be necessary to foresee exemptions under particular circumstances, in particular where the distortion caused by the price freeze would be of such a nature that its introduction would not be feasible in the first place. In this sense Article 4(2) of Directive 89/105 provides that the measures introduced by Member States to reach the objective of common interest of maintaining a sustainable cost level in the public health system must take account of this fact and must foresee the possibility of exemptions from price freezes on the basis of particular reasons.

(97) The German scheme under assessment pursues the objective spelt out in Directive 89/105 of keeping the costs of the public health system at a sustainable level and, thereby, to promote public health while at the same time ensuring, through the introduction of exemptions, that the effects of these measures for the affected undertakings are not so far reaching as to making their introduction not feasible in the first place ([30]). In this sense the German scheme introduced a hardship clause that ensures that the aim of maintaining a sustainable cost level in the public health system does not force otherwise healthy undertakings into bankruptcy.

([26]) See in this regard recital 4 or the R&R Guidelines.
([27]) See Council Conclusions on the Reflection process on modern, responsive and sustainable health systems (10 December 2013).
([28]) COM(2013) 800.
([29]) As they make it impossible for undertakings to set prices freely.
([30]) See for a similar approach the Guidelines on State aid for environmental protection and energy 2014-2020 (OJ C 200, 28.6.2014, p. 1), chapter 3.7.

(98) As such, the Commission concludes that the scheme under assessment pursues, in accordance with Directive 89/105, a well-defined objective of common interest.

Well defined measure to deliver the objective of common interest

(99) As stated above, in order to be compatible with the internal market an aid measure must be well defined to achieve the identified objective of common interest. It must, thus, in particular be an appropriate instrument to achieve this objective and must do so in a proportionate way.

(100) Under the German scheme, only undertakings that can prove that the general price freeze affects them particularly hard, in the sense that the financial burden stemming from the price freeze becomes unacceptable, can apply for an exemption. Thus, in line with the objective of maintaining a sustainable level of costs in the health care system, exemptions are only granted under limited circumstances. As described above, these circumstances are, in essence, limited to preventing a situation in which the effects of the price freeze would make its introduction not feasible in the first place. In this sense, only undertakings that can prove a direct causal link between the price freeze and their financial difficulties are eligible for the exemption. Such exemptions are necessary to ensure that the price freeze does not force otherwise healthy undertakings into bankruptcy.

(101) Thus, the Commission concludes that the scheme under assessment constitutes an appropriate instrument for achieving the aim of maintaining a sustainable cost level in the health care system while ensuring that the measures introduced to this end (the price freeze) does not lead to the result of forcing healthy undertakings into bankruptcy, which would make the introduction of the price freeze appear not to be feasible in the first place. The Commission, furthermore, observes that no less distortive instrument than to limit the eligibility to such firms that can prove a direct causal link between the price freeze and their financial difficulties seems to be available.

(102) In this regard, the Commission observes, as was described above in recitals 20-21, that any potential beneficiary for aid under the scheme must prove a direct causal link between the price freeze and its financial difficulties. This, in particular, means that it must be proven that there are no structural causes for the financial difficulties. If there are any business measures suited for avoiding or limiting the financial difficulties still available, these must primarily be taken. Any business measures already taken to that end need to be described by the affected undertaking in its application.

(103) All these conditions for eligibility in relation to the causal link between the price freeze and the financial difficulties need to be verified in an expert opinion by a certified accountant. The certified accountant, in particular, needs to expressly confirm said causal link and needs to provide reasons. The accountant, in addition, needs to assess the business measures already taken by the undertaking to avoid or limit its financial difficulties.

(104) As described above in recital 25 these conditions are subject to a strict *ex ante* and *ex post* control exercised by the BAFA. If the *ex post* control shows that the conditions were not fulfilled during the entire period covered by a preliminary exemption, the BAFA takes a final negative decision repealing the preliminary exemption.

(105) In light of the above the Commission concludes that the eligibility criteria for exemptions from the price freeze ensure that the aid is strictly limited to the minimum necessary. In addition, the few exemptions granted under the scheme (only 9 undertakings were granted exemptions during the years 2010-2013, for details see above recitals 26-28) show that the BAFA applied these eligibility criteria strictly. The Commission, thus, concludes that the aid under the scheme is proportionate.

Distortion of competition and effect on intra-EU trade

(106) Finally, the Commission notes that the scheme does not lead to distortions of competition or affectation of intra-EU trade contrary to the common interest. Due to the strict eligibility criteria described above only very few undertakings benefitted from aid under the scheme and the total amount of aid granted under the scheme (EUR 11-12 million for the period August 2010 to December 2013) must be considered, in light of the relevant market of pharmaceutical products, as relatively small. As such, the effects of the aid on competition and intra-EU trade are very limited and, in any event, do not lead to any distortions on the market contrary to the common interest.

7. **CONCLUSION**

(107) The Commission finds that Germany has unlawfully implemented the aid scheme in question in breach of Article 108(3) of the Treaty on the Functioning of the European Union. However, in light of the assessment above, the Commission finds that the scheme is compatible with the internal market under Article 107(3)(c) TFEU,

HAS ADOPTED THIS DECISION:

Article 1

The measure which Germany has implemented on the basis of Section 130a(4) of Book V of the German Social Security Code in conjunction with Article 4 of Directive 89/105 is compatible with the internal market within the meaning of Article 107(3)(c) of the Treaty on the Functioning of the European Union.

Article 2

This Decision is addressed to the Federal Republic of Germany.

Done at Brussels, 27 March 2015.

For the Commission
Margrethe VESTAGER
Member of the Commission