Pricing and Reimbursement Questions

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8

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1 Products having a marketing authorisation under EU law to which pricing / reimbursement controls are applied

Is there a requirement in your jurisdiction imposed on the MA holder or his distributor or local representative to obtain approval of the price and/or reimbursement status of the following category of products before they are placed on the market or within a stated period from launch?

1.1 Prescription-only branded products whether on patent or off-patent. If initial pricing approval is only required for products that do not contain a New Active Substance, explain what definition of NAS is applied and how it is determined whether that definition is met.

N/A

1.2 Prescription-only products, but not ones for which reimbursement will be sought under the national health / social security systems (e.g. private prescriptions for hair loss or other "lifestyle" medicines).

N/A

1.3 Prescription-only products to be supplied to hospitals or clinics and for which a pricing tender process will be applied, in any event.

N/A

1.4 Products to be supplied OTC (whether capable of prescription under national health/social security systems or not).

N/A

1.5 Generic medicinal products whether supplied under their common (INN) name or as so called branded generics.

N/A

1.6 Biosimilar medicinal products (whether the first or subsequent available product)

N/A

1.7 Orphan Medicinal Products.

N/A

1.8 Parallel imports from another Member State.

N/A.

1.9 Please add any additional other products or product types and distinctions considered relevant in your jurisdiction.

For all the above categories of products a price approval by the competent authority (Ministry of Health pricing committee) is required. Additionally, with the exception of 1.4, in order for the above products to be included in the positive list, an approval is required by the competent authority (Ministry of Health reimbursement list committee).

2 Relationships between pricing and reimbursement of products with a marketing authorisation under EU law – general principles

For those products identified in the answer to Q.1 for which approvals are required, are the pricing and reimbursement elements dealt with together or separately and, if so, by which agencies of government. Under what specific legislation are these decisions made?

Pricing approvals are regulated by Ministerial Decision of the Ministry of Health no. 90552 of 2 December 2016 (Government Gazette 3890/B/2-12-2016). Applications for the price of a medicinal product are examined and elaborated on the basis of the relevant pricing provisions by the National Drug Organisation (EOF) which operates under the supervision of the Ministry of Health. The EOF's proposal is introduced to the Ministry of Health pricing committee which approves or rejects EOF's proposal.

Reimbursement approvals are conducted pursuant to Ministerial Decision of the Ministry of Health 82961 of 9 September 2013 (Government Gazette 2219/B/2013). Applications for inclusion of a medicinal product on the positive or negative reimbursement list are examined and approved by the Ministry of Health reimbursement list committee.

More in particular

Pricing Issues:

Pricing is regulated by Ministerial Decision no. 90552 of 2 December 2016 (Government Gazette 3890/B/2-12-2016). In particular:

- On patent products (the so called reference medicinal products):

  The prices of the on patent products are determined on the basis of the average of the 3 lowest prices in EU Member States which publish reliable data under the condition that the product is marketed in at least three other EU Member States. The prices of medicinal products, as approved by the competent authority (Ministry of Health), are published in the relevant price bulletin which is uploaded on the Ministry of Health's website.

- Off patent products:

  The maximum producer's price (ex-factory) of the on patent medicinal products, after the expiration of the patent protection of the active substance and the first marketing of the first relevant generic in the local market (pursuant to EOF sales records and, if needed, validation through the first relevant invoice), is automatically reduced either to 50% of the last under protection price (i.e. the price of the product when the first generic was marketed) or to the average of the three lower prices of the EU member-states, keeping the lowest between the said two prices.

- Generic products:

  The price of a generic product, regardless of the date of its issue, preserves 65% of the wholesale price of the respective on patent product (reference medicinal product), after the later loses its patent.

- Medicinal Products produced in Greece:

  The prices of this category of products are determined on the basis of a cost assessment that includes the cost of production and packaging and the cost of administration – marketing and distribution.

- Medicinal products sold to the State (Products sold to State Hospitals):

  The price at which medicinal products are sold to the State is determined on the basis of the ex-factory price reduced by 8.74% (Hospital Price).

- Orphan medicinal products:

  Orphan medicinal products are priced on the basis of the three lowest prices in EU Member States, according to par. 6 of art. 5 of the Ministerial Decision no. 90552 of 2 December 2016 (Government Gazette 3890/B/2-12-2016). However orphan products may be priced even if prices are offered in only two other EU Member States, contrary to the on patent products which are priced only if they are marketed in three other EU Member States (see answer to question 4.1).

Reimbursement Issues

As already stated above, reimbursement is regulated by Ministerial Decision no. 104744 of 25 October 2012 (Government Gazette 2912/B/30-10-2012). According to this Ministerial Decision and article 21 of Law 4052/2012 (Government Gazette 41/A/2012), as amended by par 6 of art. 127 of Law 4249/2014 (Government Gazette 73/A/24-03-2014), the anatomic therapeutic chemical classification (ATC) of the World Health Organisation is applied for the drafting and revision of the positive reimbursement list.

Additionally, a reference price system for each therapeutic category is introduced. The reference price in question is determined by the lowest price of the cost of daily treatment among the products of the same therapeutic category.

The social security funds are reimbursing the on-patent medicinal products which have been granted marketing authorisation after 1st January 2012, provided that it is established that the latter are compensated by social security in two thirds of EU Member States or in at least 12 EU Member States (Art. 2 par. 7 of Ministerial Decision no. 104744 of 25 October 2012 (Government Gazette 2912/B/30-10-2012).

According to the same above Ministerial Decision no. 104744/2012, new generics are automatically included in the positive list upon approval of their prices. Moreover, new generics whose on patent product (reference product) is included in the negative list are automatically also included in this list upon approval of their price.

3 Other Financial controls relating to supply

Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?

Additional financial restrictions are imposed on the MA Holder on the form of rebates and clawbacks, introduced by various legal provisions, as follows:

A. **Rebates**:

i) A flat rebate of 9% for all medicinal products included into the reimbursement list (Positive List), calculated on the ex-factory price, is imposed on a quarterly basis, according to art. 35 of Law 3918/2011 (Government Gazette 31/A/02-03-2011) and Ministerial Decision No F 42000/8809/1081/2012 (1504/B/4-5-2012).

ii) An additional flat rebate of 2% is imposed on a quarterly basis for medicinal products having drastic substances which have been classified to a separate cluster in the Positive List, according to art. 13 par. 1 of the Ministerial Decision no 3457/14.01.2014 (Government Gazette 64/B/16-01-2014)

iii) An additional progressive rebate of 2% - 12% is imposed on a quarterly basis to all medicinal products of the Positive List, proportionally to the total volume of the sales of the prior quarter, according to art. 13 par. 4 of the Ministerial Decision no 3457/14.01.2014 (Government Gazette 64/ B/16-01-2014), as amended by Ministerial Decision no 70519/14.08.2014 (Government Gazette 2243/ B/18-08-2014).

iv) An additional progressive rebate of 1.5 % - 4.5% is imposed on a quarterly basis to the medicinal products that are sold to public hospitals, according to art. 13 par. 2 of the Ministerial Decision no 3457/14.01.2014 (Government Gazette 64/ B/16-01-2014), as amended by Ministerial Decision no 70519/14.08.2014 (Government Gazette 2243/ B/18-08-2014).

v) An additional flat rebate of 5% is imposed to the sales made to the social security fund EOPYY[1] and public hospitals, according to art. 35 par. 2 of Law 3918/2011 (Governmental Gazette 31/A/02-03-2011), as amended by Law 4093/09-11-2012 (Governmental Gazette 222/A/12-11-2012).

vi) An additional flat rebate 5% is imposed to medicinal products with new drastic substance for which a price is determined for the first time and for a period of one (1) year after their inclusion in the Positive List, according to art. 13 par. 2 of the Ministerial Decision no 3457/14.01.2014 (Government Gazette 64/ B/16-01-2014).

vii) An additional rebate is imposed by EOPYY to any expensive medicinal products of par. 2 of art. 12 of Law 3816/2010 that are sold by the private pharmacies, so that the final price of these medicinal products is equal to the price of the same medicinal products when these are sold by the pharmacies of EOPYY. This rebate is actually the difference between the price in the EOPYY pharmacies and the price in the private pharmacy; this difference is returned by the Marketing Authorisation Holder (MAH) to EOPYY as a rebate. At this point it has to be mentioned that on the price of the products of the category in question (expensive medicinal products) sold by EOPYY pharmacies the wholesaler margin is not included.

viii) Additionally, from 15.09.2014, when a patient choses a medicinal product for which there is no generic, and the retail price is higher than the reimbursement one, the patient covers the 50% of the difference and the remaining 50% is paid as a rebate by the pharmaceutical company representing the MAH in the country or the MAH directly, according to art. 14 par. 2 of the Ministerial Decision no 3457/14.01.2014 (Government Gazette 64/ B/16-01-2014), as amended by Ministerial Decision no. 38733/29.04.2014 (Government Gazette 1144/B/06-05-2014) and, further, by art. 3 of Ministerial Decision no 70519/14.08.2014 (Government Gazette 2243/ B/18-08-2014).

B. **Claw-backs**:

i) Claw- back for out-hospital sales has been introduced by art. 11 of Law 4052/2012 (Governmental Gazette 41/A/2012), as amended by art. 15 of Law 4346/2015 (Governmental Gazette 152/A/20-11-2015) and constitutes a pharmaceutical company's participation to the amount exceeding the preset state budget for the pharmaceutical expenditure, as this expenditure amount is determined on an annual basis (including VAT) and is allocated to the pharmaceutical companies/ MAHs on a monthly basis. The corresponding amounts are payable on a

1. The National Organization for the Provision of Healthcare Services (EOPYY) is a legal entity of public law, operating since 1 January 2012 and including the big majority of the social security funds existing by that time.

semester basis. This emergency measure is imposed until 31.12.2018 and details for implementation are provided by ministerial decisions (currently, Ministerial Decision no 63587/19-08-2015 (Governmental Gazette 1803/B/20-08-2015))

ii) Claw- back for hospital sales is regulated by Ministerial Decision 2314/17.12.2015 (Governmental Gazette 2758/B/18-12-2015) as amended by Ministerial Decision 29183/19.04.2016 (Governmental Gazette 1123/B/20-04-2016), on the basis of art. 11 of the same above Law 4052/2012 (Governmental Gazette 41/A/2012), as amended by art. 15 of Law 4346/2015 (Governmental Gazette 152/A/20-11-2015) and constitutes a pharmaceutical company's participation to the amount exceeding the preset state budget for the hospital expenditure, as this hospital expenditure amount is determined on an annual basis (including VAT) and further broken down to two semesters. The payable amounts are allocated to the pharmaceutical companies/ MAHs on a semester basis. This emergency measure is imposed until 31.12.2018 as well.

To note that:

(a) in case no claw back for a product is paid, the provision of art. 11 of the above Law 4052/2012 may be activated, according to which an emergency fee is due for the inclusion in the Positive List, equal to 15% of the retail sales of the product for which claw-back has been imposed; and

(b) amounts that are owed by pharmaceutical companies for both rebate and claw-back may be offset EOPYY's debts towards MAHs that come from the supply of pharmaceutical products for EOPYY pharmacies' needs, according to par. 1 of subpar. IB.2 of par IB. of article First of Law 4093/12 (Governmental Gazette 222/A/12.11.2012).

4 Pricing Criteria

For those products identified in the answer to Q1 for which a price must be agreed:

4.1 Is there any element of international reference pricing and, if so for what countries and how is the price of the product in the other countries determined?

According to article 6 of Ministerial Decision no. 290552 of 2 December 2016 (Government Gazette 3890/B/2-12-2016) above cited, the maximum producer's or importer's price (ex-factory) of an on patent product, so called reference product, is defined as the average of the three lowest prices in EU Member – States which publish reliable data. Access to the said data is made via designated websites of the official and reputable agencies such as EURIPID. In order for a medicinal product to be priced for the first time its price has to be determined at least in three EU Member States.

4.2 What other criteria are applied in law (and practice if different)? Please address in particular any substance or therapeutic reference pricing. Is information on clinical and cost-effectiveness required or normally supplied voluntarily?

No other criteria are applied.

5 Pricing control timelines

5.1 What, in summary, is the administrative system for the MA holder or his representative obtaining a price and what are the timelines?

New medicinal products, according to article 5 par. 2 of the above cited Ministerial Decision no. 90552 of 2 December 2016 (Government Gazette 3890/B/2-12-2016) are priced after the marketing authorisation is obtained. The timelines, i.e. 90 days from the date the MAH's application is filed, are provided by Ministerial Decision no. A3/46 of 13 December 1989 (Government Gazette 16/B of 13 January 1990) transposing EU Transparency Directive 89/105 into the Greek national legislation.

However, in practice the pricing of new medicinal products is frequently considerably delayed, while, according to this same article 5 par. 2 of the above cited Ministerial Decision 90552 of 2 December 2016 (Government Gazette 3890/B/2-12-2016), the prices of generic medicinal products are approved within a shorter time frame (30 days from the date the relevant applications were filed), due to reasons of public interest.

6 Prices increases and reductions

6.1 How often are price determinations ordinarily reviewed?

Pursuant to article 5 par. 2 of the same above Ministerial Decision no. 90552 of/2 December 2016 (Government Gazette 3890/B/2-12-2016), prices of all medicinal products are revised twice a year and the price bulletins are issued in January and July of each year.

6.2 What controls apply to the right of company to:

– **Increase its price and are the criteria applied for approval different from these given in the answer to 4 above?**

According to article 5 par. 4 of the above cited Ministerial Decision no. 90552 of 2 December 2016 (Government Gazette 3890/B/2-12-2016), no increase is permitted when prices are revised. Nevertheless, increases are accepted in case of corrections or errors made by the competent authority when determining the prices.

In addition to the above, according to par. 7 of the same as above provision, an increase in the price of an OTC

product is prohibited until 31-12-2016, meaning that after this date OTC prices are liberalised. However, for this to be materialised, relevant guidelines most probably in the form of a new ministerial decision are needed and the Ministry of Health is still in the process of issuing such instructions or come with a further postponement of the OTC price liberalization date.

– **Reduce the price generally or for a period**

According to par. 5 of articles 2 and 5 of the same above mentioned Ministerial Decision no. 90552 of 2 December 2016 (Government Gazette 3890/B/2-12-2016), the MAH may file at any time an application to the competent authority requesting a reduction in the price of its product(s).

6.3 Are product prices currently subject to any overarching price freeze for austerity or other reasons and, if so, is there a set review date?

As it arises from article 13 par. 5 of the above Ministerial Decision no 90552 of 2 December 2016 (Government Gazette 3890/B/2-12-2016), a price freeze may be imposed on certain categories of medicinal products. A review shall be carried out at least once a year to ascertain whether the macroeconomic conditions justify that the freeze be continued unchanged.

In exceptional cases the MAH can ask for a deviation from the price freeze if the latter claims that exceptional circumstances apply. The relevant decision must be fully justified and announced to the applicant within 90 days.

6.4 When a first generic product enters the market, is there any obligation imposed on the branded product originator to lower his price?

Pursuant to article 7 par. 1 of the above Ministerial Decision 90552 of/2 December 2016 (Government Gazette 3890/B/2-12-2016), the maximum producer's price (ex-factory) of the on patent medicinal products, after the expiration of the patent protection of the active substance and the first marketing of the first relevant generic in the local market (pursuant to EOF sales records and, if needed, validation through the first relevant invoice), is automatically reduced either to 50% of the last under protection price (i.e. of the price of the product when the first generic was marketed) or to the average of the three lower prices of the EU member-states, keeping the lowest between the said two prices.

7 Other Types of price control

Does your jurisdiction control any of the following prices:

7.1 Full line or other wholesaler selling price

In our jurisdiction, the price of prescription medicinal products is fully regulated by the competent authority. In addition prices of OTC products are regulated up to 31.12.2016 and the Ministry of Health need to come either with guidelines for the implementation of such liberalisation or with a new deadline for this implementation.

More in particular, the regulated prices are determined pursuant to tarticle 2 of the above mentioned ministerial decision no 90552 of 2 December 2016 (Government Gazette 3890/B/2-12-2016), as follows:

1. The maximum producer's price (ex-factory, which is the sale price by the MAHs to the wholesalers. The producer's price is based on the wholesale price reduced (a) for prescription medicinal products which are reimbursed by the social security funds with a price up to €200 by 4.67% and with a price over €200.01€ by 1.48%, b) for prescription medicinal products not reimbursed by the social security funds, by 5.12% and c) for the non-prescription (OTC) medicinal products by 7.24%;
2. The maximum wholesale price of medicinal products, which is the price at which medicinal products are sold to pharmacies. This price includes the gross profit margin of the MAH of the license for the wholesale of medicinal products, which is calculated as a percentage on the maximum price of the ex-factory as defined in the same ministerial decision;
3. The maximum retail price of medicinal products, which is the price at which medicinal products are sold by pharmacies to consumers, and which is defined by the wholesale price, adding the lawful profit margin of the pharmacy -as this is set out in the same ministerial decision-and the applicable Value Added Tax (VAT); and
4. The maximum hospital price of medicinal products, which is the price at which medicinal products are sold by the MAHs to the State, State hospitals, Social Care Units, EOPYY pharmacies and legal entities of public law referred to in par. 1 of Article 37 of Law 3918/2011, pharmacies of private clinics with over 60 beds. The maximum hospital price shall be determined on the basis of the ex-factory price reduced by 8.74%.

7.2 Pharmacy selling price

See above our answer to question 6.4 and in particular point 3 thereof.

In addition, according to article 3 of the above mentioned Ministerial Decision 90552 of/2 December 2016 (Government Gazette 3890/B/2-12-2016) profit margins are established for pharmacists at a rate of 35% on the wholesale price for OTC products and prescription medicinal products that are not reimbursed by social security funds. For all medicinal products reimbursed by the social security funds the profit margin of the pharmacists, varies depending on the price of the product from 30% for products with a price of 0.50 Euros to 2.25% for products with a price of 3,000 Euros.

8 Reimbursement – general principles and Transparency directive compliance

8.1 Please provide a brief overview of the reimbursement framework i.e. is it national or local; is it based on insurance or funding by central or local government? Does it involve co-payment? Are costs met in part by prescription / dispensing charges levied on the patient at the time of dispensing?

Medicinal products which are reimbursed by the Social Security Funds are categorized into therapeutic categories (ATC class) and are reimbursed according to the reference price for each relevant category (see also answer to question 2).

According to article 19 par. 1 of Law 1902/1990 (Government Gazette 138 A/17.10.1990) as amended and in force, a co-payment of 10% is provided for certain chronic diseases while a co-payment of 0% is established for serious diseases. For all other products, the co-payment is 25%.

8.2 Does your jurisdiction purport to operate a "positive list" or "negative list" in terms of products reimbursed i.e. is there an approved list or a list of products or categories of product that will not be reimbursed or only reimbursed where used for certain types of patient (e.g. products for erectile dysfunction due to surgery)?

Medicinal products, following approval by the Ministry of Health reimbursement committee, are included either in the positive or the negative list on the basis of a reference price system (see answer to question 2 on reimbursement issues). In addition, following the same authorities' approval, expensive medicinal products of law 3816/2010 (Government Gazette 6/A/26-1-2010) are included to the expensive medicinal products list. To note that OTC products are included in the negative list.

8.3 In respect of the product types identified as subject to reimbursement controls in the answer to Q1, is reimbursement status the subject of a formal approval or a recommendation only and, in either case, is this subject to any local or regional reassessment?

The reimbursement status is subject to formal approval by the competent authority (Ministry of Health reimbursement committee). Reassessment is available at the next review of the reimbursement list.

8.4 Where a formal decision or recommendation on reimbursement is required, or occurs in practice, who makes the decision and what are the criteria applied? What role do health technology assessments of clinical or cost effectiveness play, whether made locally or in other Member States in respect of the same product?

The Decision is made by the Ministry of Health reimbursement committee on the basis of ATC criteria (see also answer to question 2).

8.5 Where a formal decision or a recommendation is made, *can doctors override that decision or recommendation* applying their judgment on the special needs of a particular patient in a way that allows reimbursement of the product cost in whole or in part?

Doctors cannot override any formal decision or recommendation on reimbursement made by any competent authority by applying their judgement, in a way that allows reimbursement of the product cost in whole or in part. However, in accordance with and into account the provisions on drugs special import art. 29 of Law 1316/1983 (Government Gazette 3/A/11-1-1983) as amended and in force and EOF circular no. 88641/27-12-2010), doctors have the right, in case of a patient's special unmet need, to apply for the special import of a medicinal product not marketed in Greece. In case of this request's acceptance, the product will be imported by any market where the product is available at the price that applies at the exporting country. This product in that particular case will be fully reimbursed.

9 Reimbursement – Administrative Arrangements

What is the procedure and timeline for reaching agreement on the reimbursement price or a recommendation that the product should be reimbursed under national health / social security schemes?

The positive list is revised within 30 days from the issuance of a price bulletin including prices for new pharmaceutical products or the issuance of a revised price bulletin including revised prices for medicinal products already marketed. A relevant application by the MAH should be filed (article 1 par. 3 of Ministerial Decision no. 104744 of 25 October 2012 (Government Gazette 2912/B/30-10-2012). To note that as per article 2 par. 2 of the above Ministerial Decision, for new products to be reimbursed by social security is the reimbursement thereof in 2/3 of the EU countries-members or at least at 12 countries-members of the EU.

10 Reasons for decisions on Pricing and Reimbursement

The Transparency Directive 89/105/EEC requires Member State authorities to provide a "statement of reasons based on objective and verifiable criteria" in respect of a refusal to approve a price proposed by the company or refusal to include a product in the list of products covered by a national health system (positive lists) or a decision to exclude it from reimbursement (negative lists).

10.1 In practice, do your authorities provide such reasoning supported (in the case of reimbursement decision) by the expert opinions or recommendations that they have relied upon in reaching a decision?

In practice, what is notified to the pharmaceutical companies is limited to "approved"/ "not approved". However, since the relevant legal context in place is in accordance with the Transparency Directive 89/105 [see article 2 par. 7 of the Ministerial Decision 104744 of 25 October 2012 (Government Gazette 2912/B/30-10-2012)], upon relevant request of the MAH, the authorities need to provide such reasoning.

10.2 In your experience, is the level of reasoning viewed by companies as sufficient for their purposes including exercising rights of appeal?

The reasoning most of the times is not viewed by the companies as being sufficient.

11 Reconsiderations / Appeals

11.1 What internal administrative appeal mechanisms exist if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status?

In respect of the pricing issue, appeals by the companies must be addressed to the pricing committee within 5 days from the day that follows the issuance of the price bulletin (article 5 par. 4 of the Ministerial Decision no. 90552/2 December 2016 (Government Gazette 3890/B/2-12-2016). However, companies usually file appeals against pricing decisions the soonest possible. Appeals that are accepted as per the above ministerial decision are published in the corrective price bulletin which is issued within 20 days from the date the initial price bulletin was issued.

In respect of the reimbursement issue, according to article 4 par. 2 of the Ministerial Decision no. 104744/2012, an appeal can be filed by the MAH within 15 days from the date of publication of the positive list in the respective Government Gazette.

11.2 Is a dissatisfied applicant also entitled to appeal any such decision to the Courts and, if so, what time limit, if any, applies?

The applicant can also appeal to the Council of State (Supreme Administrative Court) for the annulment of the Ministerial Decision the latest within 60 days from the date the decision concerning the reimbursement of a medicinal product is issued. In addition, the applicant can file a petition to the First Instance Administrative Court requesting an indemnity for the financial damage incurred.

11.3 Have courts in your jurisdiction been engaged on pricing and reimbursement issues and decisions and, if so, what, in summary, are the main practical implications of these judgments for a pharmaceutical company?

Companies may file an application before the competent court for breach of the relevant legislation concerning pricing and reimbursement. However companies are reluctant with this option, to avoid any confrontation with national authorities.

12 Unlicensed products and off-label use

12.1 Where unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) are the costs reimbursed and, if so, is there any control over the level of price that may be charged?

When unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) the relevant cost is fully reimbursed. There is no control over the level of price that may be charge and the medicinal product is reimbursed by the Social Security Fund at the price proposed by the manufacturer.

12.2 Are there any restrictions on reimbursement for off-label use where such use is manifest from the prescription or other circumstances?

Off label use is possible according to relevant national legislation (art. 47 of Law 4316/2014 (Government Gazette 270 A /24.12.2014) amending article 12 par 1 case (a) of Law 3816/2010 (Government Gazette 6/A/26-1-2010). In particular, medicinal products included in the positive list can be prescribed and reimbursed by the social security fund for off-label indications, combinations and dosages, provided that they are included in therapeutical protocols, which are compatible with and rely to relevant international guidelines, have been proposed by competent scientific associations and have received adequate approval by the competent national authorities. On top of the above, administration and reimbursement for off label indications are allowed only exceptionally in accordance with international bibliography, on the basis of a well-documented individual request following a relevant demand of the health authorities.

13 Are there any special schemes or so-called patient access agreements that, in practice, control the reimbursement price for particular classes of products (e.g. orphan medicines or products for treating cancer) that go beyond the controls identified in the answer to question 1.

Patient access agreements are not yet established in Greece.

14 Are pharmacists subject to any annual or other pay-back/ claw-back by the authorities of their aggregate turnover on products dispensed under the national health service/social security systems such that they do not recover the full agreed reimbursement price per product for the units they have dispensed (e.g. to take account of any increase in margin they achieve by deep discounting by suppliers of generic medicines or dispensing of parallel imports).

Yes pharmacists are obliged to pay a progressive clawback pursuant to article 24 of Law 4052/2012 (Government Gazette 41/A/2012), which is calculated by reference to the pharmacists' sales invoices to the Social Security Fund. The range is from 0.5% to 5% for sales ranging from Euros 35,001 to up to Euros 100,001 accordingly on a monthly basis.

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