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Law Alert

Platis - Anastassiadis & Associates

The associate law firm of EY Greece

New Developments in the Pharmaceutical Regulation: Pricing – Clawback on HCMs – Cap on the Contribution for Generic Medicines

At the beginning of the current year, 3 ministerial decisions were adopted introducing significant changes to the regulatory framework for medicines:

1. On 9 February 2024, Ministerial Decision ("MD") No. **D3(a) 6295/2024** (hereafter "Pricing MD") was published, establishing technical and detailed provisions on the **rules and procedure for the pricing of reimbursed and non-reimbursed medicines** circulating in the Greek territory. The Pricing MD introduces two key possibilities for a pharmaceutical company:
   - firstly, a pharmaceutical company introducing a new low-priced medicinal product will have the right to request that it be non-reimbursed from the outset and made available at a higher price, and
   - secondly, for reimbursed medicinal products already on the market and priced below €10, a pharmaceutical company can request a price increase by changing the drug's category from reimbursed to non-reimbursed.

   These interventions were made in an effort to keep low-priced pharmaceutical products on the Greek market, for which the companies that distribute them cannot afford the paybacks, and would probably be withdrawn from the market.

2. Earlier, on 17 January 2024, MD No. 3410/2024 (hereinafter the "Clawback MD") was issued, amending the method of calculation and application of clawback on high-cost medicines (HCMs) distributed by the pharmacies of the Hellenic National Health Insurance Fund (EOPYY per its Greek initials). In summary, the new Clawback MD provides that the additional 3% rebate is deducted from the amount of the clawback on HCMs.

Moreover, with regard to pharmaceutical products that have been included in a closed budget on the basis of the relevant Ministerial Decisions and for which relevant agreements have been signed between the respective Pharmaceutical Companies or Marketing Authorization Holders (MAHs) and the Price Negotiation Committee for Medicines, it is possible for the allocation of clawback to follow either the procedure referred to in paragraph 1 of the MD, **or the procedure to be agreed with the pharma-ceutical companies and clearly described in the relevant agreements**. It should be noted that the Clawback MD has retroactive effect and applies from 1 January 2023. In conclusion, both these measures provide a "breathing space" to the MAHs of these products, which have been heavily burdened through the payback mechanisms.

In addition, under the new MD no. 10186/16.02.2024, a **cap of €3 is applied to the patient's contribution for generic medicines**. As the Minister stated, "through the political penetration of generic drugs, our goal is to save space from the public health expenditure to allow for the introduction of innovative treatments that the people desperately need".

The amendments brought about by the new Ministerial Decisions are detailed below.

Chapter I – Amendments regarding the Pricing of Medicines

MD no. D3(a) 6295/2024 ("Pricing MD") amends the decision of the Minister of Health no.82331/22.11.2019 entitled "Provisions on pricing of medicines" (Government Gazette B' 4274), as amended by Decision no.79525/15.12.2020 (Government Gazette B' 5511). In particular, the Pricing MD, in article 4 para. 1 provides that in order to determine the prices of medicinal products on the basis of prices in the Member States of the Eurozone, the National Organization for Medicines (EOF, per its Greek initials) Pricing Department shall survey prices in all Member States of the Eurozone using the EURIPID database, as well as official data posted by the competent authorities of each Eurozone Member State **or other data that EOF assesses as reliable**. The last provision has been added by the new MD.

In addition, para. 4 of the same article stipulates that for the **pricing of new medicines**, regardless of the category to which they belong, prior to their pricing, they must be classified by the Committee for the Evaluation and Reimbursement of Medicinal Products for Human Use ("Evaluation & Reimbursement Committee") into:

a) potentially reimbursable medicines and

b) non-reimbursable medicines.

If the estimated Retail Price of the product **is less than or equal to €10**, the MAH **may indicate** in which of the above categories the product should be included. In case the Pharmaceutical Pricing Department of EOF expresses a different opinion, the request shall be referred to the Evaluation & Reimbursement Committee, following the MAH's prior notification.

As regards **reimbursed drugs with a Retail Price of less than or equal to ten (€10) euros**, the MAHs may request **a change of category to non-reimbursed medicines** by submitting a request to the Evaluation & Reimbursement Committee. Excluded from this option are **reimbursed medicines related to the treatment of life-threatening diseases, as defined by the OECD/Eurostat list as potentially treatable mortality, medicines related to oncological or neurological indications, as well as orphan drugs**. The Evaluation & Reimbursement Committee is the competent authority to advise and recommend to the Minister of Health the medicines that it considers as eligible for transfer to the list of non-reimbursable medicines. The Committee may also make a negative recommendation for reasons of public health protection.

According to para. 6 of article 4 of the new Pricing MD, for **new medicines that qualify for classification as non-reimbursed**, the pricing rules and methodology as described in paragraph 5 of article 13 of the abovementioned MD apply. Non-reimbursed medicines are **not repriced** in the annual procedure for issuing the Revised Drug Price Bulletin. Upon application of the pharmaceutical company to the Pricing Department of EOF, the right to **reprice non-reimbursed medicinal products** shall be granted.

In the above categories of medicines, including generic medicines (reimbursed and non-reimbursed), an **increase in their ex-factory price of up to 15% of the current price** may be applied, and the resulting price may not exceed:

a) the average of the two (2) lowest different euro area prices, or of one euro area country in the case of a single country where it is only available in one country; and

b) the Retail Price of €10.

The updated prices will be posted on EOF's website at the same time as the prices of new medicines. The request for a price increase shall be submitted to EOF's Pharmaceutical Pricing Department and shall be accompanied by a mandatory fee of one hundred and fifty (€150) euros per packaging code number of EOF. Change requests will be evaluated quarterly simultaneously with any requests for pricing of new medicines.

In cases where the applicable Retail Price of the product is **higher than €10**, the MAHs may submit a request for **de-listing of the medicine from the reimbursed medicines list** to the Evaluation & Reimbursement Committee. Products that will be included in the list of non-reimbursed medicines will not be entitled to a price increase.

Furthermore, para. 12 of article 4 of the Pricing MD, **specifies the criteria for the pricing of medicines in exceptional and special cases** related to the uninterrupted availability of medicines and the protection of public health and patients. In such cases, EOF may submit reasoned proposals for the application of specific criteria to each category of medicinal products when pricing or repricing them, in order to be priced by a specially reasoned decision of the Minister of Health.

For the application of this provision, the following criteria shall be taken into account: **the market share of the medicinal product, which should be significant, the sufficiency of similar medicinal products on the market, and in particular if the medicinal product has a price of up to €5 low or if its price has a large deviation from the average price of the two (2) lowest eurozone countries, as well as the excess cost that would result from the increase.**

Regarding the rules on pricing and repricing of particular categories of medicinal products, article 13 para. 5 of the Pricing MD provides that in order for a new non-reimbursed medicinal product to be priced for the first time, the specific pharmaceutical form, content and packaging (nine-digit EOF code) must have been priced in at least one (1) Member State of the Eurozone. The maximum net ex-factory price shall be defined as the average of the two (2) lowest different prices in the Member States of the Eurozone area for the same medicinal product, in terms of active substances, pharmaceutical form, content and packaging (nine-digit EOF code), otherwise it shall be priced according to the available price in one country, if no prices can be found in two (2) countries. The rules and methodology for price setting shall be as set out in article 4 of the MD. In the case where no official prices are available in the Member States of the Eurozone for the nine-digit code of the medicinal product, the MAH may provide an official letter from the manufacturing company with the prices of the medicinal product in the Member States of the Eurozone and a solemn declaration stating the requested manufacturer's price.

Finally, article 16 of the Pricing MD on the MAH's option to provide an additional discount on the hospital selling price, abolishes the MAHs' obligation to provide pharmacies, pharmacists and cooperatives with a credit of at least two (2) months' duration, provided that it is indicated on the sales invoice, as well as the obligation of wholesalers to provide pharmacies and cooperatives with the corresponding credit.

This MD was entered into force on 9 February 2024.

Chapter II – Amendments regarding Clawback

The new Clawback MD (no.3410/17-01-2024), which amended the Ministerial Decision no.40646/11-07-2022, introduces **changes to the method of calculation and application of clawback on high-cost medicines (HCM) of para. 2 article 12 of Law no.3816/2010 distributed by EOPYY pharmacies (hospital and outpatient pharmaceutical expenditure of the pharmacies of EOPYY), as well as other medicines distributed by EOPYY pharmacies**.

In paragraph 1, it is provided that the amount resulting from the calculation referred to in the above subsections of the same paragraph **shall be reduced, inter alia, by the rebate of paragraph 2a of article 87 of Law No. 4472/2017, i.e., the additional rebate of 3%** that may be imposed as of 1 January 2022 on high-cost medicines (HCM).

In paragraph 2, it is provided that in cases of pharmaceutical products which **es** have been included in a closed budget based on the relevant Ministerial Decisions and for which relevant agreements have been signed between the respective Pharmaceutical Companies/MAHs and the Medicines' Price Negotiation Committee of Article 254 of Law No. 4512/2018, it is possible for the allocation of any excess to follow the procedure referred to in para. 1 of the MD, or **to follow the procedure to be agreed with the pharmaceutical companies** and clearly described in the relevant agreements.

In paragraph 4, the word 'hospital' has been deleted and it is made clear that the provision refers to **the pharmaceutical expenditure (hospital and outpatient) of EOPYY pharmacies.**

It is noted that the Ministerial Decision issued in 2024, **is effective from 1 January 2023** (retroactive effect).

Chapter III – Cap on the Contribution for Generic Medicines

With the new Ministerial Decision No. 10186/2024 (Government Gazette 1126/B/16-2-2024), it is stipulated that the amount covered by the patient beyond the statutory contribution cannot exceed the amount of €20 per unit formulation and, in particular for generic medicines, **it cannot exceed the amount of €3 per medicinal product.** Therefore, a cap of €3 is imposed on patients' participation in generic medicines, effective from 16 February 2024.

In conclusion, the above interventions are the first step for significant changes to be implemented in the near future in the health sector relating to medicines and the rationalization of public health expenditure according to the announcements of the Minister of Health has already announced that will be implemented in the near future. With regard to the amendments in the regulatory framework on the pricing of low-cost medicines, it is noted that, although in the short term there may be additional costs to the patient, in the mid-term both citizens and the health system will benefit, as the possibility of substitution is removed, i.e., a low-cost drug being replaced by a more expensive one, after the former has disappeared from the market. In addition, the possibility of withdrawal of these medicines from the Greek market due to the payback measures so far imposed on MAHs in order to market these medicines in Greece is also removed.

Regarding the changes in the method of calculation and application of clawback on high-cost medicines distributed by EOPYY pharmacies and other medicines distributed by EOPYY pharmacies, and even with retroactive effect (from 1.1.2023), they admittedly give "breathing space" to MAHs by deducting the additional 3% rebate from the amount of clawback, as well as through the possibility to follow the procedure agreed between the Negotiating Committee and the pharmaceutical companies for the drugs included in a closed budget. Lastly, the imposition of a cap on patient participation for generic medicines attempts to expand the penetration of generic medicines and rationalize public expenditure, while protecting patients from excessive costs for medicines.

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