Article 22
Pricing of medicinal products and relevant issues

1. The maximum price of the reference on-patent medicinal products as regards the first patent of the active substance is defined as the average of the three lower prices of the member states of the European Union. According to the above clause, the maximum prices must be regularly revised downwards each time a prices bulletin is published, as set out in the provisions of paragraph 4 and point 5 below.

2. The prices of the original pharmaceutical products, after the certification by all means expedient, of the expiration of the validity of the first National or European patent of the active substance of the respective products, if a generic is traded for those, are automatically decreased, either at 50% of the last on-patent price or at the average of the three lower prices of the member-states of the European Union, provided that it is lower than the 50% of the last on-patent price and in cases where there is no generic traded, at the average of the three lower prices of the member-states of the European Union. According to the above clause, the maximum prices must be regularly revised downwards, each time a prices bulletin is published, as set out in the provisions of paragraph 4 and point 5 below.

3. The maximum price of generics is defined at 65% of the price of the respective reference medicinal product, whose patent protection has expired, whose price is set out in accordance with the provisions of this article. When more than one generics obtain a marketing authorisation, a dynamic pricing applies, based on the sales volume, as it will be specified by the Decision of the Minister of Health. According to the above paragraph, the maximum prices must be regularly revised downwards, each time a prices bulletin in published, as set out in the provisions of paragraph 4 and point 5 below.

4. The specified prices, as set out in paragraphs 1 to 3 hereof, represent the maximum enacted prices and the marketing authorisation holders may offer at any time, lower prices, which are later enforced with a supplementary prices bulletin. In the cases where the marketing authorisation holders of medicinal products whose patent has expired offer lower prices, these do not automatically affect the prices of the respective generics, whose prices may be reduced in these cases, upon the request of the marketing authorisation holder. Price mark-up is not permitted when prices are revised with the application of the provisions of paragraphs 1 to 3, except in the cases where they concern corrections. The pricing rules, as set out in paragraphs 2 and 3 hereof, retrospectively apply since 1/1/2012. More specifically, for the application of the above provisions before 1/1/2012, horizontal price decreases will be applied, which will be specified by Decision of the Minister of Health.

5. Prices are issued within the time limits set out by the EC Directive on transparency. Full prices revision is effected twice a year and in the meantime, pricing of new medicinal product is performed. In the case of generics, prices are published within 30 days from the date of the application of the marketing authorisation holder and then dynamic pricing is applied. After their pricing, the new generics are automatically included in the positive list of Law 3816/2010 with medicinal products whose cost is reimbursed by the social insurance agencies and EOPYY, provided that the respective reference medicinal products are listed therein. New reference medicinal products are

included in the positive list, following the evaluation of their clinical and financial data and in accordance with the existing relevant provisions and more specifically, the provisions of paragraph 7 of article 21 of Law 4052/2012.

6. In paragraph 1a of article 22 of Law 4052/2012, a sentence is added as follows: An additional 2% is added to the aforementioned 9%, especially in the case of active substances that concern medicinal products listed by themselves in a therapeutic category, in the positive list of paragraph 7 of article 21 of the above law.

7. The table in paragraph c of article 22 of Law 4052/2012 is substituted as follows:

Total quarterly sales volume per medicinal product	Additional rebate of case (a) of this paragraph
100,000-400,000	2%
400,001-800,000	4%
800-001-1,200,000	6%
1,200,001-1,600,000	8%
1,600,001-2,000,000	10%
Above 2,000,000	12%

The above rebates are calculated on the basis of the producer prices.

8. In article 24 of Law 4052/2012 a paragraph is added as follows: 7. Pharmacies are not subjected to any rebate or return to the social insurance agencies for the amount of monthly sales that relate to the medicinal products sold and their daily treatment cost is below the reference price. In addition, they are not subjected to any rebate or return when 70% in volume of medicinal products sold or 50% in value, are medicinal products with daily treatment cost lower than the reference price.

9. Medicinal products included in the special list of article 12 of Law 3816/2010 which have a marketing authorisation only for in-hospital use are sold exclusively and only from the hospital's pharmacies and from EOPYY's pharmacies only in highly exceptional cases and in clinics with less than 60 beds capacity. More specifically, for the trade and administration of the medicinal products included in the special list of article 12 of Law 3816/2010 through private pharmacies, special wholesaler and pharmacies profit margins and special rebates are specified by Decision of the Minister of Health, for their inclusion in the positive list of medicinal products whose cost is reimbursed by the social insurance agencies, and the additional escalated rebate, with regard to the total quarterly sales volume, as specified in article 22 of law 4052/2012 and amended with the provisions hereof. These medicinal products are not subjected to rebate or pharmacy discounts to the social insurance agencies. The medicinal products of the list of article 12 of Law 3816/2010, except of those intended only for in-hospital use, may be offered to the patients from three distribution channels (hospitals, EOPYY pharmacies, private pharmacies). More specifically, the sale of the above medicinal products in private pharmacies lies with the right of marketing authorisation holders to choose, in case there is no patients' registry.

10. By Decision of the Ministry of Health the profit margins of wholesalers and pharmacists as well as rebates and discounts are specified, for the achievement of the

goals of pharmaceutical policy. In addition, in full performance of applicable legislation that concerns prescribing based on the active substance, targets for the prescribing of generics or medicinal products with daily treatment cost lower than the reference price for all physicians prescribing medicinal products or for separate medical specialties may be determined by Decision of the Minister of Health and motives and sanctions may be enacted in case these goals are not achieved.

11. Any provision to the contrary is hereby abolished. The details for the performance of paragraphs 1 to 10 hereof will be determined by means of Ministerial Decision that will be issued by the Minister of Health, within 15 days from the publication of this law.