THE MINISTER OF HEALTH

Having considered:

1. The provisions of article 14, par. 3 of Law 3840/2010 (Gov. Gazette A' 53).
2. The provisions of article 90 of the P.D. 63/2005 "Codification of legislation for the Government and Government bodies" (A΄ 98).
3. The provisions of the L.D. 96/1973 and mainly article 17 as amended and in force (Gov. Gazette A 172).
4. The provisions of the L.D. 136/1946 "for the Market Police Code" (Gov. Gazette A' 298), as amended and in force.
5. The provisions of article 13 of Law 3408/2005, as amended and in force (Gov. Gazette A 272).
6. The provisions of Law 3842/2010 (Gov. Gazette A 58) as amended and in force.
7. The provisions of article 4 par. 2 of Law 3899/2010 ((Gov. Gazette A 212), for the amendment of VAT Code.
8. The provisions of article 32 of Law 1316/1983 "Establishment, Organisation and competencies of EOF" (Gov. Gazette A 3), as already amended and in force.
9. The provisions of the P.D. 95/2000 "Organisation of the Ministry of Health and Welfare" (A΄ 76), as amended and in force.
10. The provisions of articles 38, 39, 40 and 51 of Law 3918/2011 (Gov. Gazette A 31) as amended and in force.
11. The provisions of articles 19, 20, 21 and 23 of Law 3052/2012 (Gov. Gazette A 41).
12. The Joint Ministerial Decision (KYA) No ΔΥΓ3α/οικ.82161/24.8.2012 (Gov. Gazette B 2374) "approximation of Greek legislation to the respective European one in the area of production and marketing of medicinal products for human use, in compliance with the directive 2001/83/EC "on the Community code relating to medicinal products for human use (Law 311/28.11.2001) as in force and as amended by the Directive 2010/84/EU, regarding pharmacovigilance (Law 348/21.12.2010" and mainly article 10 thereof.
13. The Ministerial Decision No ΔΥΓ3(α)/οικ.86767/10.9.2012 "Revocation of the decision for the application of competencies to EOF regarding the pricing of medicinal products" (Gov. Gazette B 2462).
14. The Ministerial Decision No ΔΥΓ3(α)/οικ.94274/28.9.2012 "Application of article 15 in Law 4052/2012" (Gov. Gazette B 2675).
15. The P.D. 85/2012 "Establishment and renaming of Ministries, transfer and abolishment of services" (Gov. Gazette 141 A).
16. The Decision of the Alternate Minister of Health No ΔΥΓ3(α)/οικ.7789/22-01-2013 (Gov. Gazette B' 94).
17. The Decision of the Alternate Minister of Health No 57508/14-06-2013 (Gov. Gazette B' 1446).
18. The P.D. 119/013 "appointment of the Vice-President of the Government, Ministers, Alternate Ministers and Deputy Ministers" (Gov. Gazette A 153).
19. The fact that no expenditure is incurred against the State Budget from this decision, we decide:

Article 1:
Definitions

1. Reference medicinal product is a medicinal product which is approved by virtue of article 11, par. 2(a) of the Joint Ministerial Decision (KYA) No ΔΥΓ3α/Γ.Π.32221/2013 (Gov. Gazette 1049/B/29.4.2013), according to the

provisions of article 9 thereof. Exclusively and only for pricing purposes, a medicinal product is no longer patented (off-patent) after the documentation by all means expedient, that the on-patent period of its active substance has expired, either in Greece or in other countries of the EU. In case no reliable data exist, in relation to the expiration of the patent of the active substance, as an alternative, the expiration of the ten-year or possible eleven-year patent period provided for by article 11, par. 1 of the Joint Ministerial Decision No ΔΥΓ3α/Γ.Π.32221/2013 (Gov. Gazette B 1049) applies, and respectively the six-year protection period for the medicinal products that obtained a marketing authorisation before the Joint Ministerial Decision No ΔΥΓ3α/83657/2006 (Gov. Gazette B 59/24.1.2006) entered into force. Generic is a medicinal product, as defined in article 11, par. 2(b) of the above Joint Ministerial Decision, with the same quantitative and qualitative composition in terms of active substances, the same pharmaco-technical form with the reference medicinal product whose bioequivalence with the reference medicinal product has been proven, based on the appropriate bioavailability studies. Various salts, esters, ethers, isomers, isomer mixtures, complexes or derivatives of an active substance are considered to be one and the same substance, unless their properties differ substantially, in terms of safety and/or efficacy. Various pharmaco-technical forms administered orally with direct release are deemed as the same pharmaco-technical form.
The characterisation of a medicinal product as a reference medicinal product, as an on- or off-patent, generic or not, is made by EOF.

2. The maximum producer's or importer's price (ex-factory) is the sale price from the marketing authorisation holders (MAHs) and the importers, manufacturers, packagers and distributors deemed equal therewith, to the wholesalers. The maximum wholesale price of the medicinal products is the sale price to the pharmacies. The said price includes the gross profit percentage of the holder of the license for the wholesale of medicinal products, which is calculated as a percentage on the maximum MAHs price. The maximum retail price of the medicinal products is the one at which those products are offered to the public by pharmacies, and it is determined by the wholesale price, adding the lawful profit for the pharmacy and the Value Added Tax (VAT). The maximum hospital price of medicinal products is the price at which the MAHs sell their products to the State, State Hospitals, Social Care Units, pharmacies of EOPYY and public law legal entities set out in par. 1 of article 37 of Law 3918/2011, private clinics' pharmacies with capacity of over 60 beds and to pharmacies and wholesale drugstores set out in par. 2 of article 12 of Law 3918/2011. The maximum hospital price is determined based on the maximum producer's price.

3. The way the above maximum producer's prices are calculated for each category of medicinal product separately and thereafter, the margins and the way the other prices set out in the preceding paragraph are calculated, is defined in detail by virtue of the Ministerial Decision of the Minister of Health, before the publication of occasional Prices Bulletin, which acts as a market police regulation.

4. The MAHs may request reductions from the maximum ex-factory prices which are immediately accepted. The MAH is entitled to file an application for the deletion of a medicinal product from the Prices Bulletin, if the termination of the marketing thereof has been previously approved. The MAHs may grant additional discount on the hospital price without any limitations, only to the State, the State Hospitals, the Social Care Units referred to in article 37 of Law 3918/2011 and to the pharmacies of

EOPYY, provided that it is recorded on the sales invoice. The MAHs may also grant a discount on the wholesale price without any limitation for the non-prescribed (OTC) medicinal products, as well as for the medicinal products set out in article 12 of Law 3816/2010. For all other medicinal products, manufacturers, packagers and importers may grant a discount of up to 5% to traders of medicinal products, pharmacies and partnerships, provided that the amount of the discount is recorded on the sales invoice. MAHs are obliged to grant credit to the pharmacies, traders of medicinal products and partnerships, provided that such credit is also recorded on the sales invoice. The credit granted must have a term of at least two months. The ability to grant the same discount percentage and credit period applies also for wholesale drugstores to pharmacies, provided that they are recorded on the sales invoice. For pharmacies of private clinics with a capacity of over 60 beds, the aforementioned in par. 1 additional discount is granted on the hospital price. The prerequisite is the recording of the above additional discounts on the sales invoice. Discovery of transgression of the discounts or the non-observance of the conditions set out in paragraph 2 of this article, from the sales invoices of companies that are filed to EOF, leads, apart from the sanctions provided for in the Market Police Code, to the prompt reduction of the price of the medicinal product, at a percentage corresponding to the additional discount granted.

Article 2
Procedural and administrative issues

1. The maximum price of all categories of medicinal products is calculated by the competent service of EOF, as described in the provisions of this Ministerial Decision and the relevant laws and is filed to the Ministry of Health in order for its lawfulness to be examined and for approval. All sources of data, dates, assumptions, conversion factors and exchange rates, as well as any relevant information applied to the calculation of prices are each time posted at EOF's website. The prices bulletins are attached to the Ministerial Decision following the evaluation and granting of opinion by the Medicinal Products Prices Committee and the consent of the competent service. The Ministerial Decision illustrates all relevant prices, while the website of the Ministry of Health depicts only the ex-factory, the wholesale and the retail sale price of the medicinal products.

2. According to the law, the prices of medicinal products are revised twice per year and the prices bulletins are issued, in January and July respectively, of each year. Before their submission to the Minister of Health, EOF sends the concluded, based on the data available to it, prices, to each MAH separately for any comments. Any remarks are filed within three (3) business days to EOF, who, after examining them, makes its final suggestion to the Minister of Health and publishes it.

3. Objections are all answered by the competent department in writing, with the proper justification and documentation. At any time, MAHs may request further reductions of the prices by the competent service of the Ministry of Health, which (reductions) may later be automatically applied without the need for EOF or the Pricing Committee to grant their opinion.

4. No increases are permitted at any price revision. The new price may be equal or less than the applicable ones. Increases are accepted only in case of error corrections. Once the marketing authorisation is granted and the application is filed, the new

medicines are priced within the time limits defined in the Transparency Directive, as transposed into National Law. In the case of generics, prices are published within 30 days from the application of the MAH. Prices are not issued for medicinal products that did not show any sales during the past three years, before the issue or revision of prices. For these medicinal products, prices are issued upon the application of the marketing authorisation holder, which are included in the first Prices Bulletin issued after the application, only if they have been exempted from the revocation of their marketing authorisation, in accordance with article 40, par. 6 of the ΚΥΑ ΔΥΓ3α/Γ.Π.32221/2013 (Gov. Gazette 1049/B/29.4.2013). In exceptional and special cases that relate to the unobstructed distribution of medicinal products and the protection of public health and patients, the competent service of EOF may file justified suggestions for the application of special criteria in order for them to be approved by a ministerial decision, upon the consent of the Prices Committee.

Article 3
Pricing of on-patent reference medicinal products

1. The maximum producer's or importer's price (ex-factory) of the on-patent reference medicinal products is defined as the average of the three lower prices of the EU member-states which publish reliable data. Maximum prices are regularly revised downwards, each time a prices bulletin is published. In order for a medicinal product to be priced for the first time, it must have been priced in at least three EU member-states.

2. In order for the prices of the reference medicinal products to be determined, the competent department of EOF investigates in the member-states of the European Union, where data exist and is published by the competent authorities. It also investigates the agencies of these countries, the official or reputable European agencies. Access to the said sources for the collection of data is made via designated websites of the official sources of each EU member-state and/or via the official and reputable agencies such as the EURIPID and OBIG and the competent department of EOF is each time obliged to announce the said sources. During the investigation, any price available is sought (ex-factory, wholesale, retail). Special emphasis must be given so that the prices are comparable and corresponding. In the case of special medicinal products such as orphans, hospital prices must not be deemed as wholesale or retail prices and vice-versa.

3. Conversion of prices from retail or wholesale to ex-factory and in Euro is made with the methodology and the coefficients announced by the competent department of EOF and published at its website, together with any other useful information and data that was used in the determination of the prices, so that it can be reproduced by any party interested. The exchange rate used, is the one published by the Bank of Greece, on the first business day of the two-months period preceding the issue of the Prices Bulletin. The necessary data for the determination of the price is: (a) the name of the medicinal product, b) the active substance, c) the active substance content, d) the pharmaco-technical form, e) the package, f) the ATC classification, g) the person in charge for its marketing, h) the price(s) and i) the expiration date of the patent in Greece or in the EU member-states. All requests for pricing with the necessary supporting documents and other documentation are filed through EOF's portal with the technical specifications each time announced through EOF's website.

4. EOF is also able to examine, apart from the data independently collected by its competent department, the data provided by the marketing authorisation holders which is filed in the form of a statement with the respective information in the Data and Prices Research Sheets, which have been designed for the purposes of gathering all data required for the invoicing of the reference medicinal products. Data and Prices Research Sheet of Medicinal Products is filled in and filed in the above manner, via EOF's portal, by the MAH of each medicinal product and serves as a solemn declaration, thus entailing all legal liabilities and sanctions provided for by the laws in case of false statements. In addition, in case erroneous data is filed or data is concealed, sanctions may also be imposed by the Minister of Health, in accordance with article 69 of law 3984/2011, following the granting of opinion by the Prices Committee.

Article 4:
Pricing of off-patent reference medicinal products

1. The maximum producer's or importer's price (ex-factory) of the on-patent reference medicinal products following the expiration of the patent of the active substance, which was determined in article 1 above, is automatically reduced either to 50% of the last on-patent price or to the average of the three lower prices of the EU member-states, keeping the lowest between the said two prices. More specifically, for medicinal products with no generic for which sales have been realised in the market (unique medicinal products) the average of the three lower prices in the EU member-states applies. When a generic is sold in the market, the 50% reduction applies even if it is lower than the average of the three lower prices in the EU member-states. During the initial application of this decision, no increase of prices is permitted in the case of existing unique medicinal products where average of the three lower prices is higher than the existing price.

2. For the products for whose active substance the patent protection will expire after the publication of this ministerial decision as well as for those whose patent expired on 01.01.2012, the preceding paragraph applies. For all the above products, the existing prices will be reduced when the average of the three lower prices in the EU member-states is lower that their existing price and this will apply to any Prices Bulletin to be issued. For this reason, EOF takes into account before the issue of any Prices Bulletin, the average of the three lower prices in the EU member-states and proposes the implementation thereof, when it is lower than the existing price of these medicinal products.

3. For the products for whose active substance the patent protection expired before 01.01.2012, horizontal reductions of prices apply, as defined in a Ministerial Decision, each time a Prices Bulletin is published. More specifically, for the first Prices Bulletin to be issued after the publication of this decision, the prices of all medicinal products prior to 01.01.2012 with an existing retail price of over Euro 12 per package and for a 30-days treatment (i.e. €0.4 cost of daily treatment) are reduced by 10%. Similarly, the prices of all products set out in the above paragraphs with an existing retail price ranging among €6.00 to €11.99, are reduced by 5% and the prices of the products with a price lower than €5.99 are reduced by 2.5%. In case the horizontal or other reduction of prices to be applied, reduce the price of a unique

product below the average of the three lower prices in the EU member-states or below 50%, the MAH may request from the prices committee that the average of the three lower prices in the EU member-states be applied. The horizontal reductions of the prices of medicinal products with a price marginally above the aforementioned limits of €6.00 and €12.00, as well as the application of paragraph 1 on medicinal products whose patent protection expired from 01.01.2012 and forth, may not reduce their prices below the said limits, for one any only re-pricing. In the next re-pricing, the horizontal reduction provided for the category in which it has been included with the preceding reduction of prices, applies. The Ministerial Decision, which will have the force of a market police regulation, will regulate the remaining details for the application of this article.

Article 5:
Pricing of generics

1. The maximum ex-factory price of the producer or importer-marketing authorisation holder of generics is set to 65% of the price of the respective off-patent medicinal products, whose price is determined in accordance with the provisions of article 4 above. In case the reference medicinal product has a different content or package, then an approximate conversion from a similar reference product is effected or in accordance with the provisions of paragraph 4 of article 3. Moreover, if no reference medicinal product exists for a generic in the Greek market, the price of the generic is calculated based on the average of the three lower reference medicinal products in the EU member-states.

2. This regulation applies to all products that will obtain a marketing autorisation from the date this decision will be published, for generics which obtained a marketing authorisation from 01.01.2012 and forth, and for all generics corresponding to active substances whose patent protection is no longer in force from 01.01.2012 and forth. The provisions for the prices of the generics of this paragraph apply on the prices of the reference medicinal products that will result from the application of the provisions of article 4.

3. In addition, for the generics of the preceding paragraph, dynamic pricing applies. More specifically, for each €250.000 sales that correspond to producer's price in the year preceding the publication of the Prices Bulletin, the prices determined in accordance with the above are reduced, so that dynamic pricing can be applied, to a further 1%. The sales are assessed based on the sales data for the 12-months period before the issue of each Prices Bulletin, which (data) are collected by EOPYY or HDIKA. The prices can only be reduced based on this rule. More specifically, if, after a reduction that was grounded on the sales of the preceding period, the sales in the next period are lower, this does not lead to the readjustment of prices at higher levels. On the contrary, if in one of the following periods the sales are much higher than the ones that led to the determination of the prices below the level set out in the preceding paragraph, the prices are proportionally reduced.

4. For all other generics which do not fall into the scope of the provisions of the preceding paragraphs, horizontal price reductions apply, as specified by a Ministerial Decision, each time a Prices Bulletin is issued. More specifically, for the first Prices Bulletin to be issued after the publication of this decision, the prices of all medicinal

products not falling into the scope of the provisions of the preceding paragraph, with an existing retail price of over Euro 12 per package and for a 30-days treatment (i.e. €0.4 cost of daily treatment) are reduced by 15%. Similarly, the prices of all products set out in this, as well as in the above paragraphs with an existing retail price ranging among €6.00 to €11.99, are reduced by 5% and the prices of the products with a price lower than €5.99 are reduced by 2.5%. The horizontal reductions of prices of medicinal products with a price marginally above the aforementioned limits of €6.00 and €12.00, may not reduce their prices below the said limits, for one any only re-pricing. In the next re-pricing, the horizontal reduction provided for the lower category in which it has been included with the previous price reduction is applied. The Ministerial Decision, which will have the force of a market police regulation, will regulate the remaining details for the application of this article.

5. Moreover, for generics of the preceding paragraph with a price exceeding Euro 12, a system of dynamic pricing and retrospective application of rebates is implemented. More specifically, for each percentile increase unit of their penetration in the market, their price will be reduced by one percentile unit and the respective retrospective rebate will be imposed. The first application of the specific provision will take place in January 2014. More specifically, the sales in quantities of 2014 will be compared to the sales in quantities of 2013 regarding the cluster of the positive list in which the product has been classified so as to assess the market share thereof. If there is increase of sales and of the market share, then the price will be respectively reduced in the future and a rebate will be retrospectively imposed on the producer's price, based on the resulting new price. The sales are assessed based on the sales data available to EOPYY and HDIKA. The occasional reductions may not reduce the price of a generic lower that 65% of the price of the reference medicinal product, save the relevant application of the marketing authorisation holder.

Article 6
Rebates

1. An additional 5% is added to the existing 9% rebate for the inclusion in the positive list, for medicinal products containing active substances that have been classified by themselves in cluster in the positive reimbursement list of article 12 par. a of Law 3816/2010 or which are exempted from the determination of a reference price.

2. An additional 3% rebate is added as a discount on the hospital price for all medicinal products of the special list of medicinal products for severe diseases set out in par. b of article 12 of Law 3816/2010, which EOPYY and the hospitals are supplied. In the cases these medicinal products are administered via the private pharmacies, the above percentage is added to the volumes and import rebates set out in the positive list.

3. Especially for the medicinal products with new active substances which are priced for the first time, apart from the fixed entry fee, an additional 5% rebate or a discount is accordingly introduced, as the case may be, for the medicinal products included in the provisions of the preceding paragraphs respectively, as a percentile entrance fee for the inclusion of all new medicinal products under a reimbursement regime, for a period of one year after their inclusion date.

4. The additional escalated rebate, is determined in the following table, with regard to the total sales volume of the medicinal products for the preceding three-months period:

Three-months total volume per active substance medicinal products	Additional rebate
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%

5. The ex-factory prices are used for the calculation of the said rebate. The said percentages may be fixed by a Ministerial Decision in accordance with the achievement of the pharmaceutical targets. This article enters into force from 1/1/2014. The rebates of marketing authorisation holders to the social insurance agencies and EOPYY are regulated by the applicable provisions. For pharmacies, the existing rebates apply.

Article 7
Reimbursement of the cost of medicinal products

1. After the revision of the prices or after the approval of the new prices of medicinal products, the positive list and the respective reference are revised within 30 days. The new generics are automatically included in the list, since the reference medicinal products (off-patent) are also included therein.

2. On the next revision of the list, the reference price of each cluster must be based on the average of the three cheaper generics of each cluster with a volume market share over 4% in the said cluster, if it extracts prices lower that the existing system.

3. When an objection is issued, a written and justified answer for the final decision to the relevant entity in charge of the marketing must be filed by the competent Committee of EOF.

Article 8
Prescription Protocols

By virtue of the decision of the Minister of Health, a 5-member National Committee for monitoring the pharmaceutical expenditure and the application of the therapeutic prescription protocols is established, with the participation of a representative of EOPYY, which has as its object: a) The selection of the diseases and conditions for which prescription therapeutic protocols will be developed (diagnostic and pharmaceutical) with epidemiologic incidence criteria (prevalence and impact) and the need to intervene in order to adequately cover common diseases/conditions and hospitalisation b) The determination of a framework and monitoring of an audit mechanism for the implementation of the therapeutic protocols (audit indexes), c) The proposing of measures to the Minister of Health in case of transgression of the therapeutic protocols and over-prescribing, d) the determination of the special

therapeutic categories for the development of patients' registries, the framework for the functionality of the registry and the access thereto for auditing, regulatory and epidemiologic purposes, e) the making of suggestions for the improvement of the whole system, with regard to needs and malfunctions that may occur and f) the management of any objections of any person having relevant legal interests.

2. In order for the work of the Committee to be implemented, all agencies involved are obliged to provide any information necessary. For the more effective function of the Committee, it may, with the relevant decisions thereof, form special committees or working groups (e.g. oncology committee, in order to propose a list of bio-indexes and tests, as well as the conditions required in order for oncology and biologic products to be prescribed).

3. The responsibility for the preparation of therapeutic protocols, following the relevant invitation of the National Committee, lies to the scientific societies of medical specialties and specialties recognised by the KESY, in co-operation with the Medical Society of Athens, which is responsible for the co-ordination of the development of therapeutic protocols and digital presentation thereof, as well as the support of the audit mechanism and training of physicians in the application thereof, with the co-operation of the special scientific medical societies. The scientific societies are obliged to for Work Groups for this purpose, ensuring the procedures of the strong scientific consent in the development of the therapeutic protocols, with the participation of Unions of patients. In case of denial or inactive participation of the scientific societies, respective Work Groups according to the merit may be established, upon the suggestion of the National Committee.

4. KESY is the competent agency for the approval of the therapeutic protocols and for determining the framework for the update thereof, at least once per year, with the incorporation of all newer scientific data.

5. By virtue of the decision of the President of EOPYY, which will be published within one month from the date this decision is published, the prescription limits for each physician co-operating with EOPYY are determined. More specifically, the monthly expenditure of all prescriptions of each physician may not exceed 80% of the average monthly expenditure thereof during 2013. For this reason, EOPYY calculates the average monthly expenditure per physician for 2013 and sets the limits of the monthly prescription expenditure per physician for 2014. HDIKA adjusts the electronic prescription system so that the physician will not be able to prescribe per month, medicinal products whose total expenditure exceeds by 20% the monthly limit set for each physician. The physician may exceed the set limit for two (2) months, however, in the third month the system does not allow him/her to prescribe a total amount above the monthly amount, less the transgression of the preceding two months. The physician may in the following month continue with the same terms that applied for the preceding three-months period. The new-entrants are permitted to have expenditure respective to the average of their specialty for the year. EOPYY is entitled, during the year, to re-adjust the said limits per physician, in proportion to the work produced by the said physician and the course of the total pharmaceutical expenditure.

6. In addition, by decision of the President of EOPYY which will be published within one month from the date this decision is published, limits for the prescribing of medicinal products can be specified, per specialty or therapeutic category, in off-patent active substances, together with mandatory targets for prescribing generics. For the calculation of the targets per specialty, the prescriptions issued per specialty are calculated, together with the availability of generics in each cluster, so as to potentially assess the prescriptions that may concern off-patent medicinal products or generics. HDIKA will re-adjust the electronic prescription system so that the physician cannot exceed the enacted limit. In addition, HDIKA is obliged to readjust the system so that the physician is able to suggest the cases in which a generic must be administered. If the physician suggests a generic upon the prescription, the offer of a non-generic medicinal product by the pharmacy is prohibited. The prescription target for generics must be by average, set to 60%. EOPYY may establish a bonus and incentives for physicians who comply with the above target.

7. EOPYY's administration undertakes to perform the necessary actions and develop the knowledge, systems and specialisation required in order to implement price-volume and risk allocation agreements with the producers, especially in the cases of selected expensive medicinal products, such as biological ones. In addition, EOPYY and HDIKA, in co-operation with the competent committee, will see that until June 2014, at least the 20 most costly therapies are included in the prescription system. In addition, EOPYY and HDIKA will develop registries for the monitoring of very expensive and orphan medicinal products.

8. Until the necessary infrastructure is developed, EOPYY may purchase consultant services from the appropriate public or private agencies, who will assist in its services for the better monitoring and thorough analysis of pharmaceutical expenditure, the analysis of compliance with the therapeutic protocols and relevant activities aiming at the more effective and efficient use of medicinal products.

9. For the development of the targeted-therapy, within one month from the publication of this decision, the oncology committee is called to propose a list of bio-indexes, tests and conditions required in order for oncologic and biologic products to be prescribed. In parallel, reimbursement prices for these indexes must be filed, so as to be included in the EKPY and serve as a prerequisite, upon the decision of the President of EOPYY, for the administration of oncologic medicinal products.

Article 9
Biologic factors and orphan medicinal products

1. The selection regarding the therapy to be prescribed falls under the exclusive jurisdiction of the physician. Biological factors as related to each other, but also as related to the bio-similar products are not deemed of direct exchangeability. EOPYY may rule for specific categories of biological factors, such as erythropoietin for example, that the first choice treatment for new patients must be the one with the lowest price or treatment costs.

2. Orphan medicinal products may be priced even if prices are offered in only two other European countries. EOF's website must have a link of the European Medicines Agency in order to present the official European registry of orphan medicinal products. After pricing, the orphan medicinal products may be posted in 30 days on

the positive list of medicinal products. EOF must appoint a committee which will propose actions for adopting incentives that will promote the availability of orphan medicinal products in accordance with the European standards.

This decision must be published in the Government Gazette.

Athens, December 5, 2013

THE MINISTER

SPYRIDON-ADONIS GEORGIADIS