SECTION I

PROVISIONS OF THE MINISTRY OF HEALTH

PART A

HEALTH TECHNOLOGY ASSESSMENT AND REIMBURSEMENT OF MEDICINAL PRODUCTS FOR HUMAN USE

Article 247

Establishment and Duties of the Health Technology Assessment Committee

1. A Committee is established at the Ministry of Health for Health Technology Assessment and Reimbursement of Medicinal Products for Human Use (HTA Committee), as these products are defined in Article 2 of Decision Ref. Δ.ΥΓ3α/Γ.Π.32221/2013 of the Minister of Health (Government Gazette Series B, Issue No. 1049). The Committee shall be established by decision of the Minister of Health; it will be based at the National Organisation for Medicines ("EOF") and will be supervised by the Minister of Health.
2. The HTA Committee's main task is to issue a recommendation to the Minister of Health, following an assessment of the medicinal products for which marketing authorisation has been granted and which are marketed in Greece, whenever the Minister has to decide on the following matters:
    a) The inclusion or removal of medicines from the Positive List of Article 12 of Law 3816/2010 (GG A 6) (List of Reimbursable Medicinal Products) and
    b) A revision of the List of Reimbursable Medicinal Products mentioned in the preceding Article.

The Minister of Health may decide differently from the Committee's opinion, on the basis of a reasoned decision under the criteria laid down in Article 249.

3. The Committee's Rules of Operation, regulating any particular matters and technicalities relating to the evaluation procedure and their practical implementation, the Committee's operations, the particular obligations of its members and any other details relating to the execution of Committee's tasks, will be authorised by decision of the Minister of Health which is published in the Government Gazette.

Article 248

Composition, Appointment and Dismissal of Members

1. The HTA Committee comprises of eleven (11) regular members, including its Chairman and Vice-Chairman. Its members are persons with provable scientific expertise or professional experience in at least one of the following sectors: a) pharmacology; b) clinical pharmacology; c) pharmacoepidemiology; d) evaluation of clinical studies or cost/effectiveness analyses in Health Technology; e) pharmacoeconomics, and f) development of treatment protocols or a disease registry. Members shall be appointed with due regard to ensure a sound balance between the specialties stated in sections (a), (b) and (c), on one part, and those mentioned in sections (d), (e) and (f), on the other part. The Committee's sittings may be attended by the regular member of the Committee for Medicinal Products for Human Use appointed by Greece from time to time in the European Medicines Agency, without a voting right, as well as by one representative of IDIKA SA (e-Governance Centre for Social Security Services SA), again without a voting right, where technical support matters are being discussed.

2. The HTA Committee will be supported by ten (10) Secretaries, all with scientific expertise or professional experience in any of the sectors mentioned in paragraph (1), who will be employed on a full-time, exclusive basis. These persons will be selected among the staff of the Ministry of Health or appointed for that purpose by the Minister of Health, under a procedure which is subject to supervision by the Supreme Council for Civil Personnel Selection ("ASEP") or will be transferred for that purpose from any legal entity which is subject to supervision by the Ministry of Health, following a call for expression of interest. The terms, procedure and evaluation criteria relating to the placement, appointment or transfer of these employees and all relevant technicalities shall be determined by decision of the Minister of Health.

3. The HTA Committee and its Secretariat will be constituted by decision of the Minister of Health. The Minister of Health will select the Committee's members following a call for expression of interest which is posted on the website of the Ministry of Health. Candidates shall file applications within ten (10) days from such publication. Candidates shall be selected by a Recruitment Committee to be established by decision of the Minister of Health, comprising one Professor appointed by the Senate of National School of Public Health ("ESDY"), the Chairman of EOF and the Chairman of the Central Board of Health ("KESY"). The members of the Recruitment Committee mentioned in the preceding sentence shall not be remunerated and their main task will be to draw up a ranking list of the three (3) first candidates from each sector mentioned in paragraph (1), namely a list of eighteen (18) candidates in total. If fewer than three (3) candidates are nominated in any sector or if candidates are fewer than eighteen (18) in total, the Committee will submit a candidate selection/ranking report to the Minister of Health indicating fewer candidates, as applicable, who will essentially meet the qualification requirements laid down in the law and in the call for expression of interest. The procedure, terms and criteria of evaluation / selection applicable to the members of the Recruitment Committee and all relevant technicalities shall be regulated by decision of the Minister of Health.

4. The HTA Committee shall be assisted in their duties by external experts/assessors, to be selected from the special list of certified professionals kept by EOF in respect to their scientific area of expertise. In the context of each assessment, external assessors will be selected on the basis of scientific expertise and provable scientific skills in the treatment category of the medicine which is under evaluation. The HTA Committee may request a preliminary recommendation for the assessment of a medicine from a scientific, academicor research institution.

5. The remuneration of the regular members of the HTA Committee shall be determined by joint decision of the Ministers of Health and Finance, in accordance with the provisions of Law 4354/2015 (GG A, 176) and the applicable regulations on single payroll status in the civil sector. The same decision will also determine the fees of assessors.

6. The members of the Committee shall be appointed for a term of three years. Such term may be renewed once by decision of the Minister of Health, following a recommendation by the Committee of paragraph (3), which submits an evaluation report of active members compared to new candidates. Such report is drafted with

due regard to the qualifications listed in paragraph (1), any experience gained and the members' performance in the execution of their duties.
7. The Minister of Health may dismiss temporarily or replace the members of the HTA Committee for a serious cause relating to the performance of their duties. The Minister of Health may also dismiss temporarily or replace any member(s) of the HTA Committee who meet(s) any of the following criteria: (a) has breached the applicable regulations on impartiality, membership impediments or confidentiality, or (b) has failed to attend more than six (6) sittings of the Committee within a period of six months, irrespective of the causes.

Article 249
Assessment Criteria and Methodology

1. The basic criteria to be applied by the Committee in the assessment of medicines are: a) the clinical benefit, as measured by the severity and the burden of the disease, the impact on mortality and morbidity, andsafety and tolerability data; b) comparability with existing reimbursable medicinal treatments; c) reliability/robustness of the data in the clinical studies; d) cost effectiveness ratio and e) budget impact. The HTA Committee's opinion to the Minister of Health regarding the inclusion of a medicine in the List of Reimbursable Medicinal Products will include the particular therapeutic indication(s) for which the medicine will be reimbursed, and the pharmaceutical forms, strengths and contents. Together with each therapeutic indication the report will essentially mention the clinical characteristics of the patients for whom the medicinal product is recommended for reimbursement, the stage and treatment line (therapeutic algorithm) for which the drug is recommended for reimbursement and the size of the population to which the treatment is is targeted in order to assess the budget impact.
2. Medicinal products under data protection, and for which marketing authorisation was granted under the national or the decentralised procedure, the mutual recognition procedure or the centralised procedure of Regulation 726/2004/EC (OJ L 136), are subject to assessment and will only be included in the List of Reimbursable Medicinal Products if they are reimbursed in two thirds (2/3) of the EU Member States in which they are marketed, provided that the Members States in which they are marketed are at least nine (9), and at least half of the Member States in which the medicine is reimbursed are included in the following list of Members States applying Health Technology Assessment mechanisms in respect of medicinal products for human use: Austria, Belgium, Great Britain, France, Spain, Netherlands, Portugal, Sweden and Finland. The provisions of this paragraph shall not apply to: a) medicines authorised for marketing as orphan medicinal products, provided that they are covered by international protocols; b) medicines for Thalassemia; c) the vaccines listed in Article 2(5) of Joint Ministerial Decision Ref. Δ.ΥΓ3α/Γ.Π.32221/2013 (GG B, 1049); d) medicinal products derived from human blood or human plasma, as defined in Article 2(11) of Joint Ministerial Decision Ref. Δ.ΥΓ3α/Γ.Π.32221/2013 (GG B, 1049); e) combinations of known active substances, which are characterised as medicines combining active substances, whose data protection period has expired, provided that they are reimbursed at a price lower than the aggregate reimbursable price of the medicines containing the individual active substances; f) "clone" medicines, which are defined as medicines with a different brand name, identical pharmaceutical form, identical qualitative and quantitative composition both in terms of active substance and excipients, which are authorised for marketing based on the same pharmacochemical, pre-clinical and clinical documentation as medicines which are already included in the List of Reimbursable Medicinal Products, and g) "bio-similar" medicines, namely medicines of biological origin, authorised as per Article 10(4) of Directive 2001/83/EC, with reference to medicines of biological origin, which are already included in the List of Reimbursable Medicinal Products.
3. By decision of the Minister of Health to be issued after 1.6.2018 on the basis of a prior opinion of the HTA Committee, which is posted on EOF's website, the above list of EU Member States applying Health Technology Assessment mechanisms may be revised. The decision provided for in the preceding sentence may not be amended before one year has elapsed from its date of effect.
4. The members of the HTA Committee and the external experts/assessors shall have access to all information available to EOF, EOPYY and IDIKA SA relating to the medicines which are under assessment for inclusion in the List of Reimbursable Medicinal Products, or in relation to any other medicines in general.
5. The HTA Committee may take account of the assessments and the decisions of the health technology assessment bodies of any other European countries, and it will essentially take account of any assessments conducted in the context of the European Network for Health Technology Assessment (EUnetHTA).

Article 250
Assessment Process

1. For the assessment of a medicine by the HTA Committee and for its inclusion in the list of Article 12 of Law 3816/2010, the Holder of the Marketing Authorisation (MAH) shall: a) file an application to the HTA Committee, accompanied by a full dossier including all information and documentation, and b) pay a lump-sum assessment fee, at the amount to be determined by joint decision of the Ministers of Finance and Health. The form of the application and the information and documentation to be submitted by MAHs will be determined by decision of the Minister of Health. The assessment fee mentioned above is public revenue, which is delivered to the Ministry of Health by virtue of a joint decision of the Ministers of Health and Finance. Any amounts credited to the Ministry of Health on this basis will be charged with the relevant member remuneration expenditures, assessors fees, secretaries' fees and general operating expenses of the HTA Committee and the Negotiation Committee provided for in this Law.
2. To assess the budget impact related to the inclusion of a medicine in the List of Reimbursable Medicinal Products, the HTA Committee shall essentially refer all applications having received a positive recommendation based on the criteria of sections (a) through (c) of paragraph (1) of the preceding article, to the Negotiation Committee of Article 254. The Negotiation Committee shall then initiate and conduct a negotiation procedure in respect of the medicine and shall provide a reasoned opinion, based on the outcome of the negotiation procedure, on the budget impact related to the medicine's inclusion or maintenance in the List of Reimbursable Medicinal Products. In any revision of the List, the medicines' budget impact or reimbursed prices shall not increase. In any case, the HTA Committee shall take account of the Negotiation Committee's reasoned opinion as to the budget impact of the medicines' reimbursement, either on the basis of a successful

negotiation or on the basis of a non-initiated or non-completed negotiation, before rendering a final opinion to the Minister of Health regarding the inclusion or removal of medicines and the revision of the List of Reimbursable Medicinal Products.
3. If an application for inclusion of a medicine in the List of Reimbursable Medicinal Products is rejected, the MAH may file a new application after six months from the date the relevant decision was rendered, provided that the second application includes information and documentation which justifies a new substantive assessment of the medicine on the basis of the health technology assessment criteria laid down herein.
4. As part of their duties, the HTA Committee shall essentially evaluate and recommend to the Minister of Health on the maintenance or removal from the List of Reimbursable Medicinal Products: a) of any medicines under data protection status, which were included in the List of Reimbursable Medicinal Products any time up to three years before the initial Ministerial Decision establishing the Committee was issued. Such evaluation shall be completed within two years from the date the aforementioned decision was issued. This evaluation procedure shall be essentially initiated every three years after expiry of the previous evaluation and shall be completed within one (1) year, in respect of all medicines under data protection status which have been included in the List of Reimbursable Medicinal Products since expiry of the previous evaluation, and b) of any medicines already included in the List of Reimbursable Medicinal Products, which are therapeutic equivalents of medicines for which an application for inclusion has been filed. The HTA Committee may re-evaluate all medicines included in the List of Reimbursable Medicinal Products and recommend to the Minister of Health, whenever the latter needs to decide on a revision of the List and on the maintenance or removal of medicines.
5. By decision of the HTA Committee, one of its members, excluding the Chairman, will be appointed as Handler of the assessment file, and at least two (2) external assessors will be appointed from the names listed in the external assessors' registries.
6. A summary of the HTA Committee's opinions which were adopted by the Minister of Health, including essentially their reasoning, shall be posted on EOF's website, following elimination of any information relating to: a) business secrecy, and b) personal data. The Committee's Rules of Operation will include the relevant original documents.
7. The HTA Committee may request an opinion from the representatives of any patients' associations, scientific associations or medical associations.

Article 251
Revision and Drafting of the List of Reimbursable Medicinal Products

1. The HTA Committee's recommendations, which are prepared with due regard to the Negotiation Committee's opinion, are forwarded to the Minister of Health, who issues a decision ordering the inclusion or removal of a medicine from the List of Reimbursable Medicinal Products and revision the List accordingly. Based on the Minister's decision the revised List of Reimbursable Medicinal Products is issued by the competent department of the Ministry of Health and is then posted on EOF's website, only for the correction of errors, for a period of three (3) days. The MAH files a written report in respect of any errors identified, which are then corrected by the Committee's Secretariat, which notifies on the corrections the competent department of the Ministry of Health, in order for the Minister to issue a revised decision.
2. The Minister's decision as to the inclusion or non-inclusion of a medicine in the List of Reimbursable Medicinal Products is issued and notified to the MAH concerned by any expedient means, within an exclusive deadline of one hundred and eighty (180) days from the submission date of the application. The decision's publication on the Internet is considered an expedient means to notify the applicant. If the above deadline lapses, the application is considered to have been tacitly rejected.
3. The deadline mentioned in the preceding paragraph shall be suspended for as long as the MAH: a) fails to pay the assessment fee provided for in Article 250(1), and b) fails to present the information and documentation prescribed in the Committee's Rules of Operation. Upon lapse of (60) days from written notification to the MAH in respect of these failures, the application shall be rejected by decision of the Ministry of Health, following an opinion of the HTA Committee.
4. All decisions issued by the Minister of Health following an opinion of the HTA Committee shall be essentially posed on the Internet, as per the requirements of Law 3861/2010 (GG A, 112), and on the website of the Ministry of Health, and shall take effect as of the date they are posted as per the aforementioned law, save otherwise determined in the body of the decision concerned. The outcome of the negotiations shall not be publicised.
5. The acts provided for in this article shall be subject to appeal before the Three-Member Administrative Court of Appeal at the district in which the applicant/MAH is domiciled, as per the provisions of Presidential Decree 18/1989 (GG A 8) and Law 702/1977 (GG A 268). The legal remedies afforded to MAHs and the applicable deadlines for their exercise shall be essentially indicated in the relevant decision of the Minister of Health.
6. By decision of the Minister of Health issued following a recommendation by the Committee of Article 15 of joint ministerial decision Ref. οικ. 3457/2014 (GG B 64), which essentially integrates any prescription restrictions imposed by the HTA Committee, in respect of individual medicines or groups of medicines, prescription protocols shall be issued, compliance with which is imperative for the reimbursement of the relevant medicinal products, and integrated in the system of IDIKA SA. Such protocols shall be developed by the aforementioned Committee with due regard to the applicable scientific standards, including epidemiological data (incidence and prevalence), the needs for coverage in terms of diseases and hospitalization, as well as economic criteria, including the budget impact based on the reimbursed price, as same is determined from time to time. All details pertaining to the procedure of integration of the applicable prescription restrictions and of the prescription protocols provided for in the preceding sections in the system of IDIKA SA shall be regulated by decision of the Minister of Health.

Article 252
Principle of Impartiality – Membership Impediments

1. In the performance of their duties, the regular members and the Secretariat of the Evaluation Committee shall be bound by the principles of impartiality and objectivity, as same are defined in Article 7 of Law 2690/1999 and Article 36 of 3528/2007 (GG A 26).
2. In any case, the members of the Evaluation Committee and their relatives up to second degree by blood or marriage may not maintain any direct financial interests in

the undertaking which is the MAH or in the undertaking of any drug manufacturer or wholesaler, any time up to two (2) years prior to their appointment and also at the time of their appointment and throughout their tenure. "Direct financial interest" means: a) any employment contract, works contract or independent services agreement; b) any consultancy relationship; c) any financial interests in undertakings, e.g. holdings in capital, shares, stocks, bonds, pre-emption rights, indemnity rights, intellectual property rights; d) membership in the Board of Directors or the capacity of legal representative of the aforementioned undertakings. Throughout their tenure, the members of the Evaluation Committee may not maintain any other interests in relation to the MAH, whose application is being evaluated.
3. The members of the Evaluation Committee shall not engage in legal relationships of any kind with any pharmaceutical companies whose products have undergone evaluation by the Committee, for a minimum period of one (1) year after expiry or termination of their tenure in any manner.
4. The members of the Evaluation Committee are liable to declare in writing any interests or impediments of those provided for in this Article, which may exist at the time they submit an application for their appointment and throughout their tenure, within five (5) days from the time they gain knowledge thereof. The relevant written declarations shall be entered in a special record to be kept at the Committee's Secretariat for that purpose.
5. Any parties found to be in breach of the provisions of paragraphs (1), (2) or (3) shall be subject to minimum three-month imprisonment and a €5,000.00 fine. Any parties found to be in breach of the provisions of paragraph (4) shall be subject to one (1)-year minimum imprisonment and a €5,000.00 fine.
6. The illegal character of the acts described in paragraphs (1) and (2) is lifted if a declaration is filed as per paragraph (4) and at the same time the member concerned files his/her resignation and refrains from his/her duties thereafter.
7. The provisions of this Article shall not apply to external or internal evaluators, to the members of the Committee's Secretariat and to the members of the Negotiation Committee.
8. Any other (non-financial) interests falling within the scope of paragraph (2) and the contents of the written declaration provided for in paragraph (4) shall be specified by means of a decision of the Minister of Health.

Article 253
Confidentiality Obligation – Liability of Members

1. The members of the Committee, the handlers, the members of the Secretariat and any persons attending the Committee's sittings are bound by confidentiality in respect of all information which is made available to them as part of their duties, especially any information relating to trade or business secrets, and are liable to sign and submit a written statement of confidentiality before they take up duties or before the opening of the sitting which they will attend. The confidentiality obligation shall survive the termination of their duties for any reason or cause.
2. The members of the Evaluation Committee shall not bear civil liability towards third parties, save towards the Hellenic Republic and EOPYY, for any actions or omissions performed in the context of their duties, as per Article 3 of Law 4208/2013, unless they have acted with intention or grave negligence or they have breached the confidentiality of any information or data which has come to their knowledge as part of their duties, or they have breached the confidentiality obligation of Article 26 of Law 3528/2007. The provisions of Articles 26 and 27 of Law 3528/2007 shall apply to all persons mentioned above.
3. Article 30(9) of Law 2324/1995 (GG A 146) shall apply to the members of the Evaluation Committee during their tenure.
4. The form of the confidentiality statement of paragraph (1) of this Article shall be specified by decision of the Minister of Health.
5. The provisions of this Article shall apply also to the external or internal evaluators, to the members of the Committee's Secretariat and to the members of the Negotiation Committee.

Article 254
Drug Prices Negotiation Committee

1. A Drug Prices Negotiation Committee ("Negotiation Committee) is established, which will be based at EOPYY and will be subject to supervision by the Minister of Health.
2. The Negotiation Committee shall be empowered to negotiate the prices and discount rates of any medicines reimbursed by EOPYY or supplied to public hospitals; conclude agreements with the MAHs that participate in the negotiation procedure, in relation to the scope of the negotiation, and file recommendations to the HTA Committee in respect of the budget impact of the reimbursement of medicines. Any agreements entered between the Negotiation Committee and MAHs shall become binding upon EOPYY, the MAHs concerned and the public hospitals upon entry into effect of the decision of the Minister of Health regarding the inclusion or removal of medicines from the List of Reimbursable Medicinal Products or the revision of that List, provided that the Minister's decision adopts the HTA Committee's opinion which is integrated in the Negotiation Committee's recommendation.
3. The Negotiation Committee shall be established by decision of the Minister of Health and shall comprise nine (9) members as follows: five (5) members [three (3) of whom will have expertise or experience in pharmacoeconomics or in the pharmaceutical market or in the pharmaceutical legislation, one (1) will be a hospital pharmacist and one (1) will be the Director or Deputy Director of the Regional Healthcare Directorate (RHD), all appointed by the Minister of Health; two (2) members appointed by EOPYY; one (1) member appointed by EOF, and one (1) member appointed by IFET SA. All members shall be appointed for a term of three years, which can be renewed once by decision of the Minister of Health. Upon expiry of their first tenure, the tenure of at least three (3) regular members of the Negotiation Committee shall be essentially renewed by decision of the Minister of Health.
4. The members of the Negotiation Committee shall not bear civil liability towards third parties, save towards the Hellenic Republic and EOPYY, for any actions or omissions performed in the context of their duties, as per the provisions hereof, unless they have acted with intention or grave negligence or breached the confidentiality of any information or data which has come to their knowledge as part of their duties, or breached the confidentiality obligation of Article 26 of Law 3528/2007 (GG A 26). The provisions of Articles 26 and 27 and 36 of Law 3528/2007 shall apply to all persons mentioned above *mutatis mutandis*.
5. Article 30(9) of Law 2324/1995 (GG A 146) shall apply also to the regular and deputy members of the Negotiation Committee during their tenure.

6. The terms and the procedure of negotiation and the terms of operation of the Negotiation Committee, the terms governing the conclusion of agreements with MAHs, the Negotiation Committee's Rules of Operation and the terms governing the determination of reference prices (RPs) which represent the reimbursement prices of Social Security Organisations (SSOs) and EOPYY shall be laid down by decision of the Minister of Health. The remuneration payable to the members of the Negotiation Committee from the budget of the Ministry of Health, and all details necessary for the implementation of this paragraph shall be regulated by joint decision of the Minister of Finance and Health.

Article 255
EOPYY Negotiation Committee

Article 29(4) of Law 3918/2011 (GG A 31) is replaced as follows:

"4. A Committee is established in EOPYY for the Negotiation of Fees and Prices of Medical Devices, whose main task will be to negotiate the fees of any providers contracted with EOPYY, the terms of the Organisation's agreements and the prices of medical devices and materials, and submit recommendations to EOPYY's Board of Directors with respect to the preservation or modification of the above. The members of the Committee shall not receive remuneration. The Committee's composition, constitution, terms and procedures of operation, its Rules of Operation and all other details necessary for the implementation of this paragraph shall be determined by decision of the Minister of Health.

Article 256
Transitory Provisions – Repealed Provisions

1. Until a ministerial decision is issued as per Article 248(3) hereof, the Positive List Committee provided for in Article 12 of Law 3816/2010 (GG A 6) shall continue to exercise the duties assigned to it under the law, and only the fee prescribed in paragraph (4) of this Article shall be levied.
2. Until a ministerial decision is issued as per Article 248(3) hereof, all duties assigned to the Positive List Committee of Article 12 of Law 3816/2010 (GG A 6) under the law, including those not explicitly stated herein, shall be transferred to the Evaluation Committee of this law, and only the fee prescribed in Article 250(1) relating to the integration of medicines in the List of Reimbursable Medicinal Products shall be levied. Any references in the applicable regulations to the Positive List Committee of Article 12 of Law 3816/2010 shall be deemed to refer to the Evaluation Committee which is established hereunder.
3. Until a ministerial decision is issued as per Article 254(3) hereof, the EOPYY Negotiation Committee mentioned in Article 29 of Law 3918/2011 (GG A 31) shall continue to exercise the duties assigned to it under the law and any duties assigned hereunder to the Negotiation Committee of Article 254.
4. After a ministerial decision is issued as per Article 254(3) hereof, all powers assigned under the law to the Negotiation Committee of Article 29 of Law 3918/2011 (GG A 31) relating to the negotiation of drug prices, including those not explicitly mentioned herein, shall be transferred to the Negotiation Committee established hereunder. Any references in the applicable regulations to the Negotiation Committee of Article 29 of Law 3918/2011 (GG A 31) relating to the negotiation of drug prices, shall be deemed to refer to the Negotiation Committee of Article 254.
[...]

Article 259
Abolition of the Drug Prices Committee

1. Paragraphs (1), (2) and (3) of Article 17 of Legislative Decree 96/1973 (GG A 172) are replaced as follows:
"1. Maximum retail and wholesale prices, hospital sale prices, ex-factory prices and any other specific sale prices, excluding the prices of Non-Prescribed Medicines (NPMs) shall be determined by means of Price Lists issued by the Minister of Health, following an opinion of the National Organisation for Medicines (EOF). These Price Lists shall take effect as of the day following the day they are posted on the website of the Ministry of Health, unless a Price List provides a later date of effect, in any case within forty-five (45) clear days after such posting.
2. Before providing an opinion to the Minister of Health as per paragraph (1) above, EOF shall post the Price List on its website, only for the identification of manifest errors by any parties having a legitimate interest, who must submit their observations within three (3) business days from such posting. EOF will either accept or reject these observations and submit a final opinion to the Minister of Health.
3. Anyone having a legitimate interest may raise objections against the decision referred to in paragraph (1) before the Minister of Health, within an exclusive deadline of five (5) days from the day after the decision is posted on the website of the Ministry of Health. Objections will be filed to EOF electronically. Exclusively in the case of force majeure, objections shall be filed to EOF in writing. Objections shall be accepted or rejected by decision of the Minister of Health, following an opinion of EOF, and a modified Price List shall be issued and posted on the website of the Ministry of Health, which, as far as its modified parts are concerned, shall be valid as of the date of such posting. Any other matters pertaining to drug pricing procedures shall be regulated by decision of the Minister of Health".
2. Any pending drug pricing procedures, save in respect of NPMs, shall continue as per the regulations applicable prior to the enactment hereof.

[...]

Article 264
Treatments by medicines not marketed in Greece and high-cost medicines for special conditions

Where the use of medicines which are not marketed in Greece or of high-cost medicines for special conditions as per Article 12(2) of Law 3816/2010 (GG A 6) is required, these medicines shall be reimbursed on the basis of a decision of the Board of Directors of the National Organisation for Healthcare Services ("EOPYY"), issued following an opinion of three (3) physicians of a specialty relevant to the medical condition for which the medicine is prescribed, as per the procedure laid down in the following articles. The above medicines shall be procured exclusively from EOPYY pharmacies or public hospital pharmacies.

Article 265
Electronic Pre-Authorisation System (EPAS)

1. An integrated Electronic Pre-Authorisation System (EPAS) is established at EOPYY, for the electronic management and review of applications for

reimbursement of drugs, for which an EOPYY decision is rendered as per the applicable regulations, which relate to the following categories of medicines:
a) High-cost medicines for special conditions, as per Article 12(2) of Law 3816/2010 (GG A 6);
b) Medicines which are not marketed in Greece (foreign medicines) and will be dispensed by way of emergency import or individual applications;
c) Medicines dispensed outside the scope of their authorised indications;
d) Medicines which are not included in the List of Reimbursable Medicinal Products (positive list), have not undergone evaluation and their dispensation is requested by way of exception for the treatment of diseases or medical conditions which pose a direct threat against the patients' life or are capable of causing irreparable health damage;
e) Early-access medicines which are not dispensed by the MAH or the local agent free of charge, for which temporary individual authorisation is requested from EOF.
2. The submission and processing of applications through the EPAS requires the processing of particular types of personal data without the consent of the data subjects, for reasons of public interest relating to the Social Security sector. Throughout such processing proper measures shall be applied to effectively protect the rights and freedoms of individuals. Any processing of health data for reasons of public interest is strictly prohibited where it leads to data being processed by third parties (other than EOPYY) for any other purposes. The data controllers or processors are liable to respect trade secrecy.

Article 266
List of Physician Advisors

1. By decision of the Minister of Health a list of Physician Advisors shall be issued, which will be renewed every two years, including at least five physicians from each of the following specialties:
a) Haematology
b) Radiotherapy / Oncology
c) Anaesthetics
d) Gastroenterology
e) Gynaecology
f) Dermatology
g) Endocrinology
h) Cardiology
j) Neurology
k) Nephrology
l) Pathological Oncology
m) Orthopaedics
n) Urology
o) Ophthalmology
p) Pathology
q) Paediatrics
r) Pulmonology
s) Rheumatology
t) Psychiatry
The selection criteria shall be determined by decision of the Minister of Health. The eligible physicians shall be selected following a recommendation by the RHD Directors. Physician Advisors are subject to the impediments applicable to the members of the Committee for Evaluation and Reimbursement of Medicinal Products.
2. Physician Advisors are liable to accept their appointment. Timely performance of their duties, within the deadlines prescribed herein, constitutes due performance of a service duty. Failure to meet such duty constitutes a disciplinary offence.

Article 267
EPAS Certification

1. The Physician Advisors included in the relevant list, and any attending physicians forwarding applications for reimbursement of drugs intended for the uses mentioned above, shall be electronically recorded in, and certified through, the EPAS, in accordance with any instructions to be issued by decision of the Board of Directors of EOPYY. The minimum information required for such electronic registration and certification includes the physician's name, surname, father's name, mother's name, work address, contact details, registration number with ETAA (Integrated Fund for Self-Employed Persons) (formerly: "TSAY"), Social Security Number ("AMKA"), medical specialty and email address.
2. In addition, two EOF employees appointed by the Chairman of the Organisation and at least two Secretaries of the Committee for Evaluation and Reimbursement of Medicinal Products for Human Use appointed by decision of the same Committee, as well properly mandated employees of EOPYY appointed by decision of EOPYY's Board of Directors, shall also be registered in and certified through the EPAS.

Article 268
Submission, Management and Review of Applications

1. Upon completion of the certification procedure as per above, the attending physicians shall file an application online. The essential information to be completed in the mandatory fields of the application and the justification details required shall be determined by decision of the Minister of Health. In addition to the medical necessity that dictates the drug, the application must essentially state the drug's documented benefit for the patient, the ineffectiveness of all other treatments available and any other relevant information. The individual Medical Opinion Forms per Disease / Medicine shall be authorised by decision of the Board of Directors of EOPYY.
2. Applications concerning high-cost medicines for special conditions shall be instantly forwarded by the EPAS operator to three physicians of a specialty relevant to the disease, randomly selected from the above list, who will render an advice as to the approval or rejection of the application within five days, having due regard to the treatment protocol. The physicians' advice is then forwarded to the Board of Directors of EOPYY, who will render a final decision on the matter.
3. Applications concerning medicines which are not marketed in Greece (foreign medicines), which will be dispensed by way of emergency import or individual applications shall be instantly forwarded online by the EPAS operator to the competent EOF officer. Within five days EOF shall provide online information as to the marketing authorisation and shall state whether the marketing of the medicine is authorised, so that EOPYY can authorise or reject the medicine's reimbursement. Once such notification has been provided by EOF, it will be instantly forwarded by the EPAS operator, together with the application, to three (3) physicians of a specialty relevant to the disease, randomly selected from the above list, who will render an advice as to the approval or rejection of the application within five days, having due regard to the treatment protocol. The physicians' advice is then forwarded to the Board of Directors of EOPYY, who will render a final decision on the matter.
4. In situations where there is a justified, urgent need (direct threat against the patient's life or risk of irreparable damage to patient's health) to dispense a

medicine which is not marketed in Greece to a hospitalised patient, the certified attending physician will file an application bearing the indication "Urgent Drug Dispensation", which will be entered in the EPAS, along with a statement by the patient (where this can be obtained) stating that he/she is aware of the possibility of the application being rejected. The medicine will then be instantly dispensed by the hospital pharmacy and the application will be later accepted or rejected under the procedure described above. If rejected, the medicine will not be reimbursed by EOPYY.

5. Applications concerning medicines which are dispensed outside the scope of authorised indications shall be instantly forwarded online by the EPAS operator to the competent EOF officer. Within five days EOF shall provide online information as to the marketing authorisation and the medicine's authorised indications. Once such notification has been provided by EOF, it will be instantly forwarded by the EPAS operator, together with the application, to three (3) physicians of a specialty relevant to the disease, randomly selected, who will render an advice as to the approval or rejection of the application within five days, having due regard to the treatment protocol. The physicians' advice is then forwarded to the Board of Directors of EOPYY, who will render a final decision on the matter.

6. Applications concerning medicines which are not included in the List of Reimbursable Medicinal Products and are dispensed by way of exception shall be instantly forwarded online by the EPAS operator to the Committee for Evaluation and Reimbursement of Medicinal Products for Human Use, which will render a reasoned opinion on the matter. The Committee's opinion will be forwarded online within an exclusive deadline of five days. If this deadline lapses, the Committee will be deemed to have rendered a negative opinion. The application is then forwarded instantly together with the Committee's opinion to the Board of Directors of EOPYY, who will render a final decision. The decisions of the EOPYY Directors addressing applications of this category shall be essentially notified to the attending physicians within ten (10) days from submission of the application.

7. Applications concerning early-access medicines which are not dispensed by the MAH or the local agent free of charge, for which temporary individual authorisation is requested from EOF, shall be instantly forwarded online by the EPAS operator to the EOF officer specifically authorised for that purpose. Within five days EOF shall provide online information as to the marketing authorisation and the medicine's prescription inside or outside the authorised indications, stating also whether a special programme is in place for the free dispensation of the medicine. Once such notification has been provided by EOF, it will be instantly forwarded by the EPAS operator, together with the application, to three (3) physicians of a specialty relevant to the disease, randomly selected, who will render an advice as to the approval or rejection of the application, having due regard to the treatment protocol. The physicians' advice is then forwarded to the Board of Directors of EOPYY, who will render a final decision on the matter.

Article 269
Completion of the Procedure

1. The Board of Directors of EOPYY shall hold a meeting at least once a week in order to address applications.

2. The decisions of EOPYY's Board of Directors accepting or rejecting an application, on the basis of the advices of three physicians, shall be ratified on the same date and forwarded online through EPAS to the attending physicians who filed the relevant applications, essentially within two (2) days. If the application is rejected, a second application may only be filed on grounds of a substantial change of circumstances, along with a reasoned opinion of the attending physician.

3. The procedure and details for electronic registration of medicines for which applications have been accepted shall be regulated by decision of the Minister of Health.