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Athens, 24 / 01 / 2020
G.P. B1.B2/4577

JOINT

MINISTERIAL

DECISION

Subject: “Procedure, terms and conditions of offsetting the automatic rebate in pharmaceutical expenditures against part of R&D expenses and against the costs of investment plans relating to development of products, services or production lines - Determination of a maximum rate for 2019 expenditures”.

THE MINISTERS OF

HEALTH, DEVELOPMENT AND INVESTMENTS, AND FINANCE

Having regard to:

1. The provisions of:

(a) Law 4052/2012 (Government Gazette Series A, Issue no. 41) “Responsibility of the Ministry of Health and Social Solidarity and the Ministry of Labour and Social Security for implementing the law entitled “Approval of (i) the Draft Financial Assistance Facility Agreements between the European Financial Stability Fund (E.F.S.F.), the Hellenic Republic and Bank of Greece, (ii) the Draft Memorandum of Understanding between the Hellenic Republic, the European Commission and Bank of Greece, and other urgent provisions to reduce the public debt and rescue the national economy" and other provisions”, in particular Article 11 thereof;

(b) Law 4172/2013 (GG A, 167) "Income Taxation, Urgent Measures Implementing Law 4046/2012, Law 4093/2012 and Law 4127/2013 and other provisions” as in force, in particular Articles 22A and 23 thereof

(c) Law 4310/2014 (GG A, 258) “Research, Technological Development and Innovation and other provisions”, as amended and in force;

(d) Presidential Decree 121/2017 (GG A, 148) “By-Laws of the Ministry of Health", as in force;

(e) Presidential Decree 81/2019 (GG A, 119) “Establishment, Amalgamation, Renaming and Abolition of Ministries and Determination of their Responsibilities – Transfer of Services and Responsibilities between Ministries”;

(f) Presidential Decree 83/2019 (GG A, 121) “Appointment of the Vice-President of the Government, Ministers, Deputy Ministers and State Secretaries”;

´(g) Article 90 of the “Legislative Code on the Government and the Governmental Bodies”, as same was ratified by Article One of Presidential Decree 63/2005 (GG A, 98) "Codification of Laws on the Government and Governmental Bodies”;

(h) Law 4622/2019 (GG A, 133) “Executive State: Organisation, Operation and Transparency of the Government, the Governmental Bodies and the Central Public Administration”;

(i) Law 4633/2019 (GG A, 161) “Establishment of a National Organisation for Public Health (“EODY”), Regulations on Tobacco Products, other matters of the Ministry of Health and other provisions”, in particular Article 20 thereof.

2. Joint Decision no. 109343/I2/11.07.2017 (GG B, 2351) “Criteria for Characterisation of Scientific and Technological Research Expenses of Corporations” of the Ministers of Education, Research and Religious Affairs and Finance.

3. Recommendation no. B1, B2/oik.3092/17-1-2020 Recommendation by the Directorate General of Financial Services (“GDOY”) as per Article 24(5) of Law 4270/2014, as in force.

4. The fact that the provisions hereof entail a Capital Transfer expenditure up to an amount of fifty million Euros (EUR 50,000,000).

WE HEREBY DECIDE AS FOLLOWS:

Article 1
Definitions

For the purposes hereof, the following definitions shall apply:

1) “Research and Development Activities in relation to Pharmaceutical Products (“R&D Activities”) means any actions performed for the purpose of placing a pharmaceutical product on the market (e.g. development of raw materials to produce a medicine, reference medicines, generic medicines, hybrid medicines, bio-similar medicines, development of research applications software etc.) as per the requirements of EU and national laws. This includes various different sets of activities, procedures and services, as well as specific targets and deliverables.

The same term also refers to the activities described in Article 2(1d) hereof, where such activities are carried out by a corporation which holds marketing authorisation for pharmaceutical products or by its local representative in Greece, if the latter is designated in the marketing authorisation, or by one of its affiliates, for the purpose of identifying ways to improve human health.

2) “Investment plan for development of products, services or production lines (“Investment Plan”) means any activities performed for the purpose of launching a new production process or modernising an existing production process, with a view to improving the existing production procedures, increasing their capacity and improving the quality of the products concerned.

“Beneficiary” means any Holder of a Marketing Authorisation (MAH) relating to medicines intended for human use, or its local representative in Greece, if the latter is designated in the marketing authorisation, and generally any pharmaceutical company which is liable to pay a clawback rate of its pharmaceutical expenditures of EOPYY and its hospital pharmaceutical expenditures.

Essential conditions for the involvement of the above persons in the set-off procedures described in Article 11(1)(g) of Law 4052/2012 (GG A, 41), as same are specified herein, are the following:

(a) The MAH or pharmaceutical companies concerned have no outstanding tax or social security liabilities;

(b) A settlement arrangement is in place in relation to any outstanding clawback liabilities relating to pharmaceutical expenditures of EOPYY or hospital pharmaceutical expenditures, as well as any outstanding rebate liabilities as per Article 35(3) of Law, and

(c) All applicable rebates as of year 2020 onwards were timely paid.

Article 2
Definition / Classification of Activities (Inclusions - Exceptions)

1. In summary, R&D activities relate to the following actions - development stages:

(a) Performance of laboratory R& of pharmaco/technical form (pre-formulation/formulation studies, analysis methodologies studies etc.), R&D in raw materials for drug production, analysis methodologies and development of research applications software.

(b) Phase 1, 2 and 3 testing, which is necessary to complete the product approval dossier (efficacy, safety, pharmacokinetics / pharmacodynamics, bioequivalence, stability, etc.). The above phase 1,2 and 3 testing is recognised provided that it is conducted under the procedure laid down in the national law.

(c) Trial batch production and evaluation of the process on a pilot basis, based on a sufficient size and number of lots.

(d) Research and development in the field of new technologies, intended to identify ways to improve human health, such as digital technology, artificial intelligence and big data analysis,

network and data security, production, procedures/ services quality controls, software development, computer programming and information systems support, file and data storage and management.

2. In defining / classifying the above R&D activities, the following are included or excluded, as applicable:

(a) The design and development of one or more prototypes and related tests is included. The construction of a series of prototypes to meet other needs, following the successful completion of the initial prototype tests, is excluded.

(b) The construction and operation of pilot projects on an experimental basis, in order to gain experience and combine design studies and other data to establish new product specifications, design specific equipment and structures and draw up operating instructions and procedure / methodology manuals, is included.

(c) Industrial design activities are only included to the extent they are essentially required to carry out scientific and technological research activities. Production process design activities are excluded.

3. Activities performed as part of investment plans relating to development of products, services or production lines include any actions serving the establishment of new installations or the modernisation of existing installations with a view to improving the quality of the manufactured products, improving the existing production processes and/or increasing the capacity of the production process. These activities are carried out through design activities, technology transfer, construction of building and special E/M production facilities, purchase and installation of production process equipment / laboratory equipment / control and information systems, which meet particular specifications.

Article 3
Eligible Expenditures

1. Expenditures relating to the performance of R&D activities in accordance with Articles 1 and 2 hereof are:

(a) Cost of purchase / construction / expansion / repair / maintenance / renovation of building installations, to the extent they relate exclusively to R&D activities;

(b) Cost of purchase / leasing of mechanical equipment or laboratory infrastructure equipment, such as devices, tools, scientific instruments, or any arrangements or components thereof (of laboratory or semi-industrial size) and semi-industrial (demonstration) testing facilities. This category of expenditures may also include additional transportation and installation costs as well as staff training expenses.

(c) Cost of purchase of intangible assets / rights of use of specialised scientific software “packages” required to carry out the research. Any ordinary, general-purpose software, not specifically designed to meet the computational requirements of the project concerned, are not included.

(d) Staff fees, (irrespective of the staff ranking, e.g. persons employed under employment contracts of definite or indefinite term or on the basis of service agreements) payable to staff involved in the implementation of the R&D project during its implementation, such as special scientists, postgraduate students and technical staff. It is noted that technical staff costs may not exceed twenty percent (20%) of the total payroll costs of the approved research team of the project. If the costs relating to each staff ranking as above concern existing staff, who were involved in an R&D project before January 1st, 2019, then such costs are eligible at a rate up to 50% of the total payroll costs of the approved research team of the Project. (e) Costs of consumables required to develop the products (e.g. raw materials, excipients,

solvents, reagents, reaction catalysts and primary packaging materials).

(f) Outsourcing to external associates or bodies (private laboratories or undertakings, public research centres and laboratories, Higher Education Institutes), a specific and clearly defined part of the scientific research project. For the purposes hereof, the eligible outsourcing expenses (involving either natural persons or legal entities) may not exceed in total seventy per cent (70%) of the research project's budget.

(g) The costs of clinical trials which are carried out and essentially required to document the application for marketing authorisation or for an extension of the marketing authorisation granted for a medicinal product for human use (e.g. new indication, form, content) or any modification thereof, as well as bioequivalence / bioavailability studies conducted in the same context. Clinical trial costs include any payments which relate exclusively to clinical trials, such as, without limitation, payments (of fees and costs) which are made to hospitals, physicians or companies specialising in clinical trials (CRO - Clinical Research Organisations) and providing related services to the sponsors of clinical trials or to their affiliates; payments for medicines, materials, travel expenses, employee payroll expenses relating to the clinical trials etc. The seventy per cent (70%) limit prescribed above shall not apply to any outsourcing expenses paid to Legal Entities of Public Law.

2. Expenditures incurred to implement Investment Plans relating to development of products, services or production lines in accordance with Articles 1 and 2 hereof, consist in the following:

(a) Tangible Assets:

(a1) Cost of purchase or construction of building installations or special / auxiliary installations and cost of configuration of surrounding areas, up to 45% of the total expenditure.

(a2) Cost of purchase or leasing of new, modern equipment or second-hand equipment not exceeding ten
(10) years in use since the date of manufacture, and cost of purchase or leasing of other equipment, technical installations and internal transportation equipment.

(a3) Special or mechanical installations (purely production spaces, E/M networks, etc.).

(b) Intangible assets relating to technology transfer, purchase of intellectual property rights / operation licenses / patents / know-how and off-patent technical know-how. The eligible expenditures relating to intangible assets may not exceed 20% of the project’s total eligible expenditures.

3. The expenditures referred to in paragraphs (1) and (2) of this Article are set forth restrictively, so that no other expenditures may be regarded as eligible. The expenditures that are considered as eligible in the context of a R&D Project or an Investment Plan shall be calculated on the basis of the actual cost, i.e. as long as they were actually incurred by the Beneficiaries and they are documented by settled invoices or accounting information of equivalent probative value, or on the basis of simplified cost as regards payroll expenses (payroll payments effected on the basis of employment contracts of definite/indefinite term or on the basis of services agreements). For year 2019 in particular, eligible expenditures are those that were incurred during the year, for which agreements were signed in year 2019 (i.e. on or after January 1st, 2019).

Advances, instalments, and final settlement of expenditures of investment projects and R&D projects are also eligible. To obtain approval of an advance payment, the beneficiary shall submit a solemn declaration stating that the purchase transaction or the project has been completed within 18 months, whereas to obtain approval of a final settlement or an instalment, the implementation of the project must have started within year 2019 (i.e. on or after January 1st, 2019).

4. In formulating the budget for the category of staff expenditures referred to in paragraph (1)(d) of this Article, due account shall be taken of the total annual remuneration of any employees to be involved in the project (gross remuneration, social security contributions, holiday benefits, paid leaves and other allowances). Any extraordinary remuneration which is paid outside the employment agreement on a case-by-case basis are not eligible.

5. The following are not eligible as expenditures incurred in the context of Scientific or Technological Research Projects or Investment Plans as per paragraphs (1) and (2) hereof:

(a) Fees paid to shareholders, owners, CEOs, Chairmen or members of Board of Directors, partners, managers, general managers, their 1st-degree relatives and their spouses or civil partners, including any fees paid to natural persons holding any of the above capacities in entities which are affiliated to the entity concerned according to Article 2 of Law 4172/2013 (GG A,
167), or fees paid to persons holding the above capacities in the two tax years preceding the one in which the expenditures concerned were incurred.

(b) Expenses relating to severance pay, extraordinary fees and provisions in kind.

6. If an R&D Project is jointly financed by a subsidiary and a parent entity or by affiliated entities, then the relevant expenditures are only eligible if it is solidly established, in accordance with Article 5 hereof, that they relate to the physical scope of the R&D Project, even if the undertakings concerned are different legal entities, provided that they maintain a branch or have an affiliated entity in Greece which meets the requirements of Article 1 and the relevant expenditures of the project / service were incurred in Greece.

7. For year 2019, the total amount of expenditures to be offset within year 2020 in accordance with Article 6 hereof by way of automatic clawback of the pharmaceutical expenditure, may not exceed fifty million Euros (EUR 50,000,000). The relevant amount will be allocated as a percentage rate to the two (2) categories of expenditure as follows:

1) Category 1, which includes R&D project expenditures. The budget of this category of expenditures may not exceed fifty percent (50%) of the total set-off amount.

2) 2) Category 2, which includes Investment Plan expenditures. The budget of this category of expenditures may not exceed fifty percent (50%) of the total set-off amount.

8. If the total eligible expenditure declared by the beneficiaries for set-off by way of automatic clawback of the pharmaceutical expenditure exceeds the budgeted amount per expenditure category (EUR 25,000,000 and EUR 25,000,000, respectively), then the amount to be offset per beneficiary and expenditure category will be equal to a percentage rate of the declared amount. The set-off rate per category will be calculated by dividing the budgeted amount to be offset by the total amount of eligible expenditures incurred by all beneficiaries. The expenditures to be deducted shall be returned to the body that declared them by means of a deduction certificate issued by the General Secretary for Research and Technology, stating the reason of such deduction. The beneficiary may use any costs that will not be offset to obtain financing from any other national, European or international organisation. If either expenditure category does not absorb the entire amount assigned to it, whereas the other category exceeds it, then the surplus shall be transferred to the other category.

Article 4
Obligations of Beneficiaries

To offset the automatic clawback amounts of pharmaceutical expenditures, the following conditions must be essentially met:

1) Any R&D Projects and Investment Plans which are implemented by the Beneficiary must be exclusively self-funded. That is, any R&D Projects and Investment Plans which are financed in whole or in part by any national, European or international organisations are

excluded from the set-off process.

2) Beneficiaries are liable to keep a separate account in their accounting records, where the offset expenditures shall be entered, and to keep the accounting records, the relevant decisions of the competent bodies (decisions of the Directors, the General Manager, etc.) and the documentation dossiers that were filed to the General Secretariat for Research and Technology of the Ministry of Development and Investments for the implementation of the R&D projects and Investment Plans concerned, for the period prescribed in the provisions of Law 4172/2013 (GG A, 167) and Law 4308/2014 (GG A, 251).

Article 5
Certification Procedures

1. The expenditures referred to in Article 3 hereof are adequately documented if they are certified by a certified auditor/ accountant or an audit firm registered in the Public Register referred to in Article 14 of Law 4449/2017 and having civil liability insurance coverage in place for at least one million Euros (EUR 1,000,000) per incident and a minimum total coverage of five million Euros (EUR 5,000,000) per year. For this purpose, an audit report shall be prepared, following an audit as per the International Financial Reporting Standards and the applicable tax legislation.

2. For verification purposes, each Beneficiary is liable to submit a documentation dossier for the expenditures of R&D projects and Investment Plans with the General Secretariat for Research and Technology, containing essentially the following supporting documents:

1) Minutes of the Board of Directors, if the Beneficiary is a Société Anonyme, or a Decision of its Managers, if it is a Limited Liability Company or a General or Limited Partnership, including essentially the following information:

(a) the scope and objectives of the R&D project or Investment Plan concerned;

(b) the implementation schedule;

(c) the composition of the project

team;

(d) the budget by expenditure category and the total budget of the R&D Project or Investment Plan concerned; and

(e) a breakdown of expenditures.

2) Copies of the evidence of expenditures, by category of expenditure, following an audit by a certified auditor/accountant or an audit firm, in accordance with the provisions of paragraph (1) of this Article. In particular:

(a) invoices or other accounting documents of equal probative value, as per the applicable Greek laws;

(b) evidence of thorough settlement of any invoices payable by wire transfer;

(c) a detailed accounting report of the project based on the beneficiary's systems or records (as it emerges from the relevant accounting records, cost centres, purchase orders or from any other appropriate means which are used by the Company) by category of expenditure in case of double-entry records, or a copy of the income-expenses book in case of single-entry records, signed by the Beneficiary's legal representative and the Accounting Officer.

3) An audit report, signed by a certified auditor/accountant or an audit firm, in accordance with paragraph (1) of this Article. Such Report shall essentially certify cumulatively the following:

(a) That the expenditures of each expenditure category were indeed incurred (eligibility of

expenditures) within the time limits prescribed herein;

(b) That the expenditures are indeed associated with the scope and the objectives of the R&D Project or Investment Plan concerned;

(c) Compliance with the applicable laws on payment of certified expenditures;

(d) The uniqueness of the statement of certified expenditures in the context of the R&D Project or Investment Plan concerned and the fact that such expenditures have not been declared in the context of any other project subsidised by the Greek State and/or in the context of any tax exemption granted in relation to the implementation of any research or technological programmes or any developmental laws, including essentially a solemn declaration as per Article 8 of Law 1599/1986, legally signed by the Beneficiary;

(e) The legality and regularity of the issue and payment of each invoice/proof of expenditure;

(f) The fact that a separate accounting record is kept for the R&D Project or Investment Plan concerned in the company's systems or records, in the form of accounting records, cost centres, purchase orders or other appropriate means;

(g) A solemn declaration by the Beneficiary stating any advances or instalments that were paid within the relevant period as well as the dates on which the relevant orders were placed or the relevant agreements were signed as per Article 3 (3) hereof.

4) Supporting documentation evidencing that the Beneficiary has no outstanding tax or social security liabilities or clawback/rebate liabilities, based on Article 1(4) hereof.

3. For a certification of the physical scope of the R&D Project or Investment Plan concerned, the following shall have to be submitted:

1) A report by the Beneficiary documenting:

(a) the necessity to implement the R&D Project or Investment Plan concerned;

(b) the research or investment/developmental nature of the R&D Project or Investment Plan concerned, as appropriate;

(c) the composition of the project team, in respect of

R&D projects; and (d) the completeness of the scope

of the R&D Project.

2) Solely in respect of Investment Plans, an Implementation Certificate issued by a Civil Engineer, and, where this is imperative due to the nature of the Investment Plan concerned, an implementation certificate issued by a mechanical engineer or another professional.

4. The supporting documents referred to in this Article, which are included in the Beneficiaries' documentation dossiers, must be submitted either in original documents or in legally certified copies, in accordance with the provisions of Law 4250/2014 (GG A, 94). All supporting documents shall be executed and submitted in Greek or shall include an official Greek translation. All foreign public documents and supporting documentation shall be duly Apostilled as per the Hague Convention of 5.10.1961, as ratified by Law 1497/1984 (GG A, 188).

5. Requests may be submitted by the Holders of Marketing Authorisation (MAHs) relating to pharmaceutical products or by pharmaceutical companies which are subject to the automatic clawback procedure in respect of pharmaceutical expenditures of E.O.P.Y.Y. and hospital pharmaceutical expenditures, irrespective of their legal form, in accordance with Article 1 hereof.

6. The physical and financial scope of R&D Projects and Investment Plans shall be

established and certified by the Certification Committees to be set up by decision of the General Secretary for Research and Technology. The Certification Committees shall operate outside the regular business hours and their members may be remunerated through funds of the Public Investment Programme or other resources outside the regular budget. The above Committees shall consist of three members, including essentially one expert from the field of the evaluated proposal, selected from the Register of Evaluators/Certifiers of the General Secretary for Research and Technology, in respect of the physical scope of R&D projects / Investment Plans, or by two members of the staff of the General Secretariat for Research and Technology or Experts selected from the Register of Evaluators/Certifiers of the General Secretary for Research and Technology, in respect of the financial scope of R&D projects / Investment plans.

7. The above Committees may carry out on-sight verifications of the physical and financial scope at the Beneficiaries' premises.

8. The Expenditure Certification Committees shall complete their tasks by submitting a Physical and Financial Scope Certification Report to the Service to be approved by the General Secretary for Research and Technology.

9. Once the above process is completed, the General Secretary for Research and Technology shall issue relevant certificates and shall forward them to the Beneficiaries and to the competent Tax Authorities, the Ministry of Health and EOPYY. Once the clawback form is received by EOPPY and/or the Ministry of Health, the Beneficiaries shall file within ten (10) days the GSRT Certificate to EOPYY and/or to the Directorate of Financial Services, Ministry of Health, depending on the type of expenditures (hospital or non-hospital expenditures) they intend to offset.

Given that beneficiaries can offset clawback expenditures both with EOPYY and with the Ministry of Health, the GSRT Certificate which is filed to EOPYY or to the Ministry of Health will essentially include a solemn declaration by the beneficiary stating the rate of the amount certified in the GSRT certificate which the beneficiary wishes to offset with each of the two organisations. As regards EOPYY in particular, both the non-hospital and hospital expenditures of EOPYY shall be essentially stated. As regards hospital clawback expenditures, once the ten (10)-day deadline lapses, the General Directorate of the Ministry of Health will readjust the clawback amount imposed on each beneficiary per hospital. Accordingly, the competent EOPYY departments shall readjust the clawback amount to the extent they are empowered to do so.

Once the relevant solemn declaration is filed to the Ministry of Health and EOPYY, it is no longer subject to readjustment with respect to the amounts which will be offset by the beneficiary vis-à-vis the corresponding recipient of the declaration (Ministry of Health or EOPYY). Beneficiaries are liable to declare, as part of their solemn declarations which are addressed to the Ministry of Health or EOPYY, respectively, the amount to be offset against each organisation, so that the competent Financial Departments can establish the consistency of the set-off declarations with the total amounts which are offset (against both organisations) compared to the GSRT certificate. If the aggregate amount stated in the declarations filed to EOPYY and to the Ministry of Health is lesser than the total amount indicated in the GSRT certificate, then the Ministry of Health and EOPYY shall immediately demand an amendment to the set-off declaration through partial withdrawal of the initial declaration, within a reasonable deadline to be set to that effect.

10. Beneficiaries are responsible for stating thoroughly and accurately the information which is included in their request for classification of expenditures as R&D expenditures or Investment Plan expenditures. In case any inaccuracy is identified in the information included in the request, the Service shall revoke the relevant certificate and shall impose any applicable penal or administrative sanctions. The revocation of the certificate shall be notified

to the Ministry of Health and to EOPYY, which may either readjust the clawback amount in its entirety at the expense of the beneficiary (in case the set-off certificate is fully revoked) or may readjust it by allocating *pro rata* the reduction in the amounts to be offset compared to the amounts indicated in the initial solemn declarations that were filed by the beneficiary.

Article 6
Deadlines

1. Requests shall be filed to the General Secretariat for Research and Technology of the Ministry of Development and Investments after the end of the tax year, strictly within the first quarter of the following year. The requests shall be assessed within one month from lapse of the deadline for submission, provided that the Certification Committees referred to in Article 5 hereof have been set up. If the relevant Committees have not been set up, the requests shall be assessed within one month from the date the decisions setting up the Committees are published in the Government Gazette.

2. In case the Committees request clarifications from the Beneficiaries who have submitted requests, the deadline for completion of the assessment shall be extended by fifteen (15) business days after the Beneficiaries have provided the requested clarifications. If the clarifications submitted by the Beneficiaries are considered to be inadequate, an on-site certification procedure shall be scheduled to take place no later than one month after the clarifications were provided by the Beneficiaries. A Certificate of Eligibility (or a Rejection Decision) shall then be issued within fifteen (15) business days.

Article 7
Date of Effect

The provisions hereof shall apply to expenditures of R&D Projects and Investment Plans incurred during the second half of tax year 2019 onwards.

This decision is to be published in the Government Gazette.

Athens, 17 January 2020

THE MINISTERS OF

HEALTH	**DEVELOPMENT AND INVESTMENTS**
Vasileios Kikilias	**Spyridon – Adonis Georgiadis**

THE DEPUTY MINISTER OF FINANCE

Theodoros Skylakakis