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Offsetting pharmaceutical expenditure clawback with R&D and investment expenses for FY2020

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Article 20 of Law 4633/2019 (A' 161/16.10.019), as defined by joint ministerial decision B1 B2/84482 (B' 5863/31.12.2020)

A joint ministerial decision issued by the Greek government on 31 December 2020 sets out the circumstances in which a pharmaceutical expenditure clawback may be offset with research and development (R&D) expenses and investment expenses for the development of products, services, or production lines).

Under the clawback rules—which are designed to control public spending on drugs— pharmaceutical companies are required to return funds to the Greek government when public spending on drugs exceeds the amount the government budgeted for this expense.

A 2019 law allows marketing authorization holders (MAHs) for pharmaceuticals or pharmaceutical companies to offset their pharmaceutical expenditure clawback (article 20 of Law 4633/2019, adding a provision to Law 4052/2012 article 11 paragraph 1). The offsets may be made with: (a) a percentage of R&D expenses, including clinical trial expenditure that are directly related to specific targeting and reasonable R&D activities; or (b) a percentage of expenditure related to investment plans for the development of products, services, or production lines.

The 31 December joint ministerial decision sets out the procedure, specific terms and conditions, and general information needed to implement the 2019 law, as well as the maximum expenditure that may be offset for fiscal year 2020.

Beneficiaries

The beneficiaries of the law include MAHs or their local representatives in Greece, and pharmaceutical companies with mandatory clawback payments.

Conditions

The following conditions must be met to qualify for participation in the clawback offset process:

- MAHs and pharmaceutical companies must have a tax clearance certificate and a social security clearance certificate;
- Clawback payments and past rebate amounts (other institutionalized discounts that private providers give to the Greek government) for years through 31 December of the year prior to the reference year must be settled in accordance with applicable rules (Law 3918/2011 (A '31) article 35 paragraph 3); and
- As from 2020, rebates should be paid in a timely manner.

The reference year is the year for which an application for a pharmaceutical expenditure clawback offset is submitted.

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Activities eligible for the offset

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Pharmaceutical R&D activities:

- Laboratory R&D pharmaceuticals formulations (preformulation studies, formatting, analytical methods, etc.), R&D of raw materials for drug production, as well as methods of analysis and development of research application software.
- Phases 1, 2 and 3 of clinical trials necessary to complete the product approval documentation (efficacy, safety, pharmacokinetics/pharmacodynamics, bioequivalence, stability, etc.). These clinical trials are eligible provided that they are carried out in Greece by a body that has the necessary certification and infrastructure as required by law, unless the know-how and the production of the formulation that will be evaluated through the clinical trial have been developed and produced in Greece and there is no corresponding certified entity to implement the clinical trial.
- Test batch production and production process evaluation with a sufficient number and volume of batches on a pilot production scale.
- R&D in the field of new technologies ultimately used to seek ways to improve human health, such as digital technology, artificial intelligence and big data analysis, network and data security, product quality control, processes and services, software development, computer programming and information systems support, and storage and management of files and information.
- Feasibility studies, management of research projects, and regular monitoring and supervising of clinical trials conducted within the country and abroad.

02

Activities related to investment plans for the development of products, services, or production lines:

- Installing new or modernizing existing facilities to improve the quality of the products produced.
- Improving existing production processes and/or increasing the capacity of the production process.

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Eligible expenditure for R&D activities

According to the joint ministerial decision, eligible R&D expenditure categories are limited to the following (further limitations apply to each category):

- Remuneration for salaried staff;
- External personnel fees;
- Consultant/subcontractor fees;
- Building expenditure (purchase, construction, extension or repair, renovation);
- Purchase or leasing costs for mechanical equipment, laboratory infrastructure instruments, semi-industrial (demonstration) testing facilities, and other technical equipment (this may include any additional equipment transportation and installation costs, as well as user training costs);
- Intangible assets purchase costs (know-how, approval fees and patent fees for projects under development and production formulations for R&D projects submitted for clawback offsetting as from 2019, scientific packages/computer programs, specialized software licenses);
- Consumable purchases; and
- Clinical trial costs (payments to hospitals, doctors, and clinical research organizations; drugs; materials; travel expenses; payroll expenses; clinical trial fees; insurance expenses).

Eligible expenditure for investment activities

According to the joint ministerial decision, the eligible expenditure categories for activities related to investment plans for development of products, services, or production lines are limited to the following (further limitations apply to each category):

- Building expenditure (purchase, construction, extension of buildings, special, ancillary facilities and landscaping);
- Purchase or leasing costs for new or used machinery not older than 10 years from the manufacturing date and other equipment, technical installations, and means of transport (this may include any additional equipment transportation and installation costs, as well as user training costs);
- Expenses for special and mechanical installations;
- Intangible assets purchase costs;
- Modernization and maintenance costs for existing buildings, mechanical installations, and production equipment; and
- Remuneration for salaried staff.

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Non-eligible costs

The following do not qualify as eligible expenditure for R&D and investment activities and are excluded:

- Remuneration for shareholders, CEOs, members or president of a board of directors, business partners, company administrators, general managers, or business owners. In addition, remuneration paid to individuals who hold any of the above positions in related enterprises, and remuneration paid to individuals who held any of the above positions within the two fiscal years preceding the year in which the costs were incurred, are excluded.
- Expenses related to severance payments, bonuses, and fringe benefits.

Total amount of offsetting expenditure for 2020

The total amount of FY2020 expenditure that may be offset in 2021 may not exceed EUR 100 million. The amount will be based on a percentage of two groups of expenditure categories, as follows:

- No greater than 50% of the total offset amount from Group 1, which includes R&D costs; and
- No greater than 50% of the total offset amount from Group 2, which includes investment plan expenditure.

If the total approved expenditure exceeds the above thresholds, the offset will be applied proportionately and the excess costs may be used for financing by a national, EU, or international body.

Eligible R&D expenditure that will not be offset can be included under the provisions of article 46 of Law 4712/2020 for the reference year (which provides up to 200% R&D super deduction), following the application of the beneficiary, in accordance with the provisions thereof.

If one of the two categories of expenditure does not absorb all the amount budgeted for it while the other exceeds it, then the surplus will be allocated to the other category.

Other requirements

To qualify for the offsetting program, entities must meet the following requirements:

- They must maintain a separate ledger in their accounting records for the offsetting expenditure; and
- They must fulfill the following obligations for a period of five years after completion of the investment (in cases of financial leasing, this period is extended for as many additional years as the lease agreement lasts):
    - Comply with the terms of the joint ministerial decision;
    - Not cease the operation of the enterprise;
    - Not interrupt the productive activity of the investment;
    - Acquire ownership of the leased equipment upon termination of the relevant leasing agreement;

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Other requirements

- They must fulfill the following obligations for a period of five years after completion of the investment (in cases of financial leasing, this period is extended for as many additional years as the lease agreement lasts):
    - Not transfer, for any reason, fixed assets that have been offset based on the joint ministerial decision, unless they are replaced by other fixed assets owned by the entity and of similar value and that correspond to the productive operation of the company; and
    - Not change the use of the property that is included in the joint ministerial decision.

Eligibility audit procedure - Deadlines

Requests must be submitted to General Secretariat of Research and Technology (GSRT) of the Ministry of Development and Investment after the end of the tax year and no later than within the first quarter of the following year.

The GSRT is expected to complete its audit 45 days after the submission deadline.

The GSRT's certification committees may request clarifications from the beneficiaries, which must be provided within 15 days of the request. Within this period, on-site audits may be carried out if this is deemed necessary.

The documentation and verification of the offsetting costs require the filing of the R&D and/or investment plan documentation, which should include the following:

- A report describing the physical subject matter and financial aspects of the R&D and/or investment plan activities;
- An audit report on the certification of the expenditure by a certified auditor-accountant or audit company (registered in the Public Register of article 14 of Law 4449/2017), with professional liability insurance covering at least EUR 1 million per event and a total of at least EUR 5 million per year (if the R&D projects are co-financed by a subsidiary or parent company or by affiliated companies, the audit report must concern the beneficiary submitting the application and the affiliated companies);
- For investment plans only, an implementation certificate issued by a civil engineer, and if required by the type of investment plan, an implementation certificate issued by a mechanical engineer or other competent professional;
- Board minutes in the case of an SA or a Decision of the Managers in the case of a Ltd., OE, or EE, with the following information:
    - The scope and objectives of the R&D project or investment plan being executed;
    - The execution schedule;
    - The composition of the project team;
    - The budget by expenditure category and the total budget of the R&D project or investment plan; and
    - A table with an expenditure breakdown;
- Copies of expenditure documentation by category that has been audited by a certified auditor-accountant or audit firm; and
- An expenditure breakdown in an excel file by R&D project and/or investment plan for each expense category.

Upon completion of the eligibility audit, the GSRT will issue the certificate of eligibility (or rejection finding). Following the GSRT's certificate, the procedure for offsetting the eligible amount may then be followed.

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