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Offsetting pharmaceutical expenditure clawbacks with R&D and investment expenses

Article 20 of Law 4633/2019 (A' 161/16.10.019), as defined by

A Joint Ministerial Decision issued by the Greek government on 24 January 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

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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) with certain expenses. The offsets may be made with: (a) a percentage of R&D expenses, including clinical trial expenditure that are directly related to specific targeted 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 24 January 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 2019.

Beneficiaries

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

Conditions

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

- MAHs and pharmaceutical companies must have both 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) due must be settled in accordance with applicable rules (Law 3918/2011 (A '31) article 35 paragraph 3); and
- As from 2020, rebates must be paid in a timely manner.

Activities eligible for the offset

1) Pharmaceutical R&D activities: The processes necessary to bring a new pharmaceutical drug to market (in compliance with EU regulations and national law), including:

- Laboratory R&D pharmaceutical formulations (pre-formulation 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 dossier (efficacy, safety, pharmacokinetics/pharmacodynamics, bioequivalence, stability, etc.). Such clinical trials must be carried out in accordance with the procedure established by Greek law;
- Test batch production and production process evaluation with a sufficient number and volume of batches on a pilot production scale; and
- R&D in the field of new technologies ultimately used to pursue 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.

2) Activities related to investment plans for the development of products, services, or production lines: These activities may include:

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

Eligible expenditure for R&D activities

According to the GSRT announcement, eligible R&D expenditure categories are limited to the following (further limitations

and conditions apply in each category):

- Remuneration of salaried staff;
- External personnel fees;
- Consultant/subcontractor fees;
- Building expenditure (purchase, construction, extension or repair, renovation);
- Purchase costs for mechanical equipment, such as laboratory infrastructure instruments;
- Purchase costs for intangible assets (scientific packages/computer programs, specialized software licenses);
- Consumable purchases; and
- Clinical trial costs.

Eligible expenditure for investment activities

Based on the GSRT announcement, the eligible expenditure categories for activities related to investment plans for the development of products, services, or production lines are limited to the following (further limitations and conditions apply in each category):

- Building expenditure;
- Machinery purchases or leasing costs;
- Expenses for special and mechanical installations; and
- Intangible assets purchase costs.

Non-eligible costs

The following do not qualify as eligible expenditure and are excluded from the offset:

- 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 2019

The total amount of 2019 expenditure that may be offset in 2020 may not exceed EUR 50 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 excess costs may be used for financing by a national, European, or international body. If one of the two categories of expenditure does not absorb all the amount budgeted for it while the other exceeds it, the surplus will be allocated to the other category.

Other requirements

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

- An application may not have been submitted for the certification of R&D activities for projects that are co-financed by any other national, EU member state, or international body; and
- They must maintain a separate ledger in their accounting records for the offsetting expenditure.

Eligibility audit procedure - Deadlines

Requests must be submitted to the 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 secretariat is expected to complete its audit one month after the submission deadline, provided certification committees are established by GSRT in due course.

If the committees request clarification from the beneficiaries, the deadline for the completion of the audit will be postponed by 15 business days following the submission of clarification by the beneficiaries. If the committee is of the opinion that the clarification is insufficient, an on-site audit will be performed no later than one month

after the clarification has been submitted.

According to the 27 February GSRT announcement, the documentation and verification of the offsetting costs require the filing of the R&D and/or investment plan documentation, which must 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;
- For investment plans, 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, that contain the following information:
    a. Scope and objectives of the R&D project or investment plan being executed;
    b. Execution schedule;
    c. Composition of the project team;
    d. Budget by expenditure category and the total budget of the R&D project or investment plan; and
    e. Table with expenditure breakdown.
- Copies of expenditure documentation by category that has been audited by a certified auditor-accountant or audit firm; and
- 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) within 15 business days. At that stage, the procedure for offsetting the eligible amount may be followed.

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