

Tax - Breaking News

February 2020



Consistent with our commitment to keep you updated on the most significant tax developments, we outline below the most important changes set out in the Joint Ministerial Decision for the offsetting of clawback amounts against expenses related to R&D and Investment projects:

- The recently issued Joint Ministerial Decision sets the terms and conditions as well as the procedure for the offsetting of clawback payable to the Greek National Health Service Organization («GNHSO») and Hospitals, against research and development (R&D) expenses, as well as expenses pertaining to Investment Projects for the development of products, services or production lines incurred by pharmaceutical companies.

Beneficiaries

- Holders of Marketing Authorizations for Medicinal Products, their local representatives in Greece, as well as any pharmaceutical company that is subject to payment of clawback amounts to GNHSO and Hospitals.

Amounts to be offset

- For 2019, the total amount of expenses that can be offset by the Beneficiaries against clawback amounts to be paid to GNHSO and Hospitals, cannot exceed EUR 50 million.
- This amount will be allocated on a percentage basis between **R&D Projects** and **Investment Projects**; amounts however to be allocated to each category cannot exceed 50% of the above mentioned total amount that can be offset, i.e. EUR 25 million for each category. If the amount allocated to one category has been fully absorbed, any excessive amount of expenses belonging to this category can be transferred to be covered by the other category.
- The total amount of expenses that can be offset is expected to increase to EUR 100 million for the year 2020.

Eligible expenses

- The activities that qualify as **R&D Projects**, include any action necessary for the marketing of a pharmaceutical product. Indicatively, R&D activities include:

- laboratory R&D of pharmaceutical nature, R&D on the raw materials for the medicine production,
 - testing of stages 1, 2 and 3 that are necessary for the preparation of the product's approval file,
 - production of trial products and evaluation of the process on a pilot scale with sufficient size and number of trial products
 - research and development in the field of new technologies (digital technology, artificial intelligence, etc.) aiming towards the improvement of human health.
- Expenses related to **R&D Projects** considered as eligible, under conditions, indicatively include:
 - expenses for the purchase, construction, expansion, repairing, maintenance, renovation of buildings and purchase or leasing of machinery,
 - expenses for the acquisition of intangible assets, licences for the use of specialized scientific software programs,
 - payroll cost of employees of any level engaged in the implementation of the R&D project, and
 - cost for outsourcing/subcontracting to third parties or other bodies (private laboratories, public research centers and laboratories, universities etc.) the implementation of a specific and explicitly defined part of the research project.
 - As an **Investment Project** related to the development of products, services or production is considered any activity aiming to the establishment of new facilities or the modernization of the existing ones, aiming to improve the quality of the products and of the existing production methods and/or to increase the dynamics of the production procedures.

- Expenses related to **Investment Projects** considered eligible, under conditions, indicatively include:
 - expenses for the purchase, construction of buildings, auxiliary facilities, as well as expenses for the purchase or leasing of modern new or used machinery,
 - expenses for the acquisition of intangible assets to be used for the transfer of technology, purchase of intellectual property rights, exploitation licenses, patents, know how and not patented technical knowledge.
- Especially for 2019, eligible expenses are considered those effected as of 1 July 2019 assuming the relevant contracts have been signed as of 1 January 2019.

Procedure for clawback offsetting

- R&D Projects and Investment Projects must be self-funded, while the Beneficiary should record the eligible expenses in a special account and also maintain the relevant decisions and documentation files that were submitted to the competent authorities.
- Moreover, the expenses eligible for offsetting should be documented. In particular such expenses, should be certified by a certified auditor –accountant or entity, whereas the Beneficiary must submit a documentation file to the General Secretariat for Research and Technology (GSRT). Said documentation file should be accompanied by the necessary supporting documents, as these are defined by the Ministerial Decision.
- Claims for clawback offsetting and certification of **R&D Projects** and **Investment Projects** are assessed by special Certification Committees of the General Secretariat for Research and Technology (GSRT).
- Following completion of the assessment procedure and drafting of the relevant reports by the Certification Committees (for the approval or rejection of the claim), the General Secretary of Research and Technology (GSRT) issues certificates, which are then forwarded to the Beneficiaries and notified to the competent authorities.
- The Beneficiaries must file the relevant certificate issued by (GSRT) with the competent authorities within ten (10) days from its day of issuance.
- After the above deadline, the General Directorate of the Ministry of Health and the competent departments of GNHSO adjust (offset) the clawback amount that was initially imposed to each beneficiary.

Deadlines

- Beneficiaries should submit the above-mentioned documentation file and relevant supporting documentation to the GSRT within four (4) months after the end of the relevant tax year.
- The assessment of the aforementioned claims by the Certification Committees is completed within one (1) month from their submission (however, in

case further information/clarifications are requested, a two-month extension may be provided).

At KPMG we have the experience and expertise to assess and advise based on the specific circumstances of your case.

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This Newsletter aims to provide the reader with general information on the above-mentioned matters. No action should be taken without first obtaining professional advice specifically relating to the factual circumstances of each case.

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