Joint Ministerial Decision for offsetting R&D and investment projects related expenses with clawback published

The Joint Decision by the Ministers of health, development and investments and finance was published on 24 January 2020. This Decision (JMD) stipulates the procedure and the prerequisites for the offsetting of clawback by the Greek National Health Service Organisation with a proportion of research and development (R&D) and expenses pertaining to investment projects related to the development of products or services or production lines.

What is the total amount of expenses to be offset?

The total amount for tax year 2019, which will be evenly distributed between the two mentioned categories, will be capped at EUR 50,000,000.

Said amount is expected to increase to EUR 100,000,000 as of tax year 2020 onwards.

Who can be beneficiaries?

Holders of marketing authorisations of medicines for human use or their local representatives in Greece or, in general, any pharmaceutical companies subject to payments of clawback and pharmaceutical spending by hospitals, can be beneficiaries of said incentive.

However, the abovementioned beneficiaries must be cleared in terms of their tax and social security contributions payments. In addition, they need to have settled any due clawback, pharmaceutical spending and rebate payments of prior years, as well as make timely rebate payments as of 2020 onwards.

Furthermore, any covered R&D or investment projects must be self-financed i.e. not being either partially or totally financed by any national, European or international body.

Which are the eligible expenses per covered activity?

The covered - under restrictions - **R&D activities** (category 1) are, among others, the following:

- laboratory R&D of pharmaceutical nature, R&D on raw materials for medicine production
- methods of analysis and development of research application software
- stage 1, 2 and 3 trials

The covered - under restrictions pertaining to percentage and exemptions - expenses related to the abovementioned R&D activities, are, among others, the following:

- purchasing / construction of buildings and purchasing or leasing of machinery
- payroll of staff of any level during the implementation period of the R&D project
- subcontracting for the implementation of part of the research project
The covered - under restrictions - activities pertaining to investment projects related to the development of products or services or production lines (category 2) are briefly the following:

- building of new or modernization of existing facilities
- improvement of existing production procedures
- increasing of production capacity

The covered - under restrictions pertaining to percentage and exemptions - expenses related to the abovementioned activities, are, among others, the following:

- purchasing or building of premises / auxiliary sites and landscaping of the surrounding space
- purchasing or leasing of new or used machinery
- transfer of technology, purchasing of intellectual property rights, operating licenses, patents, know-how and unpatented technical knowledge

Beneficiaries must maintain a specific account in their accounting records, in which any offset expenses need to be monitored.

The abovementioned apply to R&D and investment projects related expenses incurred within the second half of tax year 2019 onwards.

However, the reference at another point of the JMD that eligible expenses will be those for which contracts were signed as of 1 January 2019 onwards, raises concerns.

Which is the opt-in procedure?

Following the attestation of the relevant expenses firstly by a certified auditor or an auditing company and secondly by special Certification Committees, the Secretary-General of Research and Technology (S.G.R.T.) issues relevant certificates, which are notified to the competent authorities. Subsequently, the beneficiaries, within 10 days from receiving the clawback determination document, submit the S.G.R.T. certificate to the competent body, depending on the type of clawback (non-hospital or hospital) they expect to offset.

Which are the deadlines?

Opt-in requests are submitted to the S.G.R.T. within the first four months after the tax year ends. Their review is completed within a month after the filing deadline lapses or the Certification Committees are composed, with the possibility to extend the completion deadline for one more month, if required.

What actions should the beneficiaries take?

In view of the abovementioned, the beneficiaries of said incentive should consider:

- tracing the amounts which are eligible for the offsetting
- setting up their accounting records for the monitoring of said amounts
- preparing the required documentation including all appropriate supporting documents

It is important to note that each individual case needs to be examined based on its own merits, and that the above-mentioned general principles might not necessarily capture all possible eventualities. Our expert advisors are in a position to advise you on the implications arising from a Greek perspective in relation to your specific case.