



HollandBIO - position on GBER and State Aid

Innovative companies thrive in an ecosystem in which capital for R&D is available and a regulatory framework that supports and stimulates innovation. Biotech companies are almost by definition R&D intensive and HollandBIO, the Dutch biotech industry association, represents over 200 of them. Especially in times of crisis, like is the case now with COVID-19, the European Union plays a crucial role in making sure that innovative startups and scaleups survive and flourish afterwards. Only in that way, they can fulfil their true potential and contribute to societal challenges like health and sustainability. Due to the fact that specific characteristics of R&D and capital intensive industries are not accounted for in the State Aid and GBER regulation these industries cannot benefit from emergency measures. HollandBIO therefore proposes to amend the criterion of “undertaking difficulty” and to look at the applicability of the rules regarding state aid.

In the past years, it has become clear that the European regulation around State Aid and the GBER, and more specifically the definition to categorize a company as an ‘undertaking in difficulty’, has led to a patchwork of different interpretations in Member States. Unfortunately most choose to exclude highly innovative companies and strategic sectors as biotechnology for R&D aid, with enormous consequences.

Interpretation of the “undertaking in difficulty” criterion

Ever since it was enacted, the “undertaking in difficulty” criterion has led to confusion in Member States on how it should be interpreted and to what extent innovative, R&D intensive companies and sectors that have long development horizons should be eligible to receive R&D aid by governments. Most of the time, the interpretation has been on the strict side leading to not provide state aid.

This situation primarily affects innovative, R&D and capital intensive companies, such as biotech companies, that develop products or solutions that require long development periods until they reach the market. They have a business model in which they accumulate losses for several years and do not usually generate sufficient income until their projects are brought to the market which can take 10 to 12 years.

The impact of the “undertaking in difficulty” criterion in the biotech sector

The current criterion of an ‘undertaking in difficulty’ and the way it has been interpreted in Member States, has led to a situation in which biotech startups and scaleups are often labelled as companies that are close to dissolution or bankruptcy whereas they are in fact, *fully viable, both technically and economically solvent companies* with ambitious, impactful projects. This ‘one size fits all’ definition of an ‘undertaking in difficulty’ has a big negative impact on startups and scaleups all over Europe as they are often automatically excluded from the calls for application for public aid. That is even now the case with several financial support measures in Member States during the COVID-19 outbreak, while it is life sciences companies that are essential in providing a solution in the shape of a vaccine or treatment.

The EU State Aid framework, and particularly the GBER, is acting as a major obstacle and is even counterproductive when it comes to achieving EU overall goals of R&D policies and incentives. This regulation is disastrous when it comes to access that companies have to instruments that support and promote R&D in an early phase, although companies in this stage need these instruments the most because of their R&D intensity and size. This reality has also been identified in the Study on the Practical Impact of R&D State Rules.¹

Recommendations for improvement

HollandBIO would like to put forward several recommendations that could address shortfalls in the current legal framework.

1. Our recommendation is that R&D-intensive companies should be exempted from the exclusion stipulated by the GBER. Companies that are R&D and capital intensive because of the underlying technology they use and the business model that is in place, show losses repeatedly. However, the current 'undertaking in difficulty' criterion does not reflect the technical or economic solvency of this type of company, meaning that aid for R&D projects to these companies should not conflict with the State Aid and GBER rules.
2. An alternative could be to change the 'undertaking in difficulty' criterion so that it does not negatively impact R&D-intensive companies with long maturation processes. Several alternatives could be considered, and some of them could even be implemented simultaneously:
 - a. Equity loans and similar instruments should be considered as net assets and therefore as a balancing element that could offset the accumulated losses for the purpose of defining an 'undertaking in difficulty'.
 - b. Similar to what occurs in cases of dissolution or bankruptcy, the base of calculation should be share capital, thus excluding the share premium.
 - c. In order to ensure that the definition includes companies with long maturation periods, the current exception for companies less than 3 years old could be changed, as in the framework of aid for risk financing, to 7 years starting from the first commercial sale. In this way, the definition would not be applied to companies whose business model consists in developing a product over a long period of time until they start to generate income from sales.

¹ European Commission, Directorate-General for Competition (2019). *Study on the practical impact of RDI State aid rules, Fact-finding inventory in selected Member States. Final report*. See also via: https://ec.europa.eu/competition/publications/reports/kd_01_9_584_en.pdf

HollandBIO is the Dutch biotech industry association. We represent and connect more than 200 life sciences companies in the Netherlands. Together we work towards our ideal future: a society in which innovations based on biotechnology contribute to health, sustainability and prosperity. In order to ensure that biotech innovations become quickly and widely available, HollandBIO removes the hurdles that get in the way of the ambitions of biotech frontrunners. We stand for progress, even when that means that we have to challenge the status quo.

