AseBio position on the impact of the regulation of State aid in R&D:
The application of the "undertaking in difficulty" definition

Dear Sir or Madam,

AMADIX, by means of this document, would like to support the AseBio position on the impact of the regulation of State aid in R&D regarding to the application of the "undertaking in difficulty" definition that results currently applicable in the application of R&D aids according with the current legal framework.

Fostering innovation depends on investment in R&D, yet it is also essential to have a regulatory system that helps innovative companies. For innovative companies, and especially for biotechnology, a key sector in this health emergency caused by COVID-19, it is essential to have both **access to financing** and a **regulatory environment** that understands the particularities of a long innovation cycle which generates disruptive solutions often far from the market.

Within this context, in the past five years the Spanish Bioindustry Association, AseBio, has worked to spotlight how European regulations around State aid are damaging our innovative ecosystem, especially the definition of an "undertaking in difficulty" included in the General Block Exemption Regulation, which is making highly innovative companies in such strategic sectors as biotechnology ineligible for aid in R&D.

State aid and the General Block Exemption Regulation (GBER)

The current framework of State aid was approved in 2014. This package of rules includes, among others, the General Block Exemption Regulation (GBER), the de minimis rule, directives on State regional aid and the framework of State R&D aid.

The GBER establishes the framework in which State aid is considered compatible with the Treaty on the Functioning of the European Union and therefore defines what aid from the Member States does not need to be first notified and approved by the Commission. Article 1 (section 4) states that its provisions, and therefore compatible aid, will not be applicable to aid to "undertakings in difficulty", and it defines this category.

Ever since it was enacted, the "undertaking in difficulty" criterion has been applied in an increasing number of calls for aid applications in R&D in Spain and has made companies working in disruptive innovations ineligible. The interpretation of the criterion has changed over time, but an increasingly restrictive definition for companies has gained ground.
This has primarily affected intensive R&D investing companies developing innovative solutions that require long development periods until reaching the market. Companies with this type of business model accumulate losses for several years, are essentially financed with capital and government grants, and do not usually generate sufficient income until their projects are brought to successful market launch, a period which can take 10 to 12 years. One clear example of this are biotech companies, which is one of the sectors that has been hit the

hardest by the application of this definition, which is used in many national calls for applications.

The impact of the "undertaking in difficulty" criterion in the biotech sector

The definition of undertaking in difficulty in the GBER states the older than 3 years which have lost more than half of their subscribed share capital as a result of accumulated losses should be considered undertakings in difficulty. The explicit definition of subscribed share capital states that it should include, when applicable, the share premium.

Soon after the GBER, the Commission issued a Communication on Guidelines on State aid for rescuing and restructuring non-financial undertakings in difficulty (2014/C 249/01) where it established that an undertaking is considered to be in difficulty when, without intervention by the State, it will almost certainly be condemned to going out of business in the short or medium term. Thereby the regulatory framework turned this definition into financial ratios, with huge impact on national innovation ecosystem.

Based on this definition, one interpretation of the GBER has gained ground in which those companies that burn half of their share capital plus the share premium shall be considered undertakings in difficulty. This interpretation has been supported by the Directorate General for Competition via the European Union's tools to advise the Member States. Likewise, Spain has consolidated this interpretation through successive regulations of the calls for aid applications and the rules of the agencies that manage R&D aid.

Biotech companies are characterized by their high intensity of investment in R&D, long maturation periods of their projects and their technological risk profile. Because of this, this type of companies are typically financed with their own resources such as capital or hybrid instruments and subsidies, while bank loans tend to be minimal.

As a consequence of their business model based on R&D and the development of innovative products and services with long maturation periods, and therefore the absence of significant sales during this period, it is common for biotech companies to accumulate losses repeatedly for several years. These losses may at times consume half their share capital + share premium, and therefore, they may be considered undertakings in difficulty.

However, these are companies that totally comply with the business and corporate laws and are not in any way subjected to dissolution cases or bankruptcy proceedings. In fact, they **are fully viable, both technically and economically solvent companies** with ambitious, impactful projects.
Additionally, the definition ignores that the Spanish Commercial Law considers share premiums as an unrestricted reserve, to which the company has access, and thus differs from subscribed share capital.
Despite this, these companies are automatically excluded from the calls for application for public aid.

Since the regulation entered into force and was implemented in Spain by the different financing agencies via national regulations, the biotech sector has suffered from differences in the application of this criterion, which has gradually become standardized and more stringent. In consequence, **more and more biotech companies are being excluded from R&D support programs**. One recent example of this is the first decision by the general director of CDTI on *aid within the framework of the extraordinary call for aid applications for R&D and investment projects to deal with the health emergency declared over the COVID-19 disease*,

in which 50% of the applications were rejected because they were considered undertakings in difficulty.

The effect of this regulation is to gradually discourage the ecosystem of Spanish biotech companies **from applying to national calls for applications**, since the effort needed to prepare a proposal for a competitive call for applications is significant, and given the certain risk of exclusion, they have simply ceased to apply. While 77 biotech companies applied in *the Agencia Estatal de Investiagación's* 2017 *Retos-Colaboración*, only 37 did in 2019 (52% fewer). Furthermore, this is **hindering public-private R&D partnerships**, as well as partnerships between large and small companies, since the inclusion of a company affected by this definition could lead the proposal to be rejected. Therefore, this has prompted mistrust towards innovative SME's, which makes the other stakeholders reluctant to jointly submit proposals with any SME that could be considered an undertaking in difficulty.

Therefore, the framework of State aid in the EU, and particularly the GBER, is acting as a major obstacle to achieving the overall goals of R&D policies and incentives. This regulation is stopping the instruments that support and promote R&D from reaching the companies that need them the most because of their R&D intensity and size. This reality has been identified in the Study on the Practical Impact of R&D State Rules.[1]

AseBio's proposals

AseBio believes that the current legal framework should be changed to reverse its pernicious effects on companies' access to domestic public financing in Europe. In this sense, it is urgent for the GBER and its provisions to be revised according to the following principles:

1. Companies that are R&D-intensive because of their business models show losses repeatedly, and the undertaking in difficulty criterion does not reflect their solvency, meaning that the aid conferred on the R&D projects conducted by these companies does not conflict with the bailout and restructuring framework of undertakings in difficulty. Likewise, no factors that could distort competition would arise by granting aid to R&D projects in R&D-intensive companies in that this definition does not match their technical or economic solvency. Accordingly, R&D-intensive companies should be exempted from the exclusion stipulated by the GBER.

2. The definition of the undertaking in difficulty criterion could be changed to make it less harmful to R&D-intensive companies with long maturation processes. In this sense, 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 purposes of defining undertaking in difficulty.
    b. Similar to what occurs in the cases of dissolution or bankruptcy, the base of calculation should be share capital, thus excluding the share premium. In Spanish law, the share premium is fully available and is not part of the company's share capital. Therefore, the accumulated losses will be charged to reserves and the share premium (as the fully available reserve that it is), and once they have been fully burned down, the consumption of social capital would be calculated by the remaining accumulated losses, and this remaining social capital would have to be

[1] EUROPEAN COMMISSION. 2019. Directorate-General for Competition. *Study on the practical impact of RDI State aid rules, Fact-finding inventory in selected Member States. Final report*.

more than 50% of subscribed share capital not to be considered an undertaking in difficulty.

c. In order to ensure that the definition includes companies with long maturation periods, the exception for companies less than 3 years old could be changed to define longer periods, as in the framework of aid for risk financing, of 7 years starting from the first commercial sale. This way, the definition would not be applied to companies whose business model consists in developing a product over long periods of time until they begin to generate income from sales.

About AMADIX

Founded in 2010, Amadix is a leading molecular diagnostics company focused on liquid biopsy, developing innovative diagnostic tests for early cancer detection in blood. The mission of the company is extending people´s lives, developing disruptive technologies to detect the tumor years in advance, before the symptoms appear to win the battle against cancer.

The company's products are oriented to non-invasive early cancer detection, avoiding the complications of existing invasive procedures, as tumor biopsies. ColoFast, the most advanced product is an innovative blood-based test for colorectal cancer (CRC) diagnosis based on a unique combination of cutting-edge biomarkers (micro-RNAs and proteins). It is indicated to screen healthy population 50 to 85 years old, for early detection of the tumour and premalignant lesions. ColoFast is expected to be commercialized in 2021. The Company's test pipeline includes two blood-based tests for early detection of lung and pancreatic cancer

Sincerely,

Signed:

Date: Valladolid, July 3rd, 2020
Name: Rocio Arroyo
Position: CEO
Organization: Advanced Marker Discovery, S.L. (AMADIX)