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BSP Position Paper: Draft Amendment to the Guidelines on Regional State Aid (RAG)

Business & Science Poland

This position paper is submitted on behalf of Business & Science Poland (BSP) in response to the European Commission's public consultation on a draft amendment to the Guidelines on regional State aid, which entered into force in 2022. It addresses the Commission's identified areas of concern with concrete simplification proposals drawn from industry experience.

Background

The amendment to the Guidelines on regional State aid in relation to the regional aid maps for the period 2028–2034 is an important step in preparing the framework that will determine the geographical availability and intensity of regional investment aid after 2027. Business & Science Poland (BSP) welcomes the Commission's work to update the regional aid maps for the next programming period and to reflect new territorial challenges, including those affecting the Union's eastern border regions. At the same time, in our view, the draft still requires further refinement in several important areas so that its final shape more fully reflects the needs of undertakings carrying out investments of strategic importance for competitiveness, transformation and the resilience of the European economy. In light of the above, we set out below our comments on the draft and proposals for amendments aimed at better aligning the regional State aid framework with the challenges of strategic resilience, industrial transformation and territorial cohesion.

Detailed Recommendations

Strategic investments and the resilience of supply chains

Regional aid rules should adequately reflect the specific characteristics of strategic investments whose importance extends beyond the economic development of the region in which they are located, including investments strengthening the resilience of critical supply chains and supporting large-scale industrial transformation, including in the e-mobility and pharmaceutical sectors, where long investment cycles and high capital intensity mean that changes in regional aid status or aid intensity can materially affect investment conditions.

In our view, the proposed amendments to the Guidelines (or other documents governing the rules for the granting of state aid) should also take into account the strategic importance of the pharmaceutical sector, in particular investments in the production of active pharmaceutical ingredients, finished medicinal products and infrastructure enhancing the resilience of supply chains for critical medicinal products.

We therefore request that the rules governing the granting of state aid take into account the particular importance of investments that fulfil the objectives of the Critical Medicines Act and strengthen the European Union's medicine supply security. When determining permitted aid intensities, account should be taken of locations where the pharmaceutical sector's expertise, infrastructure and production capacity—which are essential for the resilience of the EU's supply chains—are concentrated. At the same time, the rules on the granting of state aid should remain consistent with any sector-specific support instruments for projects relating to critical medicines, so that regional solutions do not constitute an unintended barrier to the achievement of the EU's strategic objectives.

Significance of projects that expand, modernise or diversify the sector's manufacturing capacity extends beyond the interests of the region in which they are carried out. These investments strengthen security of supply, reduce dependence on third countries, improve crisis preparedness and support the European Union's strategic autonomy in the field of critical medicines. In their case, Regional Investment Aid, with its geographical restrictions – which are replicated in the current proposal for the Guidelines – does not address the strategic challenges facing investors in this sector.

These geographical limitations should also be considered in conjunction with the GBER. As regional investment aid under the GBER remains linked to the regional aid map, changes to the Guidelines and the maps alone may not fully address the situation of strategic investments located outside assisted areas. Consideration should be given to introducing into the GBER a sector-specific derogation from the regional aid map for investments in the production of active pharmaceutical ingredients (APIs) and critical medicines. Under the current rules, investment support is unavailable in certain more developed regions of the EU, notwithstanding the fact that a significant share of existing pharmaceutical manufacturing capacity is located precisely in those regions. This concerns, inter alia, capital regions such as Warsaw, Budapest, Prague, Ljubljana and Bucharest. In practice, this limits the possibility of carrying out investments of strategic importance for medicinal security and the economic resilience of the European Union. Introducing a sector-specific derogation for investments in APIs and critical medicines would make it possible to better align the GBER with the objectives of rebuilding European manufacturing capacities and reducing dependencies on supplies from outside the EU.

Impact of regional aid maps on strategic investments

Traditional rules on regional state aid may, in practice, limit the ability to achieve these objectives of rebuilding European manufacturing capacities and reducing dependencies on supplies from outside the EU. A significant proportion of existing pharmaceutical infrastructure, research and development facilities, technological expertise and highly skilled personnel is located in more developed regions, particularly in large urban centres and their conurbations. This is not an exceptional situation, but a typical feature of the European pharmaceutical sector, where production, technological development and scientific facilities are often concentrated near major academic, clinical and industrial centres.

In Poland, this risk currently concerns, above all, the Warsaw Capital Region and nine neighbouring counties, which, even in the current programming period, operate under conditions of very limited access to regional investment aid and, in light of the proposed changes, may in practice remain outside the actual perimeter of support. This is particularly significant because this region is home to entities of great importance to national and European pharmaceutical potential, including, amongst others, Polfa Tarchomin, Polpharma Biologics, Biomed – Serum and Vaccine Manufacturing Plant, Adamed and Bioton. These are companies possessing the expertise, infrastructure and experience essential for the production, development or increased availability of medicinal products, including those of significance for pharmaceutical safety in Poland and the European Union. Without these changes, these entities may be deprived of any real opportunity to benefit from public support for investments which, from the perspective of pharmaceutical safety policy, should be treated as strategic.

The proposed changes may have a much wider impact than just on the Warsaw region. Although most Polish regions may continue to qualify for aid as ‘A’ regions, in many cases a reduction in the permitted aid intensities is to be expected. This applies, amongst others, to parts of the provinces of Eastern Poland, including Świętokrzyskie, Podkarpackie and Podlaskie, as well as the provinces of Mazovia, Łódź and Lesser Poland. A reduction in aid intensity may significantly diminish the attractiveness of implementing new manufacturing projects and expanding existing plants, even though these regions are of real importance to the pharmaceutical sector. For example, in the Podkarpackie Voivodeship, Sanofi operates in Rzeszów; in the Łódzkie Voivodeship, companies such as Aflofarm in Pabianice and Takeda in Łyszkowice, whilst Adamed operates in Pabianice and Ksawerów; in the Małopolskie Voivodeship, significant production assets of Teva and Valeant/Bausch Health are located. The Mazowieckie Voivodeship, too, regardless of the exclusions concerning the Warsaw Capital Region and selected neighbouring counties, remains a natural area for the development of

pharmaceutical investments due to the availability of personnel, logistical infrastructure, links with the Warsaw conurbation and the existing production and research ecosystem.

The Silesian, Greater Poland and Lower Silesian provinces also belong to a particularly vulnerable category, as the proposed rules could lead to a significant deterioration in the conditions for accessing regional investment aid in these areas. The Silesian Voivodeship may lose its 'A' region status and be reclassified as a 'C' area, whilst in the case of the Greater Poland and Lower Silesian provinces, geographical restrictions similar to the current model applied to the Warsaw Capital Region may be introduced.

The implications of the proposed changes are, however, not limited to the pharmaceutical sector. The proposed reclassification of the Silesian Voivodeship is of particular concern from the perspective of large-scale industrial investments, such as in the field of e-mobility or pharmaceuticals, carried out in a region undergoing a long-term economic and energy transformation. A reduction in the maximum aid intensity may weaken the investment attractiveness of the region precisely at a time when substantial new investment is required to create new industrial capacity and replace activities linked to the traditional economic structure of the region. Against this background, particular attention should be paid to the proposed change in the status of the Silesian Voivodeship from an 'a' area to a 'c' area and the resulting potential reduction in the maximum aid intensity. In the case of a region undergoing significant industrial and energy transformation, the regional aid framework should provide adequate conditions for the implementation of large-scale industrial investments, including investments in the e-mobility sector.

This challenge should also be considered in the context of the ongoing revision of the GBER and the broader framework for supporting the transformation of regions historically reliant on fossil fuels. In its position on the draft GBER published for consultation earlier in 2026, BSP highlighted that the draft continues to address just transition primarily through the lens of training aid and does not establish broader mechanisms linking support for workers with investment aid for transformation projects implemented in regions historically reliant on fossil fuels. In practice, the effective transformation of such areas requires a more integrated approach, encompassing in parallel industrial investment, workforce reskilling, and support for local communities and economies.

As for RAG, the application of traditional regional criteria alone may lead to a situation in which projects that are crucial to the resilience of European supply chains do not receive adequate support. In pharmaceuticals, the introduction of specific measures for projects supporting pharmaceutical security should not be treated as a derogation that undermines the logic of cohesion policy, but rather as a complement to it, adding a dimension of strategic resilience. The guidelines focus on regional development and

territorial cohesion, but also allow for other positive effects of investment to be taken into account, in particular where a project supports additional objectives of European Union policy. In the case of pharmaceutical projects, such an effect stems from their impact on the stability of supply across the EU, the reduction of production concentration outside Europe, the diversification of supply chains, the improvement of the capacity to respond to shortages, and the enhancement of Member States' health security.

Consistency with the GBER and regional transformation

The draft GBER, in Article 14(b), excludes from the scope of regional aid investments in the energy sector, including generation, storage, transmission, distribution and energy infrastructure. Maintaining the exclusion of energy investments from regional aid limits the possibility of supporting projects related to infrastructure modernisation, the deployment of low-carbon technologies and the strengthening of energy security. Such an approach is also difficult to reconcile with the principle of territorial cohesion and with the objectives of the Green Deal and decarbonisation strategies. This issue should be considered in parallel with the present revision of the regional aid maps in order to ensure consistency between the Guidelines and the GBER. In particular, changes to the geographical availability and intensity of regional aid should not be accompanied by sectoral rules that unnecessarily prevent regional support for investments contributing to industrial transformation, decarbonisation and energy security.

Policy change

If the current direction of the amendments to the Guidelines is maintained, and certain areas with significant potential remain outside the realistic scope of support or receive support of insufficient intensity, it will be necessary to create an additional mechanism enabling the financing of projects that are strategic for the EU's pharmaceutical security. We therefore propose that consideration be given to establishing a separate aid category, in accordance with the GBER, for projects supporting the European Union's pharmaceutical security.

At the same time, the revision should take account of the impact that changes in regional classification may have on the ability to support large-scale industrial investments. In particular, the proposed reclassification of the Silesian Voivodeship from an "a" area to a "c" area could reduce the maximum aid intensity available for major investments.

In pharmaceuticals, a solution could be to introduce, alongside the traditional rules on regional investment aid, a separate basis for granting aid to projects pursuing the objectives of the Critical Medicines Act, covering in particular investments in the production of critical medicines, active substances, intermediates, finished medicinal products and the infrastructure necessary to ensure supply chain resilience. Such an aid

scheme could function as a horizontal instrument, independent of the restrictions arising from regional aid maps, whilst maintaining objective criteria for assessing a project's strategic importance for the EU's medicine security. In this way, State aid rules could enable such projects to be effectively supported even when they are carried out in more developed regions. The criteria for strategic importance could include, in particular:

- the project's link to an EU or national list of critical medicines; its impact on increasing or maintaining production capacity for APIs, intermediates or FDFs in the EU;
- a reduction in dependence on individual suppliers, third countries or supply chain bottlenecks;
- the ability to rapidly ramp up, increase or redirect production in the event of shortages, a health crisis or geopolitical disruptions;
- the project's significance for the diversification of supply sources for the EU market;
- the use of existing pharmaceutical infrastructure and expertise in the EU; as well as the beneficiary's commitments regarding the maintenance of production capacity, ensuring product availability for the EU market, or prioritising supplies to the EU during periods of supply strain.

A solution designed in this way would not represent a departure from cohesion objectives, but rather their adaptation to new economic and geopolitical circumstances, in which the security of the supply has become one of the prerequisites for the resilience of the entire European Union.

Conclusion

The design of the 2028–2034 regional aid maps should avoid creating abrupt reductions in investment support in regions undergoing structural transformation and should remain coherent with other State aid instruments supporting strategic resilience, industrial transformation and the objectives of the just transition. At the same time, the regional aid framework should take into account the strategic importance of investments in sectors such as e-mobility and pharmaceuticals, where investment decisions can contribute to industrial transformation and security of supply that strengthen European production capacities and furnish to the overarching goal of competitive Europe.

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Business & Science Poland (BSP) combines the experience of leading Polish enterprises with the EU agenda. We represent the knowledge and interests of Polish companies employing over 180,000 people in Poland, the EU, and globally. Our goal is to support the EU Single Market in line with the need for its responsible and effective transformation. This opinion presents the position of BSP members representing the digital, financial, air transport, fertiliser, chemical, mining, refining, fuel and energy sectors.