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Introduction.

The proposed Regulation, while based on solid objectives and being, generally speaking, in line with the relevant state aid Regulations (the General Block Exemption Regulation (GBER) and the *De Minimis* Regulation), contains a number of issues that can, and should be improved in relation to the granting and administration of the proposed subsidy scheme. It also contains a violation of EU internal market law, which in turn jeopardises the very compatibility of the proposed subsidy with the internal market. Further, its favouritism towards domestic operators as well as its lack of analysis of regulatory developments in the EU has the potential to undermine the effectiveness of the proposed Regulation.

Comments.

First, in relation to the structure and content of the subsidy scheme itself, there is a need for clearer and more detailed definitions. The whole concept of the "implementation start", combined with the slightly different rules applicable to it throughout the proposed Regulation (see, e.g., Article 11(6)(b) and (c)) ought to be further elaborated and clarified, and should be cross-referenced with the concepts of process and organisational innovations, as outlined in Article 2(96) and (97) GBER. Basing it solely on the *De Minimis* Regulation, especially in the context of the new *De Minimis* package coming into force in 2024 which increases the amount of aid deemed to be *de minimis* (making it, in certain cases such as SGEIs, equal to the maximum allowed subsidy under the proposed scheme) in effect almost makes the rest of the proposed Regulation redundant, and subject to awards of subsidies based on wide discretion. This is reinforced by the fact that the requirements of Article 3.3 of the Framework Regulation on subsidies for OCW, SZW and VWS referenced in Article 9(5) of the proposed Regulation do not add substance to the requirement in the latter Article, and implementation starts are omitted from Article 11(5). Further, Articles 11(6) (b) and (c) of the proposed Regulation are also problematic in this context, as they seem to provide for wider rules for implementation starts than for other grants. Similarly, the fact that a subsidy for an implementation start is open to an individual provider, per Article 5(c) can also create issues. In a similar context, more clarity should be provided in relation to organisational and process innovations, especially in relation to the clear exclusion the GBER provides in their definition.

Per Article 5(a) of the proposed Regulation, the subsidy can be granted to a "cluster organisation", which per Article 1 is the "owner" of an innovation cluster. As the GBER definition (Article 2(92)) is used for an innovation cluster the concept of an "owner" of "structures or organised groups of independent parties" is a very odd phrase. This is especially true given Article 11(3) of the proposed Regulation, as an innovation cluster is defined to consist of "at least a supplier and a buyer". While "owner" is the terminology employed by the GBER in Article 27, there is no need for it to be a specific legal entity. Further, this distinction between owner and operator should be clearer in the agreement at the core of an innovation cluster, as said distinction also leads to differences in the type of activity that can be subsidised under the GBER and thus the proposed Regulation. In this context, specifically in relation to innovation clusters, but also more generally in relation to the proposed Regulation as a whole, a core question that is not clearly answered in this regulation is what exactly can be subsidised, which is further elaborated below.

A further major issue relates to the notion of a “proven innovation”, per Article 11(1)(a) of the proposed Regulation. Beyond the fact that as a definition it lacks content and substance, simply referring to an as of yet non-existent list on RVO, it also is problematic in the context of the subsidy being awarded. In this context, first, the concept of a “proven innovation” ought to be given a definition based on objective standards, and a range on the TRL scale. Second, if the innovation is proven (which, absent definition or clarification in effect means TRL=9) it makes the award of investment aid under Article 27(5) GBER rather difficult (“construction or upgrade of the innovation cluster”), leaving only operating aid, which under Article 27(8) GBER is rather limited and limiting. For instance, a literal reading of the proposed Regulation would mean that the design of a solution cannot be financed, despite that being perfectly in line with its objectives per Article 3. This issue links to the preceding point regarding the need for a clearer definition of and distinction between the owner and operator of a cluster.

Another element which requires clarification and further elaboration is that of the IP rights resulting from the creation of and investment in an innovation cluster. Despite the provisions of Article 5 of the Framework Regulation on subsidies for OCW, SZW and VWS, and specifically Articles 5(8) and 5(9), it is not clear who the IPR resulting from the innovation cluster, or the process or organisational innovation(s) would belong to. The relevant Articles of the Framework Regulation on subsidies for OCW, SZW and VWS only provide basic guidance – and the proposed Regulation provides no further guidance. Similarly, no guidance is offered on the licensing of IPR, the types of rights a purchaser should benefit from, or the allocation of IPR (and thus of fees related to them) amongst participants of the cluster.

The preceding point also relates to the definitional issues stemming from the notion of an innovation cluster. Beyond the fact that that definition is narrow, thusly also narrowing the field of application of the proposed subsidy scheme, it also seemingly clashes with the definition of “traditional” or typical innovation hubs. It is submitted that the definition of an innovation cluster ought to be expanded upon, so that the basic structure of the contractual agreement giving rise to such a cluster, and the allocation of obligations and rights it should provide for within the confines of Dutch and EU law, can be clarified. This will add much needed clarity to the core question of who the recipient of the aid is – clarity that is needed not just for formalistic reasons, but also to ensure correct accounting of the aid, compliance with the Framework Regulation on subsidies for OCW, SZW and VWS, compliance with the GBER, and the correct allocation of funds.

A final point, which relates, to differing degrees, to most of the previous points raised. For instance, if a vendor creates a cluster with providers/purchasers A, B, and C there is seemingly nothing in the language of the proposed Regulation which restricts the vendors ability to create another cluster with providers/purchasers X, Y, and Z. Article 11(6) relates to specific activities, and without further definitional guidance on, *e.g.*, the content and form of the cluster agreement, the allocation of IPR, or as to what exactly can be subsidised and who benefits from said subsidy, the activities of the two theoretical clusters above are not the same. This of course would circumvent the limits placed on the subsidy to be granted by the proposed Regulation itself.

In brief, in relation to the design of the overall subsidy scheme envisaged in the proposed Regulation, there are several lacunae. Those relate to key questions, such as (a) what can be subsidised; (b) who can benefit from those subsidies and how those subsidies should be allocated amongst the cluster; (c) the content of the cluster agreement in relation to rights and obligations, including but not limited to IPR; (d) lack of coherence in relation to implementation starts; (e) much needed clarification on what is meant by "proven innovation" and how that affects (a) above; (f) the lack of, per Article 5(2) of the Framework Regulation on subsidies for OCW, SZW and VWS, clear, controllable, and efficient administration of the subsidy; (g) the possibility of the provision of the same solution through various clusters by the same vendor.

Given the objectives of the proposed Regulation, it is unclear why pure innovation aid is not supported. It is also unclear why an administrative support mechanism, both for vendors and purchasers, has not been envisaged in the Regulation. Such an assistance mechanism could facilitate the creation of clusters in an optimised manner, ensure the wider participation of SMEs, and could lead to the wider adoption of organisational and process innovations within providers (within the meaning of the proposed Regulation). The proposed Regulation, in its current form, could thus, due, *inter alia*, to the concerns outlined above, lead to sub-optimal solutions and outcomes in relation to the its stated objectives.

Further, the conditions for refusal of the subsidy, as outlined in Article 11 of the proposed Regulation and as expanded upon in the Appendix of the same, can be deemed problematic from the perspective of EU free movement law, and, as a result, also from that of EU state aid law. This is because, per Article 11(1) of the proposed Regulation, the processes must either be included in an RVO overview of "proven innovations", or have to have been deployed in the Netherlands. Those two criteria, while not directly discriminatory on the basis of nationality, seem to entail indirect discrimination, as they make the exercise of the freedom to provide and to receive services (Article 56 TFEU) more difficult and onerous for undertakings not based in the Netherlands. Such indirect discrimination, or even a non-discriminatory restriction which discourages the free movement of services, is within the scope of the Treaties, and thus *prima facie* prohibited (*e.g.* Case C-76/90 *Säger*). Exceptions to this exist, per Article 62 TFEU, and one of those relates to public health (which would most likely not be applicable here, as the restriction does not relate *stricto sensu* to public health), which could be the justification applied here. However, since Article 62 TFEU is a derogation from Treaty rule, it must be interpreted strictly, and be subject to a proportionality analysis (which is also a general principle of EU law, see *e.g.* Case T-306/00 *Conserve Italia v Commission*, para127). Any other justification based on mandatory requirements would be subject to such an analysis. That analysis must examine the suitability and necessity of the restriction to achieve the desired end, and whether the restriction is excessive in relation to the objective sought to be achieved. Given the objectives of the proposed Regulation, as outlined in Article 3, and the *jurisprudence constante* of the CJEU, it is unlikely that the restriction could be argued to be proportionate, and thus justified. This conclusion is reinforced by the first-come-first-served approach of Article 8 of the proposed Regulation (which, given the onerous Article 11(1) requirements affords undertakings already active in the Netherlands a significant advantage), and by the technical specifications relating to Article 11(1) in the Appendix, as *mutatis mutandis*, if Article 11(1) can be used to circumvent the "Criteria Gebruikte toepassingen", then such technical criteria should be sufficient to circumvent the Article 11(1) restriction.

An unjustified violation of Article 56 TFEU would obviously be a violation of EU law; making it relevant for the compatibility of the subsidies outlined in the proposed Regulation. This is

because all aid granted in the EU is subject to the principle of legality – it cannot violate any provision of EU law (other than Article 107(1)TFEU), or produce a result contrary to the Treaties (see, *e.g.*, Case C-156/98 *Germany v Commission*, para 78; Case C-204/97 *Portugal v Commission*, para 41). As aid is always discriminatory, the CJEU has developed a severability approach to this general principle of compatibility. This means that if the legally problematic element of the aid scheme can be severed from the aid based on the aid's objective, modalities, and financing, then it must be severed for the subsidy scheme to be compatible with the internal market, while if it is indissolubly linked to the objectives, modalities, and financing of the aid then the aid as a whole must, as a matter of law, be deemed incompatible with the internal market (see, *e.g.*, Case C-225/91 *Matra SA v Commission*, paras 41-43; Case C-156/98 *Commission v Germany*, para 78, Case 74/76 *Iannelli & Volpi*, para 14). Thus, in relation to the proposed Regulation, the preferential treatment afforded to undertakings based in the Netherlands is such as to render the entirety of the subsidy scheme provided by said Regulation *contra legem* and thus incompatible with the internal market.

That restriction in Article 11(1) of the proposed Regulation should, as a result of the preceding, be removed, as it does not serve the objectives of the Regulation, and jeopardises its very legality in the context of directly effective and directly applicable EU law. Beyond the issues surrounding its legality, it is also practically undesirable, as it favours national/regional operators, to the detriment of open and fair competition in the EU single market.

Conclusion.

In summary, the proposed Regulation contains practical problems, outlined in the first half of this analysis, and suffers from fundamental legal issues, as outlined in the second half. On top of that, the overall structure and content of the proposed Regulation do not necessarily seem to follow from its clearly stated objectives. The manner in which subsidies are to be granted is in other words needlessly restrictive, both in terms of its structure, and in terms of its inherent favouritism towards domestic operators.

Last but not least, the proposed scheme could also lead to sub-optimal solutions, since it favours national and/or regional and/or organizational scale-up implementations by Dutch suppliers/service providers whereby it is unclear if and how these implementations are aligned with regulatory and/or technical developments on EU level on integrated care. It is recommended to analyse the regulatory and technical developments on EU level and map these with the foreseen implementation before granting any subsidy. A similar analysis is recommended for the foreseen national regulatory implementations by the Ministry in the health sector (*e.g.* Wet DIAZ). Due to the lack of any referral to (and any analysis of) any regulatory developments on national and European level in the health care sector in the proposed Regulation, the proposed Regulation could also lead to the risk of divestment of any subsidy granted on the mid- to long term.

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