**EFPIA RESPONSE TO THE PUBLIC CONSULTATION ON THE REVISION TO THE HORIZONTAL BLOCK EXEMPTIONS & GUIDELINES**

**26 April 2022**

# 1. Introduction

1. EFPIA welcomes this opportunity to comment on the review of the competition rules applicable to horizontal cooperation agreements. EFPIA limits its comments to the R&D block exemption Regulation and to the new proposed guidelines on bidding consortia.
2. EFPIA agrees with the Commission's view that the rules are not fully adapted to the modern economy and that, in places, the provisions are overly rigid and complex. Rather than layering more rules and nuances on top of an already unwieldy structure, EFPIA urges the Commission to take advantage of the current review to fundamentally rethink the approach.
3. The revised rules on R&D collaboration should have as their explicit goal the encouragement of more R&D collaboration and a more conducive environment for innovation in Europe. The current rules and the Commission's proposals fall far short of that aspiration. Before commenting specifically on the draft texts, EFPIA considers it useful to share some statistics on the importance of R&D for the pharmaceutical industry.
4. According to [Global Trends in R&D - IQVIA](https://www.iqvia.com/insights/the-iqvia-institute/reports/global-trends-in-r-and-d) (May 2021), R&D spend by the top 15 pharmaceutical companies by sales reached a staggering USD 123 billion in 2020, and exceeded 20% of sales for the first time - a more than 40% increase over a period of five years. Venture capital flows into early-stage companies increased 50% in 2020 compared to 2019, another all-time high. There are approximately 9,000 products in the pipeline, an expansion of more than 40% since 2015. The number of first-time global launches of novel active substances was a record high of 66 in 2020, 40% of which were originated and launched by emerging biopharma companies. Despite these record numbers, the reality is that the U.S. remains a much more attractive market for pharmaceutical R&D collaboration (above 40% share of total investment) and Europe is losing out.

* The U.S. share of global early-stage R&D has remained stable over the past 15 years.
* Europe’s share has declined from 33% to 22% over the past five years, while the absolute number of active programs declined by 175 — from 1,604 to 1,429.
* Products from China-headquartered companies now represent 12% of the early-stage pipeline, up from 2% a decade ago.

1. There are multiple reasons for these trends as the IQVIA report explains, but that does not detract from the fact that clear and simple competition guidelines that encourage collaborative R&D efforts have a role to play in promoting the EU as an R&D investment-friendly destination.

# 2. The Proposed Changes Further Limit the Scope of the R&D Block Exemption

1. The Commission is proposing to further restrict the already limited scope of the R&D block exemption with the addition of a new threshold that would exclude agreements from the safe harbour where the parties compete on innovation and where fewer than three competing R&D efforts would remain in addition to and comparable with those of the parties to the R&D agreement.
2. Competing R&D efforts encompasses the notions of "competition in innovation" and "R&D poles". (Innovation competition refers to R&D efforts for new products/technologies that create their own new market. R&D poles refer to R&D efforts directed primarily towards a specific aim or objective arising out of the R&D agreement that cannot yet be defined as a product or technology.)
3. It is far from clear why this change is necessary. Innovation for new products or in basic research that is pre-product should surely be incentivised. There is a strong argument that collaborative research in innovation/R&D poles should fall outside the scope of Article 101 altogether.
4. But the draft guidelines warn that "innovation may be restricted even by a pure R&D agreement", merely acknowledging that this is unlikely where there are competing R&D efforts (§88).
5. This underlying scepticism about joint R&D efforts is a fundamental fault line. The exercise becomes highly theoretical: a long list of potential hypothetical harms, and a short pro forma acknowledgment that R&D agreements can lead to efficiency gains. This balance urgently needs to be reversed.
6. The new "3+1 rule" assumes some dampening of competition that would otherwise occur. Is the concern that, absent competing R&D efforts, we would be better off if the parties came to market themselves or found alternative collaborators with no overlapping R&D efforts? The guidelines shed little light on the nature of the perceived underlying competition problem beyond a statement that the 3+1 rule provides assurances "that the parties will likely not be able to profitably maintain innovation below competitive levels for a longer period of time" (§79). This is too vague a justification.
7. Two paragraphs of the proposed guidelines hint at possible hypothetical "killer"-type theories of harm in justification of the 3+1 rule:

* *Parties may slow down the development of a replacement product/technology if they have market power and are the only ones engaged in R&D for the replacement (§82).* This theoretical concern ignores the market forces that will ordinarily encourage new market entry if there is profit to be gained from introducing a new product to replace or compete with an existing one.
* *Two or more companies engaged in R&D for a new product could restrict competition by cooperating instead of developing their new products separately (§87).* This potential problem is not resolved by the 3+1 rule: either there are objective reasons why it is efficient for the parties to combine their R&D efforts, or they are engaging in cartel-type behaviour that merits enforcement action.

1. The 3+1 rule has three prongs (§147): (a) the R&D efforts should pursue substantially the same aim or objective; (b) the third parties should be "already engaged in the R&D efforts or able and likely to independently engage in such efforts"; and (c) the third parties should be independent from the parties to the R&D agreement.
2. Relevant to this assessment are factors such as the third parties' access to relevant financial and human resources, their IPRs, know-how, and other specialised assets or previous R&D efforts (§149). There are additional rules for assessing the comparability of competing R&D efforts (§151). These complex rules present many practical problems. The factors at §149 build in a bias against including competing R&D efforts involving SMEs (that have fewer resources). It cannot be assumed that the information on competing R&D efforts will be available with any degree of certainty. How is one to divine the intentions of an independent third party that is not engaged in competing R&D but that is "able and likely" to do so?
3. The problems are further compounded by the definition of "competitors in innovation" to include, inter alia, "an undertaking engaged in an R&D pole and an undertaking able and likely to independently engage (but not yet engaged) in an R&D pole pursuing substantially the same object" (§130(d)).[[1]](#footnote-1)
4. Why are we so concerned to ensure that competing R&D efforts impose a competitive constraint on the parties to any joint R&D agreement (§152)?
5. Hypothetically, if two competitors in innovation come together and make significant high risk investments that are ultimately successful in developing a miracle cure for Alzheimers faster than would otherwise have been the case, why should we be exercised about whether or not the block exemption applies? Even if there are no competing R&D efforts at a comparable stage when the collaboration begins, the result is to be celebrated - even if it confers monopoly pricing power on the parties for a period. The size of the prize will incentivise others to quickly catch up as was amply demonstrated by the recent covid vaccine race.
6. EFPIA calls on the Commission to radically rethink its proposed approach in the interests of encouraging, not killing, innovation incentives in Europe. Most companies attest to the unhelpfulness of the current regime. The proposed 3+1 rule will render the R&D block exemption even more redundant.

# 3. The Existing Rules Are Already Too Rigid and Should Be Loosened to Support More Dynamic Innovation in Europe

1. **Seven-year rules:** The complex seven-year duration rules tied to the 25% market share threshold are hang-overs from another era. They serve little practical purpose in the real world. The revised rules should take a more progressive approach by applying the safe harbour for as long as the R&D results are protected by IPRs, and indefinitely thereafter absent conduct that is blatantly exclusionary.
2. **Access to know-how and results:** The requirement that bodies carrying out R&D as a commercial service be entitled to pre-existing know-how and to the final results of the paid-for R&D for the purposes of further research has been a long-standing barrier to R&D collaboration in the EU compared to other jurisdictions that have less stringent competition rules and deeper capital markets that are a magnet for R&D investment. The EU's stricter competition rules compound its competitive disadvantage. These restrictions should be lifted to stimulate more collaborative high-risk innovation.
3. **The joint exploitation rule:** Another significant limitation to the usefulness of the existing R&D block exemption is the prohibition on the parties agreeing to limit output or sales and to fix prices unless they jointly exploit the R&D results via a joint team, organisation or undertaking, or jointly entrust such exploitation to a third party.

Especially in the pharmaceutical sector, it may be more efficient for parties to allocate territories in which they will market and/or co-promote the results of their joint R&D given the investment in specially qualified staff and local regulatory and medical knowledge required to market specific medicines with new biochemical characteristics and safety profiles in any given territory. In this scenario, international reference pricing means that there are objective reasons for the parties to be able to coordinate in order to obtain reimbursement list prices in markets that represent an optimal outcome for the parties and patients alike, regardless of the formalities of who actually distributes the products.

From a practical outcomes perspective, what is the difference between this scenario and the scenario where both parties appoint a third party (or set up a JV) but agree to instruct the third party (or JV) on volumes and prices? Companies and their advisors struggle to understand why such conduct is black listed in Europe but permissible in other advanced economies such as the U.S.

# 4. Withdrawal Procedure

1. The Commission has never yet withdrawn the benefit of a block exemption Regulation. If this power is deemed necessary, it should be restricted to scenarios that are evidently harmful to competition in the context in question.
2. The ability to withdraw the R&D block exemption should therefore be limited to the scenario where the parties do not exploit the results of the R&D without any objectively valid reason. The phrase "vis-à-vis third parties" should be deleted from this clause (Article 10(2)(c)) because it creates unnecessary uncertainty. If the joint or paid-for R&D improves an upstream process in the development or production of a product, such "internal" exploitation by one of the parties should suffice to merit block exemption coverage.
3. It is hard to imagine the circumstances in which an R&D agreement could substantially restrict the scope for third parties to carry out R&D activities in related fields (Article 10(2)(a)), or substantially restrict third party access to the market for the contract products/technologies (Article 10(2)(b)). The draft guidelines shed no light other than to suggest that foreclosure of third parties "may arise, in particular, when at least one party to the R&D agreement has the right to exclusive exploitation of the results of the R&D and at least one party has a significant degree of market power" (§68). This unhelpful statement is indicative of the overly cautious and suspicious approach to R&D collaboration that permeates the review.
4. Article 10 (2)(d) foresees withdrawal merely on the basis of the contract products/technologies not being subject to effective competition from rival products/technologies. This is difficult to understand. As already explained, if joint R&D results in a scientific breakthrough that for a time is unrivalled, what is the threat of block exemption withdrawal likely to achieve except creating ex ante uncertainty?

# 5. Bidding Consortia

1. The draft guidelines contain a new chapter on bidding consortia in the form of subcontracting agreements entered into by the official bidder, or consortia agreements where all members participate in the tender process, usually through a special purpose legal entity.
2. The guidelines mirror the Commission 2021 [Notice on tools to fight collusion](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC0318(01)&from=EN) which warns that:

* where two tenderers cross-subcontract to each other, this may be a potential indication of collusion since they will know each other's financial offer, but
* where just one tenderer subcontracts to another tenderer, there is no general presumption of collusion and it is for the parties to demonstrate the opposite.

1. The proposed horizontal guidelines provide additional colour summarised below.

* § 389 and 390 introduce the notion of "centre of gravity" meaning that different standards apply depending on whether joint production is involved (in which case price-fixing will not be viewed as a restriction by object but an effects analysis is required), whereas joint commercialisation agreements are looked at less favourably and price-fixing will be viewed as a "by object" restriction regardless of the parties' market power.
* §391 states that regardless of the legal qualification of the consortium, it will not restrict competition if it allows the members to participate in projects they could not do alone - either because their products/services are complementary or because neither has the scale to effectively bid individually. This is to be based on a "realistic" assessment in the context of the specific tender in question (§392). Where it is clear that the parties are not competitors, their joint bid falls outside of Article 101.
* Article 101 does apply where the parties have the ability to submit bids on parts of the contract where that is divided in lots because they will be assumed to be competitors even if each cannot compete for the whole tender. In these circumstances, an effects analysis of the efficiencies of a joint bid is to be made under Article 101(3). §393
* Where it is not possible to exclude that the parties could have competed individually, or if there are more parties to an agreement than necessary, the guidelines stipulate that the joint bid might be restrictive by object or by effect depending on the content of the agreement and its context. §394
* In any event, joint bidding by competitors can fulfil the criteria of Article 101(3) based on a concrete assessment of their position in the market, the competitive context, the nature of the efficiencies, and assuming that their collaboration enables them to submit an offer that is more competitive than the offers they could have submitted alone in terms of price/quality, and that efficiencies are at least partially passed on to consumers. § 397

1. EFPIA urges the Commission to adopt a more straightforward approach, recognising:

* that a consortium will only be viewed as a by object restriction if it is a disguised cartel between competitors (substantially eliminating competition for the tender in question) with few if any consortium-specific efficiencies, or if the consortium is a vehicle to facilitate anti-competitive collusion between members in relation to other contracts or other markets, and
* where an Article 101(3) effects analysis is required, the distinction between whether the "centre of gravity" is production or commercialisation should be abandoned. The one example of joint bidding included at §405 makes no reference to the relevance of this distinction. It only adds unnecessary complexity.

1. EFPIA commends the clarity of the [practical guidance](https://www.ccpc.ie/business/wp-content/uploads/sites/3/2017/02/Consortium-Bidding-Guide_0.pdf) that the Irish Competition Commission issued to assist SMEs in bidding consortia back in 2014. The approach is easy to understand could serve as a conceptual basis for revised EU guidance.

1. The text otherwise maintains the definition of "competitor" as an actual or potential competitor, with the only change being a proposal to drop from the definition of potential competitor the SNIP test (the likelihood of entry within 3 years in the event of a small but permanent increase in price). This minor technocratic change does not detract from the fact that the definition of potential competition remains very broad and creates considerable uncertainty as to the applicability of the block exemption. [↑](#footnote-ref-1)