European Federation of Pharmaceutical Industries and Associations

EFPIA Position Paper on Verticals Review

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Introduction

- The European Federation of Pharmaceutical Industries and Associations (***EFPIA***) welcomes the opportunity to respond to the European Commission consultation on the revision of the Vertical Block Exemption Regulation[1] (***VBER)*** and the Notice providing guidance on the assessment of vertical restraints[2] (***Vertical Guidelines***).
- Since the rules were adopted in 2010, the distribution landscape has changed radically and businesses are continuously adapting to new challenges including sustainability, supply-chain security, and the impact of the COVID-19 pandemic. Given the importance of ensuring adequate supplies of medicines and a high quality and reliability of service, vertical agreements are of particular importance in the pharmaceutical sector. EFPIA therefore welcomes the initiative to update the VBER and Vertical Guidelines.
- A revised verticals regime should be significantly more flexible to preserve the necessary incentives for research, development as well as improving access to medicines in all Member States at the appropriate price. In this context:
    - EFPIA supports the aim of clarifying and simplifying the rules in relation to exclusive distribution networks and active sales restrictions.
    - EFPIA calls upon the Commission to recognise that where intermediaries merely act as a logistics service provider or as "fulfilment service providers" without determining the commercial conditions of the agreement concerned (i.e., price and rebates, range or choice of end-customer), they are not acting as independent distributors even if they take title and/or risk to products. Such relationships should be exempted without the costs associated with agency arrangements.
    - EFPIA also welcomes the consideration to remove dual pricing based on the sales channel (online/offline) as a hard-core restriction. This recognises that differential pricing structures are compliant *(or can be compliant)* with competition law as established by the Spanish competition authority and courts in considering Spanish rules on pricing in the pharmaceutical sector. In order to improve patient access to medicines across the EU and particularly in markets least able to pay, regulated prices of medicines dispensed and reimbursed in a Member State should not impact the supplier's ability to set a free price outside applicable national pricing regulations.

[1] Commission Regulation (EU) No 330/2010 of 20 April 2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of vertical agreements and concerted practices OJ L 102, 23.4.2010, p. 1–7.
[2] Commission Guidelines on Vertical Restraints, OJ C 130, 19.05.2010, p. 1.

- The revised VBER and Vertical Guidelines should above all continue to acknowledge the essential pro-competitive nature and commercial reality of vertical relationships. They should provide business with clear, pragmatic and flexible rules allowing businesses to adjust to the ever-changing market reality without introducing unnecessary rigid and formalistic rules (such as classifying dual distribution as horizontal cooperation) when there is no negative effect on customers or consumers.
- The need for greater clarity and simplicity is important to ensure that distribution systems can rapidly evolve in an extremely dynamic and often volatile market environment, and to ensure that national competition authorities and courts apply a consistent approach so that suppliers are not saddled with the costs of divergent rules and enforcement risks.

Need for increased flexibility

- Vertical agreements ensure the effective allocation of resources and can contribute to a safe and secure supply chain: since they are inherently pro-competitive, a light touch regulatory regime should suffice.
- The block exemption should apply subject to an increased market share threshold of 40% that applies only to the supplier. Absent market power, very few vertical restraints threaten effective competition to an extent that would merit a complex self-assessment under detailed Vertical Guidelines.
- The supplier's freedom to choose the distribution system that is best-suited to meet its needs should be the starting point of the revised rules. Based on that principle, EFPIA supports the introduction of wider exceptions for active sales restrictions to cover at least the following instances:
    - A supplier should be able to oblige its exclusive distributor to pass on to its customers a requirement that they respect the same active sales restrictions as those applicable to the exclusive distributor;
    - Active sales restrictions should remain valid where a territory or customer group has been exclusively allocated to the supplier or to another distributor even where the supplier or the distributor does not actually make sales in that territory or to that customer group and has no concrete existing plans to do so (but might do in the future);
    - Shared exclusivity where a supplier appoints more than one exclusive distributor dedicated to a particular territory and/or customer group should be covered by the VBER for the same reason the supplier is currently allowed to sell alongside its exclusive distributor.
    - EFPIA welcomes the proposal to exempt non-compete obligations that are tacitly renewable or have an indefinite duration provided the parties can periodically terminate or renegotiate the agreement. This will reduce an unnecessary administrative burden and facilitate often material investments in longer term commercial relationships.

Intermediaries, fulfilment services and agency

- Many industries, including the pharmaceutical sector, increasingly use intermediaries who execute an agreement between the supplier and a particular customer that demands uniform terms (e.g. pharmacy chain or a hospital network), often as the result of material buyer power. The intermediaries essentially fulfil the logistics or back office functions of the supplier without

any involvement in the commercial negotiations and without bearing any costs in relation to the promotion of the products/ acquisition of customers.

- Under the current rules, such an arrangement can be viewed as two distinct agreements (supplier-intermediary and intermediary-customer), for example, from the moment that the intermediary takes title and/or risk over the products concerned (for tax or accounting purposes). This formalistic approach does not reflect the commercial reality that the intermediary merely performs logistics, warehousing or other back-office services on behalf of the supplier.
- Competition for these sales takes place at the level of the negotiations between the supplier and the end-customer, and not at the level of wholesaler/distributor and customer. The intermediary does not act as a genuine independent distributor but does also not qualify as an agent where the intermediary takes title and/or risk to the contracted goods.
- The revised rules should recognise that this type of arrangement does not adversely affect competition, without forcing suppliers to resort to artificial and economically sub-optimal distribution structures.
- In a similar vein, EFPIA submits that the approach outlined by the Commission in its recent Working Paper on "dual role" agents[3] is overly rigid. The introduction of a legal presumption that such arrangement does not fall outside the competition rules unless it can be established that the principal bears all the costs of market specific investments, including in relation to products sold outside the agency agreement, is unduly strict. In the pharmaceutical context, recourse to an agency type arrangement to ensure that very costly products destined for a small number of patients in certain markets actually get to the patient in question may be pro-competitive by avoiding shortages and ensuring security of supply.

Removal of dual pricing as a hard-core restriction in online/offline context

- The Commission's willingness to consider permitting dual pricing based on the online/offline sales channel confirms that differential pricing mechanisms are *(or can be)* compliant with competition law. This has been accepted as a matter of principle in relation to Spanish legislation and case law that recognises that the manufacturer's free price that applies to products not dispensed and reimbursed in Spain does not constitute unlawful dual pricing.
- Regulated prices of medicines that better reflect the ability to pay (purchasing power) without the threat of significant arbitrage of products to wealthier Member States will improve patient access to innovative medicines and reduce shortages in the less wealthy regions of the EU. Differential pricing is not a panacea, but one element of a broader response that is required to address the growing discrepancy in patient access and affordability that mirrors widening gaps in GDP, healthcare spend and the level of investment into health across EU Member States. It would allow increased access to medicines in low priced countries while preserving the necessary incentives for manufacturers to invest in innovation and better healthcare.

Dual distribution and its instrumental role in distribution systems

- The VBER rightly treats dual distribution (where the supplier also sells at the same level in the market as its distributors) as inherently a vertical rather than a horizontal relationship. This is undoubtedly the correct approach and there is no justification for any policy change. EFPIA

[3] See European Commission's working paper: *Distributors that also act as agents for certain products for the same supplier.*

concurs that the current approach should be expressly extended so that the same treatment applies to wholesalers/importers that in turn compete with their buyers at the retail level.

- Suppliers should retain maximum flexibility to use the distribution channel (direct or indirect) that best meets customer demand in a particular situation without being encumbered by their distribution agreements being qualified as horizontal cooperation. Any policy option that complicates the status quo (e.g., through the introduction of a lower or additional market share threshold) will create unnecessary complexity without addressing any genuine competition concerns. The loss of legal certainty and increased administrative and legal costs could lead to increased vertical integration for no clear reason.
- The essential characteristic of any such distribution agreement remains the vertical relationship that determines the conditions for the purchase or sale of the supplier's products without requiring a horizontal assessment. This holds true not only for the distribution agreement as such, but also for the information flows that are directly related to the operation of those agreements. A free flow of information on the quantities actually sold and volumes needed going forward is essential in planning production and securing adequate supplies to meet demand.