THE COMMISSION'S PAPER ON THE OBLIGATION OF CONTINUOUS SUPPLY OF MEDICINES AND ITS IMPACT ON PARALLEL EXPORTING ACTIVITIES IN THE EU: A PARADIGM SHIFT?

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I. INTRODUCTION

On May 25, 2018, the Commission held an *ad hoc* meeting with experts from Member States to discuss the problem of medicine shortages in the European Union ("EU"). The outcome of this meeting was a Paper by the Commission on how the obligation of continuous supply established in Directive 2001/83/EC can be used to tackle the problem of shortages of medicine at the national level.[2] In this paper, I discuss the key content of the obligation of continuous supply, in light of the Commission's Paper from May 2018, and outline the potentially far-reaching spill-over effects that the Commission's initiative might have in terms of parallel trade and relations between marketing authorization holders and their wholesale distributors.

II. PARALLEL TRADE OF PHARMACEUTICAL PRODUCTS AND EU COMPETITION LAW

Parallel trade of pharmaceutical products can be broadly described as the buying of medicine in a (lower-cost) Member State, and then reselling them in a different Member State at a higher price, thus taking advantage of the price difference between the two Member States. This price arbitrage is enabled by Member States' regulatory powers over the pharmaceutical sector, which sets it apart from most other traded goods industries.[3] As summarized by Advocate General Jacobs in *Syfait*, Member States often limit the prices payable for pharmaceutical products within their national territories with the aim of protecting social insurance budgets. Notwithstanding, some Member States are willing to let pharmaceutical products sell at a higher price than the one charged in other Member States, in what appears to be a recognition of the need to compensate pharmaceutical companies for their research and development (R&D) investments, which are not adequately remunerated by 'low-cost' Member States.[4]

The Commission has long considered restrictions to parallel trade of medicine to constitute a serious breach of the competition rules, an approach that is heavily influenced by internal market considerations.[5] In a nutshell, the Commission finds that: (i) the free movement of products could be frustrated should companies be allowed to erect artificial barriers along national borders; and that (ii) there is no evidence backing the industry's claim that price discrimination between different Member States is decisive for boosting R&D in the industry.[6]

2 European Commission, Directorate-General for Health and Food Safety, "Paper on the obligation of continuous supply to tackle the problem of shortages of medicines – Agreed by the Ad-hoc technical meeting under the Pharmaceutical Committee on shortages of medicines on 25 May 2018."

3 Opinion of Advocate General Jacobs in Case C-53/03, *Syfait*, para. 77.

4 *Ibid.* para. 78.

5 MEMO/08/567, Brussels, September 16, 2008, Antitrust: Commission welcomes Court decision on parallel trade in the pharmaceutical sector.

6 Nadia De Souza, Directorate-General for Competition, unit B-2, Competition in Pharmaceuticals: The Challenges Ahead Post AstraZeneca, Competition Policy Newsletter I, 39 (2007).

This view has been partially confirmed by the Court of Justice of the European Union ("CJEU") in *GSK*.[7] In this case, the MAH had notified the Commission of a dual pricing system to wholesale distributors under which prices charged for pharmaceutical products destined to parallel exports were higher than those. The Commission considered such dual pricing mechanism to restrict competition by object and effect and therefore refused to grant an exemption under Article 101(3) of the Treaty on the Functioning of the European Union ("TFEU"). GSK appealed against the Commission's refusal to grant an exemption, alleging an infringement of Article 101(3) TFEU. In its ruling, the General Court ("GC") upheld GSK's plea that the Commission had infringed Article 101(3) TFEU. According to the GC, the Commission had failed to take into consideration all the factual arguments and evidence submitted by GSK and to duly substantiate its conclusion that parallel trade did not result in efficiency losses for GSK, since it could not significantly alter its capacity to innovate and invest in R&D.[8] Moreover, the GC states that the financial benefits stemming from parallel trading accrue to the parallel trader rather than to the health care system or the patient.[9] For the GC, competition law is only concerned with the potential impact of parallel trade on the final consumer's welfare; thus, wealth transfers between marketing authorization holders and distributors are of no interest to competition law, if they fail to bring a significant added value for the final consumer.[10]

Following an appeal by the Commission against the GC's ruling, the CJEU ruled that an agreement intended to limit parallel trade should, in principle, be considered to be a restriction of competition by object even though it can, theoretically, benefit from an exemption pursuant to Article 101(3) TFEU, taking into consideration the nature and specific features of the sector.[11] However, the Court found that the GC had erred in law by demanding the Commission to prove that the agreement between GSK and its distributors is disadvantageous for final consumers, as a pre-condition for a finding of an object restriction.[12] Hence, the CJEU brushed aside the General Court's considerations that dual pricing systems limiting parallel trading should be assessed as restrictions by effect that mitigated or eliminated some of the inefficiencies of parallel trading, and that had a limited (or non-existent) impact on consumers' welfare.

The CJEU also had the opportunity to assess restrictions to parallel trading imposed by marketing authorization holders in light of Article 102 TFEU. In *Sot. Lélos kai Sia* the CJEU was asked whether a dominant company's refusal to meet orders sent by distributors, because the latter were involved in parallel trade, constituted an abuse of dominance or whether it could be justified on efficiency grounds. According to the Court, a dominant company's refusal to supply wholesalers with the purpose of impeding parallel trade constitutes an abuse of a dominant market position, unless justified by objective reasons. However, a Member State's intervention in fixing the prices for pharmaceuticals at the national level cannot, in itself, be regarded as constituting an objective justification for restricting parallel trade.[13] To reach this conclusion, the Court focused on parallel trade impact on importing countries, claiming that distributors are not the only ones benefiting from this practice. Because parallel trade opens up new alternative sources of supply for buyers in importing countries, it should also be regarded as welfare-enhancing for final consumers in such countries.[14] In the Court's view, such an increase in welfare for final consumers is the result of a downward price pressure created by parallel trade, which creates benefits for social health insurance funds and patients, who will pay a smaller proportion of the prices of pharmaceutical products.[15]

7 Joined cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P, *GSK*, para. 60.

8 Case T-168/01, *GSK*, para. 303.

9 *Ibid. GSK*, para. 135 (quoting the Commission's Communication COM(1998) 588 final of November 25, 1999 on the single market in pharmaceuticals, Recital 161).

10 *Ibid. GSK*, para. 273.

11 Joined cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P, *GSK*, paras. 102 and 103.

12 *Ibid. GSK*, para. 64.

13 *Ibid.* para. 67.

14 *Ibid.* para. 53.

15 *Ibid.* para. 56.

The CJEU assessment of parallel trade was, however, mitigated by two important aspects: First, the Court found that marketing authorization holders must be allowed to protect their own commercial interests when confronted with orders that are out of the ordinary in terms of quantity (a criterion that is to be assessed by the national courts). In fact, a market authorization holder cannot be put in a position where the only alternative at its disposal to limit parallel trade is to simply not supply lower price Member States.[16] Second, the Court adamantly recognized Member States' right to take appropriate and proportionate steps to resolve a situation "where parallel trade would effectively lead to a shortage of medicines on a given national market," as long as those steps are consistent with the obligation enshrined in Article 81 of Directive 2001/83 to ensure a continuous supply of pharmaceuticals.[17]

This shift in approach to parallel trade reached its pinnacle when the Commission announced on May 17, 2018 the closing of infringement procedures against Poland, Romania, and Slovakia for imposing restrictions on parallel trade. In its press release, the Commission began by reaffirming the lawfulness of parallel trade under EU law. However, the Commission emphasized that Member States may also lawfully impose restrictions on parallel trade, "as long as the measures are justified, reasonable, and proportionate to ensure a legitimate public interest. For example, to ensure an adequate and continuous supply of pharmaceuticals to the population."[18] In this regard, the Commission explicitly acknowledged that parallel trade may in fact represent a critical factor influencing the occurrence of medicine shortages. Furthermore, the Commission explicitly acknowledged that several Member States have been plagued in recent years by a lack of an appropriate and continued supply of medicinal products to pharmacies, resulting in a grave impact on the treatment of patients.[19]

III. DIRECTIVE 2001/83/EC AND THE REGULATORY OBLIGATION OF CONTINUOUS SUPPLY OF MEDICINES

Shortly after announcing the closing of several parallel trade infringement procedure cases, the Commission published a Paper on the obligation of continuous supply to tackle the problem of shortages of medicine.[20] The Commission's Paper essentially tries to flesh-out the content of the obligation to ensure a continuous supply of the domestic market, which is enshrined in Articles 81 and 23a of Directive 2001/83/EC.[21]

Pursuant to Article 81, marketing authorization holders and wholesale distributors of medicine products placed on a Member State's market must ensure appropriate and continued supplies to pharmacies, and other persons authorized to supply medicinal products, so that the needs of patients in the Member State in question are covered. Additionally, Article 23a establishes that marketing authorization holders must notify the national competent authority at least two months before a product is removed from a Member State's market (either temporarily or permanently).

Building upon these two provisions, the Commission's Paper clarifies that marketing authorization holders must supply distributors (including so-called full-liners, which distribute the total range of medicines), and persons entitled to supply medicines to the public "sufficiently in advance and in adequate quantities to cover demand from patients in a Member State."[22] Distributors, on the other hand, are under the obligation of ensuring a continuous supply to pharmacists and, other persons entitled to supply the public, in order to cover the needs of the patients on the territory where the distributor is established. Most importantly, the Paper highlights that distributors can only supply other distributors provided this does not impact their ability to meet the public service obligation ("PSO") of ensuring a continuous supply to the pharmacies and other per-

16 *Ibid.* para. 68.

17 *Ibid.* para. 75.

18 European Commission Press Release - Infringement: Parallel trade of medicines: Commission closes infringement proceedings and complaints against Poland, Romania and Slovakia, May 17, 2018.

19 *Ibid.*: "After careful assessment, the Commission has concluded on the need to look for other ways than infringements to adequately solve this complex situation in order to swiftly and efficiently deal with an issue that might have negative impact on the health of European citizens."

20 This Paper follows-up on the responses to the Questionnaire on the Measures implemented in the Member States territories in the context of Article 81 of Directive 2001/83/EC, which are summarized in the PPT by Agnès Mathieu-Mendes: https://ec.europa.eu/health/sites/health/files/files/committee/ev_20180525_rd03_en.pdf.

21 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

22 Paper on the obligation of continuous supply to tackle the problem of shortages of medicines – Agreed by the Ad-hoc technical meeting under the Pharmaceutical Committee on shortages of medicines on 25 May 2018, p. 1.

sons entitled to supply to the public in the geographic area under their responsibility.[23] Thus, the Commission's Paper makes it abundantly clear that the obligation of continuous supply applies both to marketing authorization holders and distributors alike, even though Directive 2001/83/EC appears to state that only (full-line) distributors are subject to PSOs (PSO is the "obligation placed on wholesalers to guarantee permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question.")[24]

It should be noted that the legislation of most Member States does not differentiate between different categories of distributors for the purpose of applying the obligation of continuous supply. The replies provided by Member States to the Commission's questionnaire launched in 2017, which underpinned the May 2018 Paper, show that only Belgium, Germany, and France distinguish between two categories of distributors: (i) full-liners, which are linked to PSOs, and (ii) all other distributors (not subject to the obligation of continuous supply). The only other exception seems to be Slovenia, which distinguishes between full-line, contact-line, and short-line distributors. When a distributor is subject to the obligation of continuous supply, national legislation may impose a duty upon marketing authorization holders to supply distributors so that the latter "guarantee a demand-oriented and continuous supply to the pharmacies with which they do business."[25] This means that full-liner distributors subject to PSOs may not be required to proactively search for alternative ways of supply.[26] Furthermore, certain Member States have strengthened the obligation of continuous supply with the right of distributors to request marketing authorization holders for a supply corresponding to the distributor's market share.[27]

In addition to the general obligation of continuous supply, marketing authorization holders must be especially vigilant as regards to products for which there are limited or no alternatives, because their manufacturing process depends on a single facility. This obligation for an additional vigilance/duty of care on the part of marketing authorization holders in ensuring a continuous and adequate supply of medicines also extends to those medicines where a discontinuation of supply could result in public health risks (e.g. critical or essential medicines such as vaccines and medicines for life threatening conditions). Because of the critical nature of certain medicines, Member States may ask holders of marketing authorizations to develop a shortage prevention plan, within the context of their obligation to ensure continuous supply. For instance, in Portugal, Infarmed (the Portuguese sector regulator) has published a notice containing a list of active pharmaceutical ingredients in relation to which the pharmacies must inform the authorities, within 48 hours, of any lack of access to medicines experienced.[28] This PSO should, however, be regarded as a secondary safeguard in relation to the more general obligation to ensure a continuous supply that applies both to marketing authorization holders and distributors.[29]

One important consequence of the Commission's Paper has been the follow-on initiatives by national pharma regulators. For example, on January 8, 2019, Infarmed adopted a Notice that closely follows the Commission's Paper, and which appears to drastically change the regulatory approach to parallel trade. Prior to this Notice, holders of marketing authorizations and distributors were generally not held responsible for shortages in the Portuguese market, as this was considered to be a pure competition law issue. Furthermore, Infarmed had a practice of awarding a blank authorization to distributors, regardless of the geographic market supplied and of the applicability of PSOs. In reality, less than 2 percent of a universe comprising over 600 distributors in Portugal actually supply the Portuguese market and cater for patients in the national territory. Hence, the vast majority of distributors in Portugal have long been off the hook in terms of the applicability of the obligation to ensure supply.

Pursuant to Infarmed's 2019 Notice on the obligation of continuous supply, in order for the sale of medicines to operate seamlessly, it is paramount that the few distributors which actually serve the domestic market are supplied with the medicines necessary to face the pharmacies' demand. Due to the risks posed by a disruption in the supply of medicines, Infarmed stated that marketing authorization holders must supply

23 Paper on the obligation of continuous supply to tackle the problem of shortages of medicines – Agreed by the Ad-hoc technical meeting under the Pharmaceutical Committee on shortages of medicines on 25 May 2018, p. 2.

24 Article 1(18).

25 This is the case of Germany: see European Commission, Health and Food Safety Directorate-General, Summary of Responses to the Questionnaire on the Measures implemented in the Member States territories in the context of Article 81 of Directive 2001/83/EC, p. 3.

26 E.g. Denmark: see European Commission, Health and Food Safety Directorate-General, Summary of Responses to the Questionnaire on the Measures implemented in the Member States territories in the context of Article 81 of Directive 2001/83/EC, p. 4.

27 This is the case of Czech Republic.

28 Infarmed Informative Notice number. 235/CD/8.1.6, of November 21, 2012.

29 Infarmed, Informative Notice (Circular Informativa) N.º 012/CD/100.20.200, from January 8, 2019 on Duty to supply the market – responsibilities of the player involved in the medicine value chain (Obrigação de fornecimento do mercado – responsabilidades dos intervenientes no circuito do medicamento).

all distributors that are under the obligation of supplying the Portuguese territory (either nationally or regionally). Thus, holders of marketing authorizations can neither justifiably refuse to supply a distributor subject to PSOs, nor put forward efficiency defenses that could underpin such a refusal. Essentially, Infarmed, by drawing a hierarchy topped by those who favor domestic sales, has imposed on marketing authorization holders the burden of effectively monitoring the destination of the medicines sold to their distributors.

IV. CONCLUSION

Possibly the most important and contentious element of the Commission's Paper on the obligation of continuous supply is that it clearly fleshes-out the relation of subsidiarity between domestic supplies and parallel exports. The Commission's explicit recognition that Member States are permitted to set broad PSOs to ensure a continuous supply of medicines deeply encroaches on the vertical relations between marketing authorization holders and distributors. While such relations were typically subject to competition rules embedded by Internal Market considerations, there has been a noticeable shift towards the strengthening of Member States' rights to regulate such relations and, consequently, discipline parallel trade. Although it is still too soon to ascertain the full impact of the Commission's Paper, some follow on initiatives are already taking place at the national level, with the regulator taking a more active role in disciplining vertical relations with a potential impact on security of supply.

The Commission's Paper does not elaborate on its implications in terms of competition law enforcement. In particular, it is unclear whether the Commission has fully reversed its classic approach to parallel trade cases under Articles 101(1) and 102 TFEU, or if it now applies Article 106(2) TFEU to the obligation of continuous supply and related PSOs, thus setting-aside the application of the competition law rules.[30] Should this be the case, it would dovetail with the CJEU ruling in *Sot. Lélos kai Sia*, which recognizes Member States' right to take appropriate and proportionate measures when parallel trade leads to a shortage of medicines.

30 Article 106(2) TFEU reads: "Undertakings entrusted with the operation of services of general economic interest or having the character of a revenue-producing monopoly shall be subject to the rules contained in the Treaties, in particular to the rules on competition, in so far as the application of such rules does not obstruct the performance, in law or in fact, of the particular tasks assigned to them. The development of trade must not be affected to such an extent as would be contrary to the interests of the Union."

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