

Turkish Competition Authority Publishes Preliminary Report on the Pharmaceutical Sector Review

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The Turkish Competition Authority (the “Authority”) has examined the factors affecting competition throughout the pharmaceutical value chain, from the development of a medicinal product to its delivery to patients through the retail channel, and published the findings of its sector review in the Preliminary Report on the Pharmaceutical Sector Review (the “Preliminary Report”).

In addition to providing an overview of the pharmaceutical sector and the Authority’s recent decisional practice, the Preliminary Report addresses competition law issues that may arise at the production, market entry and distribution stages. In particular, it contains significant findings and recommendations concerning the exercise of patent rights, licensing and reimbursement processes, exclusive distribution arrangements and the Public Institution Discount (Kamu Kurum İskontosu - “PID”).

1. THE AUTHORITY’S APPROACH TO MERGERS AND ACQUISITIONS IN THE PHARMACEUTICAL SECTOR

The Preliminary Report notes that mergers and acquisitions in the pharmaceutical sector have occupied an important place in the Authority’s recent decisional practice. The classification of undertakings active in the field of pharmacology as technology undertakings is also particularly relevant when assessing notification requirements for transactions in the pharmaceutical sector. The Preliminary Report states that the amendments made to the merger control regime applicable to technology undertakings in 2026 narrowed the scope of the exception to a certain extent, while preserving the underlying approach.

The Preliminary Report further notes that, when assessing mergers and acquisitions in the pharmaceutical sector, not only the parties’ existing activities but also pipeline products and potential competition between the parties may be relevant. Accordingly, providing information on the potential competitive relationship between the parties in merger control filings may help ensure that notifications are complete and facilitate a more efficient review process.

• Definition of the Relevant Product Market

The Anatomical Therapeutic Chemical (“ATC”) classification is an important starting point for defining relevant product markets in the pharmaceutical sector. Although the Authority commonly relies on ATC-3 and ATC-4 classifications in its decisional practice, the Preliminary Report

emphasizes that these classifications are not, in themselves, determinative of the relevant market definition.

Accordingly, factors such as the therapeutic use of the medicinal products, the stage of the disease, prescribing practices, target patient groups, off-label use, pricing and reimbursement conditions may also be taken into account when defining the relevant market on a case-by-case basis.

2. COMPETITION AT THE PRODUCTION STAGE

• Patent Rights and Competition Law

The Preliminary Report recognizes that patent protection creates legitimate exclusivity in the pharmaceutical sector, supporting innovation and allowing the recovery of R&D investments, and emphasizes that the relevant competition law concern lies not in the existence of the patent itself, but in the manner in which patent rights are exercised.

Accordingly, the use of rights and administrative procedures inherent in the patent system beyond their legitimate purposes, in a manner that makes market entry more difficult for competitors, may be subject to competition law scrutiny. The main risks identified in the Preliminary Report include patent clusters and divisional patent applications, the provision of false or misleading information to patent authorities, the use of legal instruments such as litigation and warning letters beyond their legitimate purpose of enforcing rights, and pay-for-delay agreements.

• Patent Clusters and Divisional Patents

Patent clusters consisting of numerous patents and pending applications, as well as divisional patent applications, are ordinary mechanisms under patent law. However, they may delay market entry by creating legal uncertainty, additional costs and litigation risks for generic pharmaceutical manufacturers.

The Preliminary Report nevertheless notes that patent clusters and divisional patent applications are not yet widespread in Türkiye and remain limited in scale compared with the European Union.

• Patent Disputes, Settlements and Waivers

As a rule, patent holders' initiation of legal proceedings, issuance of warning letters and applications for interim injunctions constitute legitimate means of enforcing their rights. The Preliminary Report nevertheless notes that, particularly where dominant undertakings use information asymmetries or their financial and organizational strength to deploy these mechanisms for purposes other than legitimate enforcement, competition law concerns may arise.

The Preliminary Report does not identify a systemic issue in Türkiye. To assess this risk, the Authority reviewed approximately 350 patent disputes initiated since 2015 and separately analyzed how 26 of those disputes were concluded. Of the 76 patent infringement actions brought between 2019 and 2025, interim injunctions were granted in nine cases, and in two of those cases the decision on the merits was ultimately rendered in favour of the generic pharmaceutical manufacturer. On the basis of the available data, the Preliminary Report therefore does not conclude that interim injunction practices have created a systemic issue affecting market entry conditions.

The Preliminary Report also emphasizes that resolving disputes by settlement or waiver is not, in itself, anti-competitive. However, where indications emerge that a patent may be weak, a patent holder's waiver of its rights solely vis-à-vis the opposing party may make market entry more difficult for other generic pharmaceutical manufacturers by preventing them from benefiting from the effects

that an invalidity decision could otherwise have produced. Although four cases of this nature were identified, the Preliminary Report states that no definitive competition law conclusion can be drawn in the absence of additional evidence.

- **Pay-for-Delay Agreements**

Pay-for-delay agreements, under which a generic pharmaceutical manufacturer receives a direct payment, transfer of value or other benefit in return for delaying or abandoning market entry, are regarded as practices capable of restricting competition between potential competitors.

The Authority examined this risk extensively in Türkiye and found no indication, in the cases reviewed, of restrictive conduct or payments made in return for delayed market entry. The Preliminary Report nevertheless notes that patent settlements are not entirely risk-free and that the Authority will continue to closely monitor this area.

- **Key Recommendations of the Preliminary Report on Production**

While the Preliminary Report concludes that the legislation and practices reviewed do not, taken as a whole, create a market entry barrier for generic pharmaceutical manufacturers, it makes a number of recommendations.

In this respect, patent settlement agreements should be limited to the patents in dispute and the geographic scope protected by those patents, should not delay market entry disproportionately and should not provide benefits that cannot be explained by litigation costs or ordinary commercial considerations. The Preliminary Report also emphasizes that mechanisms such as divisional patents, warning letters, interim injunctions and litigation should not be used to prevent generic entry, and that misleading or incomplete information should not be submitted to patent authorities or courts.

At the institutional level, the Preliminary Report recommends that potentially problematic divisional patent applications be notified by the Turkish Patent and Trademark Office to the Authority, that information on patents subject to litigation be made more transparent, and that the Turkish Patent and Trademark Office database be aligned with Espacenet.

3. COMPETITION AT THE MARKET ENTRY STAGE

- **Licensing Processes and Product-Hopping Strategies**

One of the risk areas addressed in the Preliminary Report is the strategy commonly referred to as “*product hopping*”. This strategy may involve withdrawing the marketing authorization of an originator medicinal product whose patent protection is approaching expiry or has expired, and shifting the product portfolio towards a new product or formulation, thereby making market entry more difficult for generic products.

The withdrawal of a marketing authorization for an originator product or a switch to a new product does not, in itself, constitute a competition law infringement. From a competition law perspective, the relevant question is not the product switch itself, but whether the process is used as an exclusionary tool against competitors.

The Preliminary Report refers to specific precedents from the EU and the United States. In the European Commission’s AstraZeneca case, the withdrawal of the marketing authorization for the capsule form of a medicinal product in three Member States, thereby preventing generic

manufacturers from relying on the originator product, was found to constitute an abuse of a dominant position; this finding was upheld by the Court of Justice of the European Union in 2012. In the United Kingdom, in the Reckitt Benckiser case, the withdrawal of a product whose patent protection had expired immediately before generic entry and its reintroduction under a new name was treated as a competition law infringement, and the undertaking settled the case. By contrast, in the 2015 US case Mylan v. Warner Chilcott, similar conduct was not found unlawful because market entry by the competitor remained practically possible. The Preliminary Report thus contrasts the EU approach, which examines whether there is an objective justification for the conduct, with the comparatively less interventionist US approach, which places greater emphasis on whether market entry remains practically possible.

In Türkiye, the requirement for approval by the Turkish Medicines and Medical Devices Agency (“TİTCK”) for marketing authorization withdrawals requested by the authorization holder constitutes an important regulatory safeguard. Nevertheless, the Preliminary Report recommends reviewing the withdrawal process in light of the possibility that it may be used as part of a product-hopping strategy. In this context, it suggests considering a mechanism under which the relevant toxicological, pharmacological and clinical data could continue to be relied upon for generic applications for a certain period even where the originator product’s marketing authorization is withdrawn at the holder’s request.

- **Impact of Reimbursement Rules on Market Entry**

Given that a substantial portion of pharmaceutical consumption in Türkiye is financed by the Social Security Institution (“SSI”), whether a product is included within the reimbursement system is commercially significant. According to the data cited in the Preliminary Report, the SSI covers approximately 95% of pharmaceutical expenditure by volume and more than 85% by value.

- **Internal Reference Pricing**

Under the Health Implementation Communiqué, medicinal products containing the same active substance at the same dosage are grouped into equivalent groups, and the maximum reimbursable amount is calculated on the basis of the applicable reference price. Under the current system, products that have reached a 1% market share in at least one of the preceding five months are taken into account when determining the reference product.

The Preliminary Report notes that a criterion based solely on market share may not ensure that the product is actually accessible to patients. Reaching a 1% market share does not necessarily mean that the product is regularly supplied nationwide or is in practice accessible to patients. The Preliminary Report therefore recommends that product availability and continuity of supply also be taken into account.

- **Fast-Track Entry onto the Reimbursement List**

Under the Pharmaceutical Reimbursement Regulation, a fast-track mechanism allows medicinal products priced at a specified level below the lowest-priced product in the relevant equivalent or therapeutic reference group to be included on the reimbursement list without waiting for the ordinary commission periods.

The key issue identified in the Preliminary Report is that the product used as the reference for this calculation is not always required to be actually available on the market. A product that remains on the reimbursement list but is not supplied in sufficient quantities may continue to serve as the lowest-priced reference product, artificially lowering the price that a new competitor must offer in

order to benefit from the fast-track entry mechanism.

- **Key Recommendations of the Preliminary Report on Market Entry**

Rather than proposing a fundamental overhaul of the existing system, the Preliminary Report recommends targeted regulatory interventions. These include reviewing marketing authorization withdrawal procedures from a product-hopping perspective, preventing products that are not actually available on the market from being used as the lowest-price reference, and reassessing the 1% market-share criterion used for internal reference pricing by reference to patient access and product availability.

In this respect, the Authority focuses on the actual market effects of the relevant regulatory mechanisms rather than formal compliance with sector-specific rules.

4. COMPETITION AT THE DISTRIBUTION STAGE

- **Pharmaceutical Wholesaling and Market Structure**

The Preliminary Report notes that the pharmaceutical wholesaling market, which constitutes the main distribution channel through which medicinal products reach pharmacies and hospitals, is highly concentrated. In the retail pharmacy channel, among 92 active pharmaceutical wholesalers, the two largest account for approximately two-thirds of the market and the five largest for approximately 90%. In the tender channel, the two largest undertakings account for approximately half of the market, while the five largest account for approximately two-thirds.

While large-scale wholesalers benefit from economies of scale and financial strength, the presence of pharmacists' cooperatives and small and regional wholesalers plays a balancing role in preserving competitive pressure and service quality.

- **State Supply Office Health Market**

The Health Market operated by the State Supply Office ("**DMO**") for the procurement of medicinal products by public hospitals is examined in the Preliminary Report particularly in terms of its authorized seller structure and competition in tenders.

An analysis of more than 53,000 DMO purchases conducted in 2022 and 2023 found that tender prices were sensitive to the number of participants. In particular, tenders with a single participant generally resulted in prices corresponding to the price after application of the PID, whereas discount rates increased as the number of participants rose. The same analysis found that, during 2022-2023, pharmaceutical wholesalers' weighted average profit margin in DMO tenders was approximately 16-20%, while the arithmetic average was approximately 26-35%, significantly above the 8% maximum benchmark used in the analysis.

In light of these findings, the Preliminary Report recommends allowing up to five authorized sellers per province, provided that safeguards are maintained to prevent the authorized distributorships of competing products from being concentrated in the same wholesaler at the same time. Where supply-chain conditions or the technical characteristics of the relevant product make it difficult to work with more than one authorized seller, the Preliminary Report notes that an exemption may be granted by the Competition Board.

- **Exclusive Distribution Arrangements**

Exclusive distribution arrangements between manufacturers and pharmaceutical wholesalers in the private hospital tender channel are another area addressed by the Preliminary Report. The data gathered during the review do not indicate that existing exclusive distribution agreements currently result in market foreclosure to an extent that leaves no meaningful scope for other wholesalers. According to the Preliminary Report, approximately one-fifth to one-quarter of medicinal products sold through the private hospital channel are supplied by an exclusive wholesaler; the relatively low level of this ratio suggests that the current degree of exclusivity has a limited foreclosure effect.

The Preliminary Report nevertheless notes that competition concerns may arise if exclusive distribution agreements become concentrated among one or a small number of wholesalers or become more widespread.

To limit these risks, the Preliminary Report states that non-compete obligations preventing a pharmaceutical wholesaler from handling competing products should be effectively implemented in agreements providing for exclusivity. It further emphasizes that efficiencies claimed to arise from exclusive distribution should not be accepted in general or hypothetical terms for exemption purposes; rather, such efficiencies should be substantiated by concrete evidence and explained in detail.

• **Public Institution Discount**

Another important issue addressed by the Preliminary Report at the distribution stage concerns the legal and operational uncertainties arising from the application of the PID. Under the traditional model, the PID is applied directly by the supplier upon the first sale of the medicinal product. For certain products, however, the discount is subsequently reimbursed by the supplier to the pharmacy once the pharmacy documents that the relevant sale was subject to the PID.

Particularly under the retrospective reimbursement model, requests for screenshots from the Pharmaceutical Track and Trace System (“**ITS**”), Global Location Numbers (“**GLNs**”) or similar information from pharmacies may create risks relating to access to personal data and competitively sensitive commercial information, as well as data security. The Preliminary Report further considers that this practice may increase market transparency in a manner capable of restricting competition and, by allowing manufacturers to obtain indirect access to competitors’ sales information, may result in the ITS infrastructure – originally established by TITCK to ensure the traceability of medicinal products – being used beyond its intended purpose.

To address these uncertainties, the Preliminary Report recommends that the PID apply only to prescriptions reimbursed by the SSI and approved through MEDULA, and that verification of medicinal products subject to the PID be carried out through an integrated data-sharing infrastructure between MEDULA and ITS. This is intended to reduce suppliers’ need to request additional documents and information from pharmacies and the associated data-sharing risks.

The Preliminary Report also recommends establishing a guarantee account within the SSI to compensate pharmacies for losses arising where the PID is not applied or is applied only partially, with the account being triggered in such cases.

5. WORKSHOP ON COMPETITION IN THE PHARMACEUTICAL SECTOR

Following the publication of the Preliminary Report, the Authority hosted a “Workshop on Competition in the Pharmaceutical Sector” on 21 September 2026 to discuss recent developments

concerning the effective functioning of competition in the pharmaceutical sector, the issues encountered in the sector and potential solutions. The Workshop brought together representatives of public institutions, the private sector, academia and other industry stakeholders, and provided a forum for discussing the findings and recommendations set out in the Preliminary Report from different stakeholder perspectives.

During the first session, the key findings and assessments of the Preliminary Report were presented. The discussion covered factors affecting competition at the production, market entry and distribution stages; the relationship between patent protection and competition; the impact of licensing and reimbursement rules on market entry; competition between pharmaceutical wholesalers and exclusive distribution practices; competition in public pharmaceutical procurement; and issues arising from the application of the PID. Proposals for improvements that could be implemented within the existing legal, administrative and financial framework were also discussed.

The second session, attended by representatives of public institutions, focused on the future of competition and regulation in the pharmaceutical sector, including the relationship between marketing authorization, pricing and reimbursement mechanisms, access to medicines, health policy and competition policy. The final session focused on the views of private-sector representatives and addressed the impact of the existing regulatory framework on the market, as well as the challenges faced by industry stakeholders and potential solutions.

The Workshop also addressed the balance between competition, investment, innovation and access to medicines, as well as the regulatory framework required to support a sustainable and competitive pharmaceutical sector, taking into account the views of both public- and private-sector representatives.

CONCLUSION

The key message of the Preliminary Report for companies is that compliance with sector-specific regulation does not, in itself, create a safe harbour under competition law. Rights and opportunities afforded by patent, marketing authorization and reimbursement rules may be subject to competition law scrutiny where they are used in a manner that prevents or hinders competitors from entering or expanding in the market, even if such conduct complies with the applicable sector-specific rules.

Against this background, companies active in the pharmaceutical sector should assess, from a competition law perspective, in particular their patent disputes and settlements, marketing authorization and reimbursement practices, and exclusive distribution arrangements.

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