

University of New South Wales Law Research Series

**Turkey – Certain Measures
Concerning the Production,
Importation and Marketing of
Pharmaceutical Products**

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[2023] *UNSWLRS* 1
Forthcoming (2023) 117(2) *American Journal of International Law*

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World Trade Organization – General Agreement on Tariffs and Trade 1994 – Government Procurement Derogation – General Exceptions – Public Health – Localization Requirement – Shortage of Supply of Pharmaceutical Products

TURKEY – CERTAIN MEASURES CONCERNING THE PRODUCTION, IMPORTATION AND MARKETING OF PHARMACEUTICAL PRODUCTS, WT/DS583/ARB25. At www.wto.org/english/tratop_e/dispu_e/cases_e/ds583_e.htm. World Trade Organization Award of the Arbitrators, July 25, 2022.

The World Trade Organization (WTO) Arbitral Award (Award) in *Turkey — Certain Measures concerning the Production, Importation and Marketing of Pharmaceutical Products (Turkey – Pharmaceutical Products)* is the first appellate decision via arbitration based on Article 25 of the Understanding on Rules and Procedures Governing the Settlement of Disputes¹ (DSU). Since the paralysis of the Appellate Body in 2019, a small group of WTO members including the European Union (EU) have agreed to the Multi-Party Interim Arbitration Arrangement (MPIA), to preserve the appellate function by pre-committing to arbitrating appeals under Article 25.² Turkey has not signed on to the MPIA but agreed with the EU to resolve this appeal through arbitration under largely the same processes as are established in the MPIA. As such, *Turkey — Pharmaceutical Products* sets a precedent of WTO Members using arbitration as an alternative appellate mechanism to maintain binding dispute resolution. However, the decision also raises significant substantive concerns relating to the proper balance between trade liberalization and regulatory autonomy for measures designed to achieve public health objectives.

¹ Understanding on Rules and Procedures Governing the Settlement of Disputes, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401, 33 I.L.M. 1226 (1994). WTO disputes are adjudicated typically by panels in the first instance and then by the Appellate Body if panel decisions are appealed. Since December 2019, the Appellate Body has lost its quorum of three members which is required for it to hear appeals. Article 25 provides an alternative means of dispute settlement via arbitration.

² The MPIA was initially set up by 16 WTO members in 2020 and as of this writing, has 25 members (counting the EU as a single member). It is designed to provide an interim appellate mechanism that largely reproduces the Appellate Body and will cease operation once the Appellate Body becomes fully functional. See WTO, Statement on A Mechanism for Developing, Documenting and Sharing Practices and Procedures in the Conduct of WTO Disputes, JOB/DSB/1/Add.12 (Apr. 30, 2020).

The dispute arose out of Turkey's Universal Health Insurance Scheme, under which the Turkish government, through its Social Security Institution (SSI), reimbursed part of the price of pharmaceutical products distributed to outpatients by retail pharmacies.³ Apart from other eligibility criteria, the Turkish government imposed a localization requirement on foreign producers requiring them to make a commitment to produce certain pharmaceutical products in Turkey. If they failed to submit or fulfil a commitment, or if a proposed commitment was rejected by the Turkish authorities, the products concerned were no longer reimbursable. This localization requirement was at the core of this dispute.

The panel had no difficulty finding that the localization requirement conferred “an advantage on locally produced pharmaceutical products ... to the detriment of imported ones”, constituting a breach of the national treatment rule under Article III:4 of the General Agreement on Tariffs and Trade (GATT).⁴ The measure's WTO-legality hinged on whether it fell within the government procurement derogation under GATT Article III:8(a) and whether it was justifiable under GATT Article XX general exceptions, particularly Article XX(b) concerning the protection of public health and Article XX(d) concerning the compliance with domestic laws and regulations. The panel ruled against Turkey on all of these issues.

On appeal, the arbitrators questioned some of the panel's interpretations but supported its ultimate rulings. The government procurement derogation of Article III:8(a) contemplates an exemption to the national treatment rule for

laws, regulations or requirements governing the *procurement by governmental agencies of products purchased for governmental purposes and not with a view to*

³ The facts of the dispute are summarized in Panel Report, *Turkey — Certain Measures concerning the Production, Importation and Marketing of Pharmaceutical Products*, WT/DS583/12 (dated Apr. 28, 2022) paras. 2.1-33. The reimbursement was made to pharmacies based on monthly invoices. To be eligible for reimbursement, a pharmaceutical product must be included in an official list determined and regularly updated by SSI (the Annex 4/A list attached to the Health Implementation Communiqué).

⁴ *Id.* paras. 7.121-126. General Agreement on Tariffs and Trade, opened for signature 30 October 1947, T.I.A.S. 1700, 55 U.N.T.S. 194.

commercial resale or with a view to use in the production of goods for commercial sale (emphasis added).

Turkey contended that the localization requirement was a measure governing the *procurement* by SSI of pharmaceutical products *purchased* by retail pharmacies for *governmental purposes*. The panel had ruled that, to qualify as an exempted procurement under Article III:8(a), a *purchase* must be made by a governmental agency. The arbitrators disagreed, reasoning that there is not textual support for that limitation, since only “procurement,” and not “purchase,” is qualified by the phrase “governmental agencies.” This means that “the relevant purchase transaction might be entered into by a non-governmental agency” (paras. 6.46-6.47). The arbitrators then considered whether, under the reimbursement scheme, the SSI procured the pharmaceutical products purchased by pharmacies from wholesalers. In their view, procurement is not confined to acquisition of ownership but entails a certain degree of control over the relevant products and must be distinguished from “merely financing or regulating the acquisition of [such] products” (para. 6.58). Ultimately, the arbitrators accepted the panel’s (factual) findings that the pharmacies acquired ownership of the goods independently of the government and that SSI’s regulation of and involvement in the reimbursement did not amount to a sufficient level of control over the goods to constitute a procurement of the goods by SSI, as a governmental agency (paras. 6.60-6.69).

The other intensively litigated issue was whether the localization requirement was “necessary to protect human ... life or health” under Article XX(b). Turkey claimed that the measure served to “ensure an uninterrupted access to safe, effective and affordable medicines for all patients in Turkey” by reducing over-reliance on imported pharmaceutical products, which can lead to a shortage of supply in the long term.⁵ The arbitrators upheld the panel’s

⁵ *Id.* paras. 7.129, 7.139.

ruling that Turkey failed to demonstrate that the measure was designed to prevent the alleged risk of a long-term shortage of supply of pharmaceutical products.

By way of background, justification under GATT's general exceptions clause involves several stages. The first entails testing the ends and means of the measure in general under a closed list of public policy rationales (the Article XX "sub-paragraphs"). Then, the measure is tested as applied (under the Article XX chapeau). The sub-paragraphs require examining whether the measure is designed to pursue the relevant legitimate aim under the enumerated exception that is invoked and analyzing the necessity of the means toward pursuing that goal. Historically, the "design" test has been extremely deferential to the defendant state, while the necessity review has entailed a much more rigorous least-restrictive-means analysis.⁶ Here, however, the panel, and, on appeal, the arbitrators, have made the design test much more robust—a position that effectively restricts states' access to the Article XX exceptions.

The panel followed the typical two-step analysis under existing case law, beginning with a preliminary assessment of whether a measure is designed to protect human life or health before turning to a more sophisticated assessment of the "necessity" of the measure.⁷ However, the panel confined itself to the design test, concluding that Turkey's measure failed to satisfy that standard on the basis of three major findings: (1) the alleged risk of long-term shortage was theoretical, abstract and hypothetical because Turkey failed to establish "a substantial degree of probability"; (2) the localization requirement pursued an industrial policy objective rather than the declared public health objective; and (3) the requirement had no rational

⁶ In *Colombia—Textiles*, for instance, the Appellate Body clarified that the design test requires merely that there be a "relationship" between the measure and the purported policy goal, such that the means "not be incapable" of protecting the end. Appellate Body Report, *Colombia – Measures Relating to the Importation of Textiles, Apparel and Footwear*, WT/DS461/AB/R (adopted Jun. 22, 2016) paras. 5.67-5.70. This is an extremely forgiving standard. As the Appellate Body further explained, "We do not see the examination of the 'design' of the measure as a particularly demanding step of the Article XX(a) analysis. By contrast, the assessment of the 'necessity' of a measure entails a more in-depth, holistic analysis of the relationship between the measure and the protection of public morals." *Id.*

⁷ *Id.* para. 7.164.

relationship to the stated objective of meeting 60% (by value) of domestic pharmaceutical demand through domestic production (paras. 6.81-6.85).⁸ On appeal, Turkey challenged these findings, arguing that the panel's application of the design test had adopted an erroneous legal standard, mixed this threshold analysis with the necessity test, and failed to assess the evidence objectively. The arbitrators held that the panel did not err in applying the design test as a threshold assessment prior to the necessity test (paras. 6.93-6.103). Moreover, the arbitrators opined that the panel did not actually apply a legal standard of "a substantial degree of probability" (even though the panel referred to this standard) but instead allowed flexibility for governments to show the existence of a risk based on a lower evidentiary standard (paras. 6.104-6.111). Finally, the arbitrators dismissed Turkey's argument that the panel failed to "make an objective assessment of the matter" in accordance with Article 11 of the DSU. Instead, they endorsed the panel's discretion to "decide which evidence to utilize in making its findings" and its assessment of evidence in this case (paras. 6.134-6.142). Accordingly, the arbitrators agreed with the panel that there was no need to assess the remaining legal elements including the necessity test and those under the chapeau of Article XX.

Turkey's final defence was based on Article XX(d), under which it argued that the localization requirement was "necessary to secure compliance with the laws and regulations requiring [it] to ensure accessible, effective and financially sustainable healthcare."⁹ The panel rejected this argument without assessing the relevant legal elements. The panel believed that Turkey's argument largely relied on its submissions under Article XX(b) and hence extended to the Article XX(d) defence its analysis and findings under Article XX(b).¹⁰ While the arbitrators opined that "it would have been more prudent had the panel followed the order of

⁸ See also *Id.* paras. 7.165-211.

⁹ *Id.* para. 7.216.

¹⁰ *Id.* paras. 7.217-218.

the relevant analysis and articulated the applicable legal standards” under Article XX(d), they supported the panel’s approach and conclusion (paras. 6.159-6.171).

This dispute is significant both procedurally and substantively. Procedurally, it was the first use of Article 25 arbitration for appellate review. Although Turkey is not a party to the MPIA, the arbitration procedure agreed by the disputants was largely based on it.¹¹ This dispute therefore shows that the MPIA or a mutually agreed Article 25 arbitral process can perform some of the functions that the Appellate Body did in the binding settlement of disputes.¹² However, although MPIA parties have arguably given pre-consent to using the MPIA for appellate review in their disputes, such consent is still required in each dispute involving non-MPIA parties to which the Article 25 arbitration procedures would be applied. Without consent, a losing party may still “appeal into the void” to block the adoption of unfavourable panel decisions, thereby leaving disputes not formally resolved as a matter of law.¹³

The arbitrators took effort to address some of the open criticisms levelled at the Appellate Body, particularly by the United States. To justify its continuous blockage of the appointment of new members to the appellate court, the United States has condemned repeatedly the substantive and procedural mistakes that the Appellate Body has made in its practices.¹⁴ To address some of these concerns, the arbitrators confined the appellate review to issues necessary for the resolution of the dispute, paid full deference to the panel’s findings of facts,

¹¹ WTO, *Agreed Procedures for Arbitration under Article 25 of the DSU*, WT/DS583/10 (Mar. 25, 2022).

¹² Within a month after the arbitrators issued their Award, Turkey agreed to bring the measures concerned into WTO compliance. WTO, *Communication from Türkiye*, WT/DS583/15 (Aug. 22, 2022).

¹³ Weihuan Zhou, *WTO Dispute Settlement Mechanism without the Appellate Body: Some Observations on the US-China Trade Deal*, 9 *Journal of International Trade and Arbitration Law* 443 (2020).

¹⁴ USTR, *Report on the Appellate Body of the World Trade Organization* (Feb. 2020), at https://ustr.gov/sites/default/files/Report_on_the_Appellate_Body_of_the_World_Trade_Organization.pdf.

and issued the Award within 90 days of the commencement of the arbitration. In the Dispute Settlement Body meeting following the Award, the United States welcomed the parties' recourse to Article 25 for the settlement of this dispute. Nevertheless, it also reiterated that the use of arbitration in future cases should avoid incorporating prior practices of the Appellate Body.¹⁵ This ongoing concern about the Appellate Body has created uncertainties as to whether the United States would use the MPIA or an Article 25 process based on the MPIA in future disputes. It also remains to be seen what steps the United States would take to help rebuild "a fully and well-functioning dispute settlement system ... by 2024" a major pledge made by governments, including the United States, at WTO's Twelfth Ministerial Conference.¹⁶

Substantively, the arbitrators provided further clarity on the meaning and scope of how GATT Article III:8(a) on government procurement derogates from the core national treatment principle. Their interpretation that the term "procurement" requires a degree of control that is more than merely financing or regulating the acquisition of products is sound. This means that governmental regulation and provision of subsidies or other kinds of support, which do not lead to the creation of certain rights of control over the goods at issue, would fall outside of the government procurement exemption. Here, one should note that the provision of subsidies to domestic producers is exempted from the national treatment rule under Article III:8(b). This suggests a clear division of labor between the two provisions such that both exemptions should be confined to their own boundaries, consistent with the arbitrators' interpretation. In addition, the arbitrators' view that "purchases" can be undertaken by a non-governmental agency is plausible based on a strict textual interpretation of Article III:8(a). However, from a commercial perspective, where an entity purchases goods for governmental purposes, it is

¹⁵ WTO, Dispute Settlement Body Minutes of Meeting held on 29 August 2022, WT/DSB/M/469 (dated Oct. 10, 2022) at 6.

¹⁶ WTO, MC12 Outcome Document Adopted on 17 June 2022, WT/MIN(22)/24 (dated Jun. 22, 2022) at 1.

likely that the entity is already formally engaged by the government which creates a contractual principal-agency relationship in that transaction. This commercial reality may diminish the practical significance of the arbitrators' interpretation because the entity would be a governmental agency in most circumstances. Nevertheless, these interpretative clarifications are well within the bounds of the dispute and have advanced the jurisprudence under Article III:8(a).

The most controversial issue that may have systemic and far-reaching implications concerns the arbitrators' review of the panel's rulings under Article XX(b). Here the arbitrators accepted a problematic interpretation of a central provision of the GATT. Arguably they were being overly deferential to the panel's decision, perhaps pursuing procedural efficiency to minimize existing criticisms about the Appellate Body as noted above. Whatever the reasons, the arbitrators' approach resulted in an inadequate review of the panel's application of the relevant law and assessment of evidence, which may reduce, rather than enhance, the credibility and integrity of the dispute settlement system.

To start, the arbitrators should have rejected the panel's application of the *design* test. Prior to *Turkey – Pharmaceutical Products*, neither any panel nor the Appellate Body had disqualified a contested measure from being justifiable under Article XX(b) under the design test alone. In contrast, they had treated the design test as a threshold analysis imposing a low evidentiary requirement on complainants and had always inquired about whether a measure was “necessary”.¹⁷ In *Turkey – Pharmaceutical Products*, the panel itself noted that the evidentiary requirement established by case law was for Turkey to “demonstrate, *at a minimum*, that the asserted risk arising from alleged over-reliance on imports was more than a merely

¹⁷ In *EC – Preferences*, while the panel did find that the contested measures were not designed to protect human life or health, it continued to assess the necessity of the measures. See Panel Report, *European Communities – Conditions for the Granting of Tariff Preferences to Developing Countries*, WT/DS246/R (adopted Apr. 20, 2004) paras. 7.195-236. The panel's findings under Article XX were not appealed in that dispute.

hypothetical possibility.”¹⁸ However, the panel explicitly introduced a higher standard based on whether “there is a substantial degree of probability of” the risk.¹⁹ The arbitrators did not reject the panel’s approach. Consequently, they implicitly acknowledged that there may be situations where a respondent would not be able to satisfy the *design* test without proving a substantial degree of probability of risk.²⁰ The application of this higher standard led the panel to reject a host of evidence submitted by Turkey including incidents of shortage of certain pharmaceutical goods, policy and regulatory documents aimed at reforming Turkey’s healthcare system, including ensuring sufficient local supply of pharmaceuticals as a key element, and the (potential) impacts of COVID-related restrictions imposed by governments on global medicine supply.²¹ Given the unprecedented disruptions in the global supply of essential medicines and other essential goods during the COVID-19 pandemic, the panel’s finding that the alleged risk was “theoretical, abstract and hypothetical” can hardly be reconciled with the shared concerns of governments and their need to take precautionary steps to mitigate similar risks in the future.

Furthermore, prior Appellate Body case law has established that to pass the *design* test, the responding party is only required to show that the contested measure is *not incapable* of achieving the stated objective. On that basis, the Appellate Body rejected panels’ application of an “overly demanding legal standard” under the *design* test in previous cases.²² Given the evidence on record, the arbitrators should have considered whether the panel had applied the *design* test in a way that required a (higher) level of contribution (by the Turkish measure to the public health goal) which should have been assessed under the *necessity* test instead. Thus, the arbitrators failed to correct the panel’s excessively robust approach under the threshold test

¹⁸ Panel Report, *supra* note 3, para. 7.170 (emphasis added).

¹⁹ *Id.* para. 7.171.

²⁰ I thank Joanna Redelbach for this observation.

²¹ Panel Report, *supra* note 3, paras. 7.174-176, 7.185-197, 7.209 & FN 676.

²² See *supra* note 6, Appellate Body Report, *Colombia—Textiles*, paras. 5.81-5.89.

in the already rigorous Article XX review process. The panel's approach, and the failure of the arbitrators to dismiss it, would lead to reduced policy space for governments in a time when the WTO's legitimacy increasingly relies on its capacity to maintain a delicate balance between liberalization commitments and regulatory autonomy.²³

Here, the arbitrators also had an opportunity to improve the existing case law by questioning whether the *design* test is needed. Insofar as the law draws a distinction between the *design* test and the *necessity* test, Article XX(b), which refers to the term "necessary" only, does not provide the textual support for a separate *design* test. Moreover, the broad coverage of the *necessity* test already provides scope for consideration of all matters that are currently assessed under the *design* test, making the latter superfluous.²⁴

In addition, the arbitrators should have been more critical of the panel's ruling that the Turkish measure was solely for an industrial policy objective. Despite the negative impacts that localization requirements may have on trade, efficiency and economic welfare, they are used widely by governments often in the pursuit of a mix of trade and non-trade (or protectionist and non-protectionist) objectives.²⁵ In this dispute, as noted above, there was evidence to suggest that the Turkish measure at least had some bearing on the public health objective (even though it was mainly aimed at developing Turkey's domestic pharmaceutical industry). The inflexibility of the panel's ruling was incompatible with not only the established practices of

²³ See generally Robert Howse and Joanna Langille, *Continuity and Change in the World Trade Organization: Pluralism Past, Present, and Future* 117 *American Journal of International Law* 1 (2023); Nicolas Lamp, *Toward Multipurpose Trade Policy? How Competing Narratives About Globalization Are Reshaping International Trade Cooperation*, IISD Policy Analysis (Jan. 15, 2023), at <https://www.iisd.org/articles/policy-analysis/multipurpose-trade-policy>.

²⁴ For example, the *necessity* test entails an assessment of whether a contested measure contributes to the chosen policy objective and a weighing and balancing of the degree of such contribution, the importance of the objective and the restrictiveness of the measure. These tests provide sufficient scope for testing whether the means is designed to achieve the ends. See eg. Appellate Body Report, *Brazil – Measures Affecting Imports of Retreaded Tyres*, WT/DS332/AB/R (adopted Dec. 17, 2007) paras. 141-143.

²⁵ Stone et al., *Localisation Barriers to Trade*, OECD Trade Policy Papers No. 180 (May 1, 2015), at www.oecd-ilibrary.org/trade/emerging-policy-issues_5js1m6v5qd5j-en.

governments but also the longstanding, cautious approach taken by WTO tribunals to avoid second-guessing members' chosen policy objectives.²⁶ Again, in accepting the panel's ruling, the arbitrators missed a chance to maintain a proper balance between the regulation of localization requirements and the protection of policy space needed by WTO members. This balance is fundamental to the evolving world trading system as further discussed below.

The above analysis is not to suggest that Turkey's localization measure was clearly justifiable under Article XX(b). The problem is with how the tribunal constricted Article XX, and thus the policy flexibility that provision safeguards. The panel's ruling against the measure under the *design* test was doctrinally dubious and functionally troubling, and the arbitrators did not otherwise make good use of its position to modify the ruling and safeguard the credibility of the dispute settlement system. While WTO tribunals should be concerned about the trade restrictive and distortive effects of localization requirements, a reasonably balanced approach should focus on dealing with the instruments directly rather than second-guessing the chosen policy goals. A better approach to disciplining the Turkish measure in this case would be assessing whether the alternative means proposed by the EU²⁷ could be reasonably available and equally effective to achieve the public health objective under the *necessity* test, and if the measure does pass this test, whether its discrimination against imported pharmaceutical products is unjustifiable or arbitrary under Article XX chapeau. This approach is how WTO tribunals have long drawn the balance of the GATT, including those involving the most trade restrictive measures (i.e. import bans) and policy objectives of vital importance (i.e. public health).²⁸

²⁶ Weihuan Zhou, *In Defence of the WTO: Why Do We Need a Multilateral Trading System?*, 47 *Legal Issues of Economic Integration* 9 (2020).

²⁷ Panel Report, *supra* note 3, para. 7.152.

²⁸ See eg. *supra* note 24, Appellate Body Report, *Brazil—Retreaded Tyres*.

It is a balance worth defending, especially in the post-pandemic era as governments become increasingly sensitive to their regulatory autonomy under international treaties²⁹ and the WTO itself is reorienting its priorities by focusing more on using trade as a means to achieve broader goals of economic development and sustainability. This shift from a trade-oriented approach to one that emphasises the nexus between trade and non-trade values, in light of growing and varying needs of governments to pursue legitimate policy objectives, is crucial for the WTO to remain well-equipped for challenges posed by the ongoing trend of re-globalization.³⁰ Faced with the slow-paced multilateral negotiations, WTO tribunals should use the flexibility they have within their mandate to facilitate the modernization of trade rules in response to changing circumstances and priorities and in ways that advance the legitimacy and efficacy of the institution and its dispute settlement system.

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²⁹ This includes growing recourse to localization measures. See WTO, *World Trade Report 2021: Economic Resilience and Trade* (Geneva: WTO, 2021) 9, at www.wto.org/english/res_e/publications_e/wtr21_e.htm. See also generally Julian Arato, Kathleen Claussen and J. Benton Heath, *The Perils of Pandemic Exceptionalism* 114 *American Journal of International Law* 627 (2020).

³⁰ WTO, DG Okonjo-Iweala: “We need multilateral cooperation and solidarity more than ever”, Lowy Institute Public Lecture (Nov. 22, 2022), at www.wto.org/english/news_e/spno_e/spno32_e.htm.