2 WTO rules offer critical tools in the fight against illicit trade in medical products

KEY POINT

WTO rules are useful and mutually reinforcing in addressing illicit trade in medical products.

The WTO is the only international organization dealing with the global rules of trade between nations and thus is an important ally in the fight against illicit trade in medical products.

At its heart are the WTO agreements, negotiated and signed by the bulk of the world's economies and ratified in their parliaments.

WTO rules support efforts to address the threat of illicit trade by promoting transparency and predictability and setting the foundation for strengthened border and regulatory controls and enhanced cooperation.

Trade facilitation

Illicit traders in medical products take advantage of complex, non-transparent customs rules to ply illegal goods and activities. Provisions of the WTO's Trade Facilitation Agreement (TFA) strengthen border controls needed to tackle illicit trade by requiring transparency of customs rules, the advent of risk management systems and pre- and post-clearance processes, and an emphasis on improved national and international cooperation (see Table 1). They also foster cooperation and information sharing both within and among national customs regimes.

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Table 1: How illicit trade in medical products can be tackled through the implementation of the WTO's Trade Facilitation Agreement

Example	Addressed by (and relevant TFA articles)
Reducing incentives/opportunities for illicit traders in medical products by increasing transparency and predictability and streamlining and automating customs procedures	Publication of laws, procedures and required forms, including some by internet, and designation of enquiry points (art. 1) Allowing the option of electronic payment (art. 7.2) Establishment of a single entry point or "single window" (art. 10.4)
Directing proper resources to the detection of illicit trade practices by managing risks through pre- and post-import activities of medical products	Advance rulings on tariff classification, origin, etc. (art. 3) Development of risk management systems (art. 7.4) Securing compliance through post-clearance audits (art. 7.5)
Enhancing the ability to combat illicit trade in medical products by advancing national coordination and international cooperation efforts	Cooperation among national border agencies (art. 8) International cooperation and the sharing of information between national customs authorities (art. 12) Establishment of national committee on trade facilitation (art. 23.2)

These rules narrow opportunities for illicit traders in medical products by fostering transparency and predictability in the trading environment and favouring the simplification and automation of border processes. They also reinforce good governance by curbing discretionary practices that give rise to inefficiencies and corruption.

Research by Beverelli and Ticku (2022) shows that trade facilitation improvements contribute to reducing tariff evasion, especially in countries with low corruption control at the border.

Customs valuation

A prominent avenue for illicit trading activity is the misinvoicing of import transactions for money laundering or tax evasion purposes. The WTO's Customs Valuation Agreement (CVA) shores up the aims of transparency and predictability by setting out rules with regard to the proper valuation of medical goods at the border that can help WTO members to detect and prevent misinvoicing.

Product regulation

Illicit traders exploit weaknesses in national regulatory systems to sell medical products that can be substandard or unsafe. The WTO's Technical Barriers to Trade (TBT) Agreement addresses the preparation, adoption and application of conformity assessment procedures (CAPs).

CAPs are key in the fight against illicit trade because they provide governments with the means to verify that medical products comply with quality, health and safety standards and regulations – before, during and after they are placed on the market (see Box 3).

BOX 3

Conformity assessment procedures and the TBT Agreement

The medical product sector is often highly regulated due to the health and safety risks associated with non-compliance with applicable standards and regulations. CAPs may consist of a variety of specific procedures (e.g. sampling, inspection, testing, certification, accreditation) that governments use in order to verify that quality and safety specifications in standards and regulations have been fulfilled. These procedures are often applied in combination with one another.

CAPs can also vary in their levels of stringency, ranging from self-certification to third-party certification. The choice of which CAPs to use will depend on the extent and nature of the risk addressed by the underlying standard or technical regulation against which conformity is being assessed.

In the medical product sector, ill-designed and ill-enforced CAPs can have serious consequences for consumer safety and health. The weaker a CAP, the higher the risk that more non-compliant products will enter the market. This, in turn, can open pathways for illicit trade in medical products that do not meet quality, health or safety standards. Conversely, well-designed and well-enforced CAPs are a crucial element of a country's NQI and are instrumental in efforts to stem the flow of illicit trade in medical products.

The agreement also supports the strengthening of standardization regimes – known as national quality infrastructure (NQI) – and contains important provisions with regard to transparency and the use of international standards.

Intellectual property rights

Illicitly traded medical products may infringe IPRs. In the fight against illicit trade, governments may therefore consider promoting and using IPR enforcement as a complementary tool. The WTO's Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement sets minimum standards for the protection and enforcement of IPRs that guard against illicit trade in IPR-infringing goods (see Box 4).

It mandates critical enforcement tools by tasking members with installing effective border measures, promoting cross-border customs cooperation, and fostering the exchange of information with intellectual property right holders that can help in targeting trade in IPR-infringing goods, while also safeguarding legitimate trade.

Disciplines set out in the TRIPS Agreement offer an array of tools to address the protection and enforcements of IPRs, including where they may be implicated in relation to illicit trade. Box 4 illustrates dimensions of this regime.

BOX 4

TRIPS Agreement disciplines

General intellectual property enforcement standards

- TRIPS is the only WTO agreement to set out minimum standards for enforcement of IPRs
- Sets out members' general obligation to provide enforcement procedures, including injunctions, against IPR infringement
- Puts in place procedural safeguards to protect legitimate trade
- Represents the minimum foundation on which domestic intellectual property enforcement regimes are built

Border procedures

- TRIPS requires members to provide border measures targeting the import of counterfeit and pirated products – this is optional for products infringing other IPRs, as well as for export and goods in transit
- Right holders can trigger customs action to detain infringing goods at the border
- Optional: *ex officio* action by domestic authorities

Criminal procedures

- Criminal procedures must be available against wilful counterfeiting and piracy on a commercial scale
- In appropriate cases, this includes seizure and destruction

Government procurement

Illicit trade can also be implicated in public tenders for goods. The WTO's Government Procurement Agreement prescribes good governance features that assist government parties in alleviating the risks of corruption and specify rules and procedures that mitigate the incidence of illicit trade in the public sourcing of goods.

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Leveraging WTO rules

WTO rules offer a variety of tools to assist members in detecting and regulating the incidence of illicit trade in medical products. These tools are mutually supportive. Identifying the linkages between them, and exploring potential synergies, is critical in addressing the multifaceted threat posed by illicit trade in medical products.

Border controls

Improvements in border controls go hand in hand with regulating product quality, health and safety and enforcing IPRs. Improving border controls is essential to addressing illicit trade in medical products, and the TBT and TRIPS agreements, TFA and CVA all contain provisions that strengthen efficient and secure borders.

These rules and practices are also mutually reinforcing in that a particular trade facilitation improvement – for instance, implementing a robust risk management system – will also improve the ability of customs to target suspect imports due to concerns that such products do not meet quality, health or safety standards and/or infringe IPRs.

Similarly, mechanisms to exchange information between customs and other national authorities, or with the authorities of trading partners, can help to leverage resources in countering illicit trade in medical products through national and international cooperation. The WTO can serve as an important forum in this regard.

Border and regulatory enforcement

The linkages between conformity with IPRs and TBT standards means that border and regulatory enforcement in these areas are especially complementary. Highly regulated products that infringe IPRs can often also be substandard when they fail to comply with quality, health or safety standards (see Box 5).

This indicates that efforts to promote effective IPR enforcement and better regulatory surveillance frameworks can be mutually supportive and in the public interest, especially where enforcement of one set of disciplines leads to better enforcement of the other. It also suggests the potential for increased detection of the same illicitly traded medical goods in instances where both TBT and intellectual property controls are implicated.

BOX 5

Certification marks

As is often the case with medical products, governments may choose to mandate certification in order to inform consumers that certain products meet safety or health regulations.

The unauthorized use or misleading application of certification marks is a crime in many countries and persistent, widespread counterfeiting or falsification of products bearing certification marks can have serious consequences. It erodes consumers' trust that certified products are indeed safe to buy, consume or use, and in the case of medical goods, it can also pose significant risks to the life and health of consumers.

Studies suggest that illicit traders specifically targeted such marks during the COVID-19 pandemic. For instance, they bypassed conformity assessment requirements and placed non-compliant, and thus unsafe, medical products misleadingly bearing certification marks on the market.*

In Europe, there were reports that CE marking** (standing for conformité européenne, it indicates that regulated products met essential safety, health or environmental protection requirements) was applied to counterfeit and non-compliant face masks and test kits.***

The TBT and TRIPS agreements contain tools addressing different yet complementary aspects of certification marks:

- The TBT Agreement addresses regulatory aspects by providing for mandatory certification procedures that enable products to receive the "mark of the system" when they conform with certain specifications.
- The TRIPS Agreement addresses intellectual property aspects by setting out principles for categories of distinctive signs used in national legal systems to protect certification marks (although national practice differs, it may include trademarks, geographical indications and hallmarks or official signs).

Combining and using such mutually supportive WTO rules as the basis for coherent domestic strategies can harness synergies for public interest purposes by integrating better market and regulatory surveillance with the promotion of effective IPR enforcement.

* See https://www.tic-council.org/news-and-events/news/covid-19-tic-council-alerts-about-increasing-number-non-conform-imported-ppes-medical-devices-and-fake-certificates.

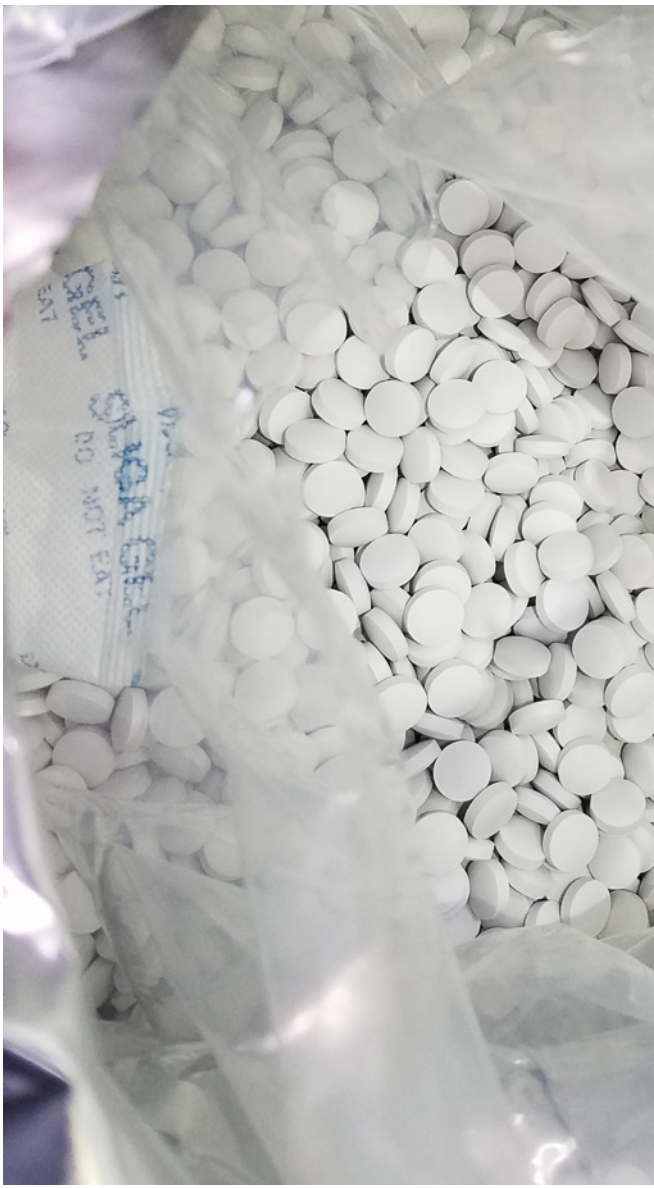
** See https://ec.europa.eu/growth/single-market/ce-marking_en.

*** See Belford *et al.* (2020), Daragahi (2020), (OECD) (2020a,b) and https://www.eu-esf.org/covid-19/4513-covid-19-suspicious-certificates-for-ppe.

Transparency

Transparency rules are important and mutually reinforcing in the fight against illicit trade in medical products. The WTO agreements contain disciplines that seek to foster greater transparency in national laws and practices. This has the benefit of creating greater predictability by alerting legitimate traders to relevant laws and regulations while reducing the opportunities for illicit trade in medical products that come with border and regulatory uncertainty.

Moreover, the existence of concurrent sets of transparency obligations in various WTO agreements increases the opportunities for information exchange and cooperation among customs authorities and national regulators. These measures can be supplemented by transparency tools that promote dialogue among stakeholders regarding relevant medical product and market notifications (see Box 6).



BOX 6

ePing – Global alert system for SPS and TBT notifications

Making good use of transparency tools is critical to addressing illicit trade in medical products. A joint initiative of the WTO, the International Trade Centre and the United Nations, the ePing SPS & TBT Platform is a publicly available website that includes an email alert service on WTO notifications covering products and markets of interest. It also allows stakeholders to discuss and share information on notifications at the national and international level.

By promoting early and better access to proposed standards and regulations, at a stage when they are still being drafted, this tool enhances member engagement bilaterally or at WTO committees with respect to proposed measures. This leads to better information exchange and improved regulatory outcomes in the fight against illicit trade in medical products.

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