



# Tackling illicit trade in medical products

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Better international cooperation for better health

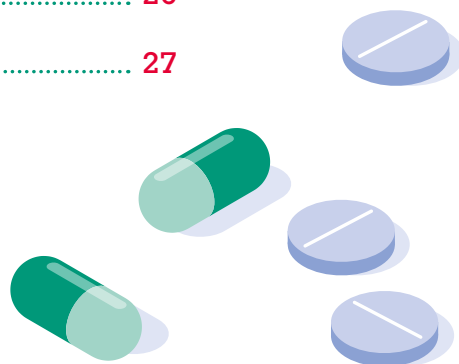
The World Trade Organization (WTO) is the international body dealing with the global rules of trade between nations. Its main function is to ensure that trade flows as smoothly, predictably and freely as possible, with a level playing field for all its members.

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# Foreword

by Director-General  
Ngozi Okonjo-Iweala

I have long been concerned by illicit trade. As Finance Minister in my home country, Nigeria, I witnessed how it harms societies and impedes economic growth and development. Although the full scale of illicit trade is often obscured by its clandestine nature, there is little doubt about its impacts. Spurious products threaten people's health as well as their livelihoods. Illicit trade undermines legitimate business activity, abets corruption, and acts as a drain on the revenue and resources governments need to address critical social and economic priorities. And when illicit traders join forces with corrupt officials and financiers, the negative impacts are amplified. Illicit trade leaves no country, developing or developed, untouched.

During the COVID-19 pandemic, especially early on, high demand and limited supplies of vaccines and other medical products created weaknesses for illicit traders to exploit. New structural challenges also came into view. Illicit traders seeking to profit from lockdowns, trade restrictions and supply chain disruptions compromised the integrity of distribution channels. The acceleration of digital trade – and hence of online transactions and smaller parcels – made it easier to operate in the shadows. Ignoring these challenges will cede greater space to illicit activity, and could limit our ability to cope with future health crises.

While the WTO exists to provide rules for licit trade, it is also a crucial ally in the fight against illicit trade. This publication, which focuses on illicit trade in medical products, outlines key areas where the WTO can support members in fashioning policy responses – by strengthening



border controls and product regulations and promoting balanced intellectual property enforcement. Illicit trade is a complex, multifaceted problem, and wider efforts are needed to deepen domestic coordination and international cooperation, and provide the technical assistance needed to build national and multilateral capacity.

Behind every challenge lies an opportunity. Even as the pandemic continues to take lives and expose weaknesses in markets and governance structures, it also provides a fresh chance to tackle persistent policy challenges like illicit trade. When governments improve trade practices and cooperation, they benefit from a “double dividend” by strengthening their ability to fight illicit trade while expanding legitimate trading opportunities and building resilience against future shocks to the multilateral trading system.

I hope this publication will prompt a dialogue with members and other stakeholders on how the WTO can help in the fight against illicit trade.

**Dr. Ngozi Okonjo-Iweala**  
Director-General

# Executive summary

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## **Illicit trade in medical products is a complex, global problem that poses a serious threat**

Measuring illicit trade is challenging but WTO estimates indicate that illicit trade in medical products constitutes between 1.3 per cent and 4.2 per cent of global trade in the sector. Available evidence suggests that such activity may have expanded during the COVID-19 pandemic, with a 5 per cent increase in seizures reported in 2020 compared with 2019.

More generally, illicit trade in medical products presents a number of health, social and economic impacts, complicating the achievement of the United Nations Sustainable Development Goals (SDGs), particularly those relating to poverty and health outcomes.

## **WTO rules and trade policy activities should be part of a global, multifaceted strategy**

Key WTO rules include those that improve customs procedures, promote coherent regulatory frameworks, and protect and enforce intellectual property rights (IPRs). Complemented by the work of WTO councils and committees, such as the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS), the Trade Facilitation Committee and the Committee on Technical Barriers to Trade, these measures support the fight against illicit trade by promoting transparency and setting the foundation for strengthened border

and regulatory controls. They also aid in curbing discretionary or sub-optimal practices that give rise to inefficiencies and corruption.

## **The WTO offers a strong framework to help members establish mutually reinforcing layers of oversight**

Reforms to strengthen border controls associated with trade facilitation measures go hand in hand with efforts to improve the conformity of medical products with quality, health and safety regulations and the protection and enforcement of IPRs. These rules can be mutually supportive by providing multiple layers of border and regulatory oversight that offer enhanced prospects for the detection of illicitly traded medical goods. In addition, the collection of transparency provisions across WTO agreements promotes cooperation between customs authorities and national regulators and the exchange of information needed to detect and stop illicit trade in medical products.

## **Developing country and least-developed country (LDC) members need improved capacity**

The WTO Secretariat provides technical assistance to support border reforms, the infrastructure that underpins standardization, such as national quality infrastructure (NQI), and

IPR enforcement. Other means are also available. The WTO's Trade Facilitation Agreement has a built-in mechanism of assistance to implement reforms, including those most needed in addressing illicit trade concerns.

Developing country members can also make greater use of existing mechanisms to request advice and technical assistance from other members on matters relevant to illicit trade, such as strengthening NQI or effectively using IPR-related tools, and a dedicated mechanism for NQI capacity building could also be developed.

### **Greater coordination within and between members, as well as among international organizations, is required**

Existing WTO mechanisms can serve to combat illicit trade in medical products by promoting greater interaction between customs authorities and regulators within countries as well as across borders. As national bodies mandated to implement trade facilitation reforms, national committees on trade facilitation (NCTFs) offer great potential for domestic coordination by involving broad stakeholder representation, including all relevant border and regulatory agencies and the private sector.

Some developing members have joined resources to establish regional committees which offer the potential to further integrate sound border practices both domestically and regionally. Improved international cooperation, with the support of international organizations, can also build on WTO rules that require or promote transparency, information exchanges and the designation of contact points, or urge reliance on international standards in harmonizing good governance practices. WTO committees also have untapped potential as a venue for the exchange of information and best practices.

### **The rise of e-commerce poses challenges and opportunities**

WTO rules and activities offer tools for members to adapt to the emergence of the digital economy. Members can optimize the use of reforms, such as implementing risk management systems, which improve the ability of customs to target suspect imports, even small consignments sold through digital platforms, while also addressing border and regulatory concerns related to illicit trade in medical products.

This can be combined with the development of new e-commerce rules, such as those being discussed in the WTO Joint Initiative on Electronic Commerce, and efforts to adopt advanced technologies like blockchain and artificial intelligence (AI) to secure and improve border and regulatory controls.

### **Supply chain disruptions create uncertainty that can be exploited**

WTO rules and activities assist members in managing supply chain disruptions. Strengthening border and regulatory practices also helps members safeguard supply chain integrity by helping them manage disruptions in the trade and distribution of key medical products that have generated illicit trading opportunities during the pandemic.

These measures can be combined with the use of advanced technologies to promote automation and improve data quality so that information can be shared and used to bolster supply chains and combat illicit trade.

# 1

## Problem of illicit trade in medical products

### KEY POINT

Measuring illicit trade and its impact is challenging; illicit trade in the medical product sector adversely impacts poverty and health.

### The international community is still reeling from a devastating pandemic

In a little over two years, the COVID-19 virus has caused over 6 million deaths, and surviving communities continue to endure the health, economic and social consequences. The challenge for the medical sector has been the ramping up and diversification of production and distribution of needed medical

technologies – vaccines, diagnostics, therapeutics and personal protective equipment – to diagnose, treat and protect populations from the ravages of the virus.

As WTO Director-General Ngozi Okonjo-Iweala noted in 2021, 80 per cent of global vaccine production was concentrated in only 10 countries, in Europe, North America and South Asia; whereas Latin America had 2 per cent of global production capacity and Africa had less than 0.2 per cent.

The pandemic has drawn attention to the medical product sector – in particular, the causes and consequences of the uneven distribution, disruptions and shortfalls of critical resources. In this context, the perils associated with illicit trade have faced fresh scrutiny (see Box 1).

**“Illicit trade in medical products threatens human welfare, endangering the health and safety of people and denying them critical resources.”**



## Illicit trade in medical products poses a persistent and evolving threat

Illicit trade in medical products threatens human welfare, endangering the health and safety of people and denying them and communities of critical resources. It undermines legitimate economic activity and leads to revenue and reputational losses for businesses that stifle product development and innovation. It deprives governments of the revenue for public investment and the resources needed to ensure good governance and freedom from corruption.



### BOX 1

#### Defining illicit trade

For the purposes of this publication, “illicit trade” is broadly understood as the selling of goods in violation of national and/or international laws, which is meant to cover goods that are illegal due to their characteristics, as well as those that contravene laws by virtue of how they are produced, distributed, marketed, labelled, identified, certified or sold.

Reference is also made to trade in “counterfeit” goods as a subset of illicit trade. In the WTO context, counterfeit trademark goods are goods involving slavish copying of trademarks. They are goods that give the false impression of being the genuine product originating from the genuine manufacturer or trader (see, for a definition, footnote 14(a) to Article 51 of the TRIPS Agreement).

#### Inherently clandestine in nature, illicit trade is difficult to measure

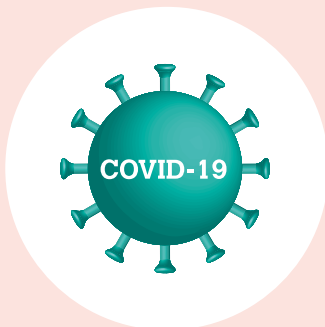
Methodologies to quantify the magnitude of illicit trade consist mainly of extrapolating from customs seizure data concerning IPR-infringing goods, or by examining discrepancies in reported import and export data (see Box 2). Although both approaches have limitations and do not lead to clear trend analysis, a few estimations reveal the nature and scope of the illicit trade problem.

**BOX 2****Illicit trade in numbers****Overall illicit trade (2019)****US\$ 535 bn****2.8% total world trade****Loss in tariff revenue US\$ 87 bn**

According to WTO estimates, the overall amount of illicit trade as measured through misinvoicing (i.e. discrepancies between reported imports and reported exports) was US\$ 535 billion in 2019, representing 2.8 per cent of total world trade in goods in that year. WTO estimates of global tariff revenue losses from illicit trade relating to misinvoicing amounted to US\$ 87 billion in 2019.

**Illicit trade in pharmaceutical products (2019)****US\$ 9-28 bn****1.3-4.2% total value  
of pharmaceutical trade**

The WTO estimates a range of illicit trade in pharmaceutical products as measured through misinvoicing between US\$ 9 billion and US\$ 28 billion in 2019, representing between 1.3 per cent and 4.2 per cent of the total value of trade of pharmaceutical products in 2019.\*

**Seizures of pharmaceutical products during COVID-19****↗ 5%****higher in 2020 vs 2019**

The average value of customs seizures of counterfeit and stolen medicines grew by 5 per cent in 2020 (OECD/EUIPO, 2021). WCO customs seizure data also shows increased illicit trading activity over this period (WCO, 2022).

\* These estimates are based on import/export data of pharmaceutical products as defined by the WTO Agreement on Trade in Pharmaceutical Products.

## Impact for people of illicit trade in medical products

The effort to assess the impact of illicit trade in medical products on the lives and livelihoods of people has been more qualitative in nature. A 2017 report by the World Health Organization identifies key public health impacts such as the effects incorrect ingredients have in producing toxicities or a lack of efficacy, generating increases in mortality, morbidity and the prevalence of disease (WHO, 2017). It also noted various economic impacts, including increased health care spending and costs, losses for those in legitimate medical product supply chains, and the increased burden for health care professionals, regulatory authorities and law enforcement.

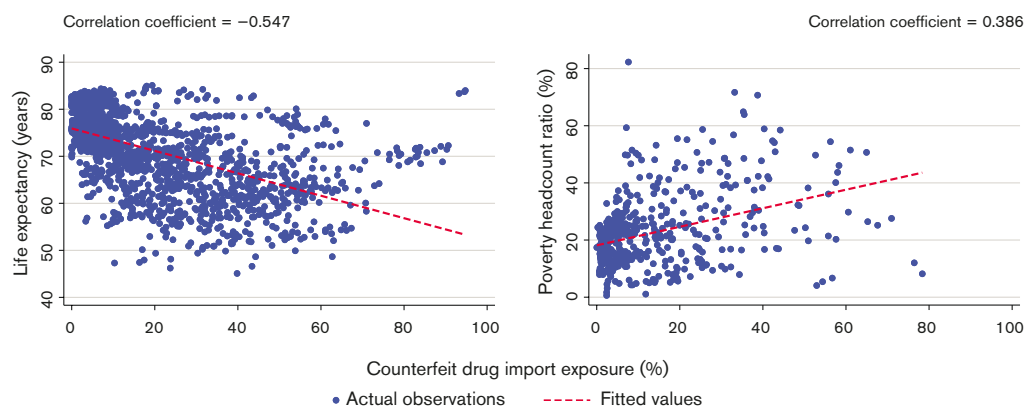
The larger socioeconomic impacts consist mainly of lost productivity and income due to prolonged illness or death, and a corresponding lack of

social mobility and increased poverty. This is supported by WTO analysis which shows a correlation between the use of imported counterfeit medical products and poverty and poor health outcomes (see Figure 1).

## Improving the quality of trade data

The use of trade statistics to assess illicit trade in medical products and its impact could be improved by increasing the quality of reported data, reporting import data net of any trade costs and increasing the level of disaggregation of data on cross-country input–output linkages. Greater collaboration between stakeholders, including intergovernmental organizations, national authorities and the private sector would be helpful in this effort.

**Figure 1: Correlations between exposure to counterfeit pharmaceutical imports and selected SDG indicators**



*Note:* WTO Secretariat calculations based on World Bank World Development Indicators, Trade Data Monitor and GTRIC-e (General Trade-Related Index of Counterfeiting for economies) data from table 4.1 in OECD/EUIPO (2020). In the right panel, the poverty headcount ratio is expressed at national poverty lines, as per cent of the population.

# 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.

**“WTO rules support efforts to address the threat of illicit trade by promoting transparency and predictability, strengthened border and regulatory controls, and enhanced cooperation.”**

**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)
<b>Reducing incentives/opportunities for illicit traders in medical products by increasing transparency and predictability and streamlining and automating customs procedures</b>	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)
<b>Directing proper resources to the detection of illicit trade practices by managing risks through pre- and post-import activities of medical products</b>	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)
<b>Enhancing the ability to combat illicit trade in medical products by advancing national coordination and international cooperation efforts</b>	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.

## 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.

**“WTO rules offer a variety of tools to assist members in detecting and regulating the incidence of illicit trade in medical products.”**

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](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.

<https://epingalert.org>



# 3

## WTO rules and activities to enhance cooperation and build capacity

### KEY POINT

Making effective use of WTO rules to tackle illicit trade relies on greater coordination within and among members and building capacity in developing country members.

Illicit trade in medical products is a multifaceted problem which requires domestic coordination and international cooperation, and involves both the public and private sector.

The TBT and TRIPS agreements and the TFA and CVA each contain provisions that require or encourage interaction between customs authorities and regulators, and this can occur between domestic agencies and stakeholders within and among WTO members.

This is an area where greater dialogue and exchange of information can improve how the customs authorities and regulators operate, thereby mitigating the harms of illicit trade in medical products.

**“Greater dialogue and exchange of information can improve how customs authorities and regulators operate – thereby mitigating the harms of illicit trade.”**

## National committees on trade facilitation

National committees on trade facilitation (NCTFs) can play a critical role in addressing concerns relating to illicit trade in medical products. All WTO members are required under the TFA to set up an NCTF to facilitate domestic coordination and implementation of trade facilitating laws and policies.

This has tremendous potential to improve domestic border and regulatory controls with regard to medical goods because it allows for the sharing of information within and among NCTFs and involves broad representation by stakeholders, including all relevant border and regulatory authorities and the private sector.

In some regions, members have joined resources to establish regional committees. This has the potential to integrate effective border practices not only domestically both also at the regional level (see Box 7).

## International cooperation

WTO rules create multiple avenues for international cooperation and the exchange of information that can assist members in the fight against illicit trade in medical products. Several WTO agreements provide for international cooperation between customs and regulatory authorities:

- The TFA contains mechanisms:
  - to share information on best practices;
  - to coordinate procedures at border crossings;
  - to cooperate in instances where customs authorities question import or export declarations.
- The TRIPS Agreement requires the exchange of information and cooperation between customs authorities with regard to counterfeit and pirated medical goods.
- The TBT Agreement does not have explicit rules on regulatory cooperation but promotes such cooperation, including with respect to CAPs, and information exchanges through its transparency provisions.
- The TBT and TRIPS agreements and the TFA also contain provisions requiring the designation of contact points for purposes of all international cooperation matters.

### BOX 7

## Regional NCTF coordination

Developing country members have set up regional NCTFs to enhance intra-regional trade coordination in three regional settings: the East African Community (EAC), the Economic Community of West African States (ECOWAS) and the Caribbean Community (CARICOM).

Even in instances where NCTFs have not been set up on a regional basis, members can still benefit from dialogue with other NCTFs to exchange information and best practices.

At present, fewer than half (45 per cent) of NCTFs have indicated that they are in contact with other NCTFs in their region. Greater coordination among NCTFs will lead to exchanges of information and best practices that will help support smoother and more effective border management, including with respect to trade in medical goods.

*Source:* See <https://unctad.org/topic/transport-and-trade-logistics/trade-facilitation/committees-around-world>.

## International standards

Reliance on international standards also helps members tackle illicit trade in medical products. The TBT and TRIPS agreements and the TFA urge recourse to or incorporate international standards in different contexts.

The aim is to foster cooperation on the basis of common practices to address various policy challenges, including those relating to illicit trade.

Aligning international practices, for example, can help countries work together to trace the sources of illicit medical goods, and customs and regulatory cooperation can be used to further support market surveillance and enforcement efforts across different jurisdictions.

## WTO councils and committees

WTO councils and committees provide useful forums to address illicit trade concerns and to share information on domestic practices. WTO members can utilize their involvement with various WTO councils and committees to share experiences and strengthen implementation and cooperation in the trade of medical goods:

- The Trade Facilitation Committee allows for the monitoring of customs reforms with a clear nexus to illicit trade in medical products;
- The TBT Committee has already witnessed exchanges on specific trade concerns relating to illicit trade in medical products;
- The TRIPS Council has served, for example, as an important forum for discussion on the impact of IPR legislation and enforcement on medical goods in transit.

Dialogue across these committees and council may serve as an additional opportunity for the sharing of experiences on illicit trade matters involving medical products.

## Developing country assistance

The WTO Secretariat is well placed to assist developing country members in strengthening their capacity to face the challenges posed by illicit trade in medical products.

There are various avenues available to provide developing country members, and in particular LDCs, with the information, training and development assistance that can solidify implementation efforts and promote the development of sound institutions and processes that will reduce the incentives for corrupt or illicit trading behaviour in medical products.

Developing country members may request technical assistance and capacity building to implement TFA commitments that are crucial in the fight against illicit trade in medical products.

Developing country and LDC members have the right to self-determine when they will apply specific provisions of the TFA, and to designate those commitments for which they are requesting a transition period together with assistance and support for capacity building.

This is of crucial significance, particularly as it relates to some of the TFA commitments that are most helpful in addressing illicit trade in medical goods, such as the implementation of risk management and a single window.

Two-thirds of developing country and LDC members have indicated they need technical assistance to implement a single window, and around half have requested such assistance to implement a risk management system.

In addition, developing country and LDC members may also have recourse to the TFA Facility, which can support them in assessing their specific needs and in identifying possible development partners to help them meet those needs.



The WTO Secretariat provides training to government officials on all matters relevant to its. The WTO Secretariat also provides technical assistance to developing country and LDC members to address illicit trade in medical products.

As part of its ongoing technical assistance programmes, the WTO Secretariat provides training to government officials on all matters relevant to trade policy activities, including, improving border controls, designing and improving regulatory frameworks and NQI, and enforcing IPRs.

The WTO Secretariat also participates in other more broad-based conferences and information sharing sessions, which can also involve the participation of other international organizations and private sector representatives. Box 8 provides further information on how the WTO helps members fight illicit trade in medical products.

Developing country and LDC members may also request assistance from other members to fight illicit trade in medical products, such as implementing and improving NQI or IPR enforcement.

WTO members with experience in countering illicit trade in medical products could support the strengthening of capacities of those members that have gaps in their customs or regulatory systems and help narrow opportunities for illicit traders of medical goods.

While LDC members are not yet under an obligation to implement the TRIPS Agreement, they may still benefit from advice and assistance where they undertake to implement and use such enforcement tools on a voluntary basis.



A chemist prepares to test the melting point of chemical compounds in drug samples for identification purposes.

## TBT coordination

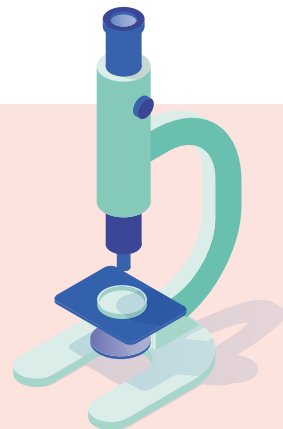
A dedicated TBT coordination mechanism for NQI-related capacity building could enable the WTO to make a greater contribution to fighting illicit trade in medical products.

As contemplated by the TBT Committee, the model of the Standards and Trade Development Facility could be used to develop a TBT coordination mechanism for NQI-related capacity building in cooperation with other organizations.

Material support for the NQI, especially in LDC members, would strengthen regulatory authorities and their ability to enforce quality, health and safety regulations and help to stem the flow of illicit trade in medical products.

## BOX 8

## A closer look at how the WTO helps members fight illicit trade in medical products



### Digital trade

During the course of the COVID-19 pandemic, the use of e-commerce platforms to conduct trade has accelerated, with retail e-commerce sales worldwide projected to increase from US\$ 3.3 trillion in 2019 to US\$ 5.5 trillion in 2022.\* This has posed new challenges in the fight against illicit trade in medical products.

While the rise of e-commerce has generated immense benefits for customers and businesses (in particular for micro, small and medium-sized enterprises) wishing to access new markets, it has also allowed illicit traders to exploit new vulnerabilities.

In particular, high volumes of small consignments of medical goods have posed significant challenges to customs authorities and regulators seeking to implement effective border or post-market controls.

These developments have been documented with regard to medical products during the pandemic period, in particular fake and substandard medicines, test kits, masks and other COVID-related goods.

### Making effective use of existing frameworks

Improving border controls is essential to address illicit trade in medical products, and several provisions of the WTO agreements are mutually reinforcing in strengthening efficient and secure borders.

The advent of risk management systems is of particular significance in dealing with digital trade, since improving the ability of customs to target suspect imports – including small consignments sold through digital platforms – may also address border and regulatory concerns relating to illicitly traded medical products.

### Developing new e-commerce rules and practices

Certain WTO developments may also require increased attention with the rise in e-commerce. Negotiations among a large group of WTO members on e-commerce aim to create a more secure and predictable environment for digital and online trade, including by promoting reliance on paperless processes.

This could lower the incidence of illicit trade in medical products by reducing the opportunities for falsified documentation and the frequency of interactions that can give rise to corruption and other illicit activity at the border.

At the same time, certain areas – such as in the case of small quantities of medical goods that may not be subject to mandatory IPR enforcement under de minimis rules – may pose new challenges in regulating illicit trade in medical products in a digital trading environment.



## Utilizing innovations in advanced technologies and data management

Customs authorities have increasingly relied on advanced technologies, such as the use of blockchain and AI, to establish more accurate and secure transaction records and to achieve greater efficiency and reliability in risk management systems.

These innovations not only ensure better and more secure data with regard to legitimate trade, but also strengthen customs and regulatory oversight in a manner that reduces opportunities for illicit traders in medical products.

Although half of customs authorities currently use some form of data analytics, for example, the clear benefits of using these systems, including in detecting illicit trade in medical products, indicates that more work remains to be done.

The success of these developments depends on quality data, and thus efforts must also focus on collecting and digitizing better quality data, so that it can be shared, used to trace medical products across the supply chain and then fed back into risk management systems.

## Supply chain integrity

Over the course of the COVID-19 pandemic, surges in demand and the imposition of lockdowns, border closures and other restrictions disrupted trade, including of key medical products. Such disruptions to the functioning of supply chains have been exploited by illicit traders in medical products.

## Strengthening customs controls can safeguard the supply chain integrity of medical products

At times when unmet demand and new restrictions hand illicit traders in medical products new vulnerabilities to exploit, it is particularly critical to maintain and strengthen existing enforcement mechanisms.

In particular, the tools available to right holders and governments to guard against trade in IPR-infringing medical products remain especially pertinent, as does securing strong NQI systems and border processes.

Even more fundamentally, all of the obligations pertaining to transparency and border and regulatory controls stabilize the trading environment in medical products to minimize supply chain disruptions.

## Adapting new approaches to supply chain management can thwart the efforts of illicit traders in medical products

The innovations in customs processes due to automation and technology that aid WTO members in addressing illicit risks in digital trade also help in securing supply chains, and trade facilitating measures that prioritize digitalization (e.g. online processes and single window requirements) are especially important in that regard.

Customs authorities have begun to adopt blockchain, AI and other technologies to ensure secure and quality transaction data that can be more easily shared. However, further work remains to be done.

In addition, WTO rules recognize the importance of allowing for checks that can occur prior to (e.g. authorized operator provisions) or following (e.g. post-market surveillance) importation, and this allows for more targeted controls that minimize supply disruptions. Initiatives to undertake product traceability could also be critical in limiting the entry of illicit medical products into the supply chain.

\*Source: <https://www.statista.com>.

# 4

## Potential next steps in the fight against illicit trade



Tackling illicit trade in medical products requires a global and multifaceted response, and the WTO offers a strong framework to anchor the trade-related features of that response.

The convening power of the WTO and the coordinated use of its tools and trade policy activities is thus crucial for members in addressing a host of pandemic-related and other challenges.

### Future policy actions

The following is a set of policy actions that WTO members and other stakeholders may consider in developing and strengthening trade policy responses to combat illicit trade in medical products.

**Promote recognition and understanding of how illicit trade in medical products** threatens people's health and safety and undermines economic growth and development opportunities for people and societies.

**Coordinate efforts with the public and private sectors** to improve the quality and analysis of data on trade in medical products.

**Raise awareness of the value of WTO rules and trade policy activities** in the fight against illicit trade in medical products.



**Strengthen data collection** and encourage sharing to harness the full potential of risk management and other trade tools to limit opportunities for illicit trade in medical products.

**Explore the use of modern digital tools** in supporting efforts by border and regulatory authorities to tackle the particular challenges posed by e-commerce in the fight against illicit trade in medical products.

**Use WTO rules and activities to bolster border and regulatory controls** of medical goods to manage supply chain disruptions and to encourage the use of such measures – in addition to advanced technologies – to safeguard supply chain integrity and combat illicit trade.

**Exploit existing WTO mechanisms, among others, to encourage greater cooperation** on illicit trade in medical products within and between WTO members and among international organizations, from the micro level of sharing data and information on illicit trade activity to the macro level of sharing best practices and coordinating policy responses.



**Strengthen dialogue and exchange of information** on illicit trade in medical products across relevant WTO committees.

**Support a coordinated, multilateral response** to illicit trade in medical products by ensuring the delivery of training, resources and other technical assistance to strengthen the capacity of developing country and LDC members.

**Consider the development of new training forums** such as a dedicated mechanism for national quality infrastructure capacity building.

# Abbreviations

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<b>CAP</b>	conformity assessment procedure
<b>CVA</b>	Customs Valuation Agreement
<b>IPR</b>	intellectual property right
<b>LDC</b>	least-developed country
<b>NCTF</b>	national committee on trade facilitation
<b>NQI</b>	national quality infrastructure
<b>SDG</b>	Sustainable Development Goal
<b>SPS</b>	sanitary and phytosanitary
<b>TBT</b>	technical barriers to trade
<b>TFA</b>	Trade Facilitation Agreement
<b>TRIPS</b>	trade-related aspects of intellectual property rights



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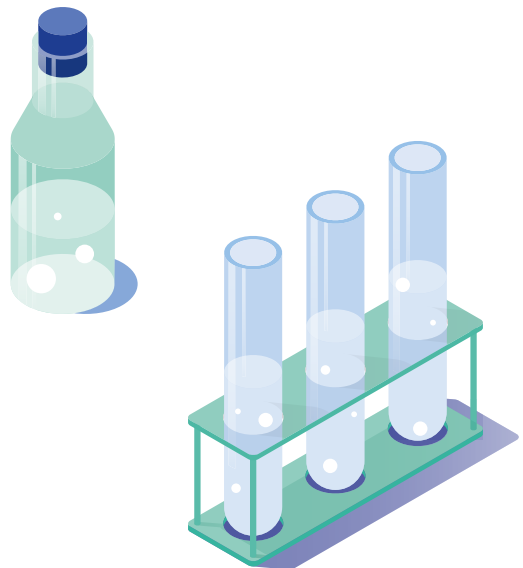


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# Tackling illicit trade in medical products

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**Better international cooperation for better health**

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

This publication explores WTO tools and activities that can help WTO members develop and strengthen their trade policy responses to combat illicit trade in medical products.

