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

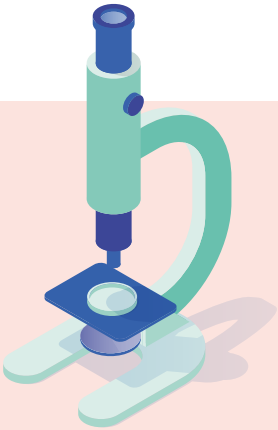
A dedicated TBT coordination mechanism for NQI-related capacity building could enable the WTO to make a greater contribution to fighting illicit trade in medical products.

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.