Pharmaceuticals Policy and Law 18 (2016) 67–78
DOI 10.3233/PPL-160433
IOS Press

Breaking New Ground: The WTO Agreement on Trade Facilitation[1]

Potential and Perspectives for the Pharmaceutical Industry

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Recently adopted, the WTO Agreement on Trade Facilitation (TFA) adds fresh momentum to worldwide efforts to speed up the movement, release and clearance of goods across borders. With all required decisions having now been taken in Geneva, preparations are under way to ensure the Agreement's expeditious entry into force. Once in operation, this ground-breaking treaty will significantly accelerate cross-border trade and reduce related costs.

This article analyses the TFA from a pharmaceutical angle, highlighting provisions of particular interest to the industry. It will look at how the new Agreement is likely to impact trade in medical goods and where business stands to benefit. A final segment will review governments' implementation plans and discuss the road ahead.

Keywords: Cutting red tape, expedited clearance, perishable goods, pharma trade, trade facilitation, ratification, WTO Agreement on Trade Facilitation, WTO negotiations on Trade Facilitation

1. Setting the stage

When Chairman Gita Wirjawan hit the gavel at the WTO's Ninth Ministerial Conference in Bali to signal the conclusion of the trade facilitation (TF) negotiations, it was met with enthusiasm, but also relief. The decision marked the end of an undertaking that had occupied the WTO's membership for almost a decade and which some had begun to fear might never actually be accomplished.

In addition to ending the TF talks, ministers set out a road map for implementing the new Accord and mandated related preparatory work, which commenced shortly afterwards. Two and a half years on, major milestones have been met and the Agreement is close to entering into force. It will usher in a new era of trade facilitation reforms and substantially expedite cross-border trade.

The article examines how the new treaty will impact the operations of the pharmaceutical industry and traders more broadly. It will identify the provisions most

[1]The views expressed in this article are those of the author alone and do not necessarily reflect the views of the World Trade Organization.

relevant for pharma trade and analyse their likely impact on the pharmaceutical sector. A look will also be taken at where we stand with respect to putting the new Agreement into force.

2. Great expectations

Expectations for the Trade Facilitation negotiations were high from the outset. Launched in August 2004, they were hailed as a "*truly historic achievement*."[1] Reference was made to them as "*the pillar [of the multilateral trading system] that had been lacking*"[2] and as an exercise that would "*affect the welfare of farmers, factory workers, small business people and other producers, consumers and their dependents in all countries*."[3]

The sizable benefits of a WTO Agreement on Trade Facilitation had already been highlighted when Members were debating the terms of a negotiating mandate. Top on the list were cost savings, both in terms of trade transaction- and administrative costs. A strengthened tax and revenue base, together with reduced losses from corruption, were equally sighted as tangible monetary benefits. References were also made to non-financial gains of an agreement, such as enhanced control and enforcement of regulations, an improved investment climate and increased participation in cross-border trade.[4]

3. Trials and tribulations

Despite widespread agreement on the benefits of trade facilitation reforms, the road to the TFA turned out to be a lengthy one. It took a long time to get to the point where the talks could even start: governments needed almost 8 years to move from a first work mandate to the beginning of rule-making, and trade facilitation was only added to the Doha Round after a 3 and a half year delay.[5] The fact that the talks already involved almost 150 Members when they started and were an integral part of a much larger round of negotiations – the Doha Development Agenda – that included almost two dozens of issues, made the environment challenging enough. Added to this was the fact that decisions on trade facilitation, like all WTO negotiating exercises, had to be taken by consensus at every step of the process.

[1] Statement by Supachai Panichpakdi, WTO Director General at that time.

[2] Statement by Bolivia at the General Council meeting where the decision to launch the TF negotiations was taken. (WT/GC/M/87, paragraph 153.)

[3] Statement by Jamaica (WT/GC/M/87, paragraph 126.)

[4] For an overview of the most frequently arguments made, see a submission by the European Communities (WTO document G/C/W/143).

[5] WTO Members needed more time to agree on the negotiating modalities.

Despite these challenges, the TF negotiations were able to get off to a good start and quickly made up for lost time. While subsequent delays and missed deadlines – usually because the pace of the TF process was tied to the broader, slower moving, and more contentious Doha Round – extended their overall duration beyond initial targets, the trade facilitation talks continued to progress and were ultimately even the first large Doha negotiating dossier to make it to the finishing line.

4. What's on the table?

The final text seeks to expedite the movement, release and clearance of goods[6] in several ways. In line with the negotiating mandate, the Agreement builds on the existing legal framework, especially parts of the General Agreement on Tariffs and Trade (Articles V, VIII and X of the GATT, dealing with publication and administration of trade regulations, fees and formalities connected with importation and exportation and freedom of transit, respectively).

A common thread running through virtually all provisions is the attempt to increase transparency and predictability and to reduce discrimination. Many also seek to improve cooperation and coordination.

Most provisions address the trading community in its entirety and cover goods in broad terms. Others have a more specific focus, and therefore a more limited scope. The vast majority of both categories should be of interest to the pharmaceutical industry.

The **first article** of the Agreement seeks to improve access to information, calling for the prompt publication of a series of data[7] in a non-discriminatory and easily accessible manner. Members are further asked to make information available through the internet and to establish enquiry points to answer queries from interested parties – together with the required forms and documents.

Article 2 mandates opportunities for traders to comment on the proposed introduction/amendment of relevant laws and regulations (which further have to be published as early as possible before their entry into force.) In addition, each Member has to provide for regular consultations between its border agencies and traders/other stakeholders.

[6]The coverage also extends to goods in transit. For details, see WT/L/579.

[7]The article mentions (a) procedures for importation, exportation, and transit (including port, airport, and other entry-point procedures), and required forms and documents; (b) applied rates of duties and taxes of any kind imposed on or in connection with importation or exportation; (c) fees and charges imposed by or for governmental agencies on or in connection with importation, exportation or transit; (d) rules for the classification or valuation of products for customs purposes; (e) laws, regulations, and administrative rulings of general application relating to rules of origin; (f) import, export or transit restrictions or prohibitions; (g) penalty provisions for breaches of import, export, or transit formalities; (h) procedures for appeal or review; (i) agreements or parts thereof with any country or countries relating to importation, exportation, or transit; and (j) procedures relating to the administration of tariff quotas.

Transparency, predictability and due process goals underpin the Agreement's subsequent provisions (**articles 3–5**), mandating advance rulings, procedures for appeal or review and other measures to enhance impartiality and non-discrimination.

Article 6 sets out several disciplines on fees and charges imposed on or in connection with importation and exportation, seeking to reduce their number and diversity. Members are also restrained in their ability to impose penalties for a breach of their customs laws, regulations or procedural requirements.

The next article – **7** – is of special significance for the pharma industry. It contains a series of measures to facilitate the release and clearance of goods. The first sets out provisions on pre-arrival processing (article 7:1), calling upon each Member to "*adopt or maintain procedures allowing for the submission of import documentation and other required information, including manifests, in order to begin processing prior to the arrival of goods…* ". Members shall further "*provide for advance lodging of documents in electronic format for pre-arrival processing of such documents*."[8] Provision is also made for electronic payments. According to article 7:2, "*Each Member shall, to the extent practicable, adopt or maintain procedures allowing the option of electronic payment for duties, taxes, fees, and charges collected by customs incurred upon importation and exportation*." The next segment – article 7:3 – calls for the separation of release from final determination of customs duties, taxes, fees and charges. It is followed by language on risk management, mandating Members to adopt or maintain related systems for customs control (article 7:4).[9] Article 7:5 requires the adoption (or maintaining) of post-clearance audit to ensure compliance with customs and other related laws and regulations. Members are further "*encouraged to measure and publish their average release time of goods periodically and in a consistent manner*" (article 7:6). Article 7:7 sets out provisions for authorized operators, calling upon each Member to provide "*additional trade facilitation measures related to import, export, or transit formalities and procedures (…) to operators who meet specified criteria*". They are further required to "*adopt or maintain procedures allowing for the expedited release*" of specified goods[10] (article 7:8).

The last segment of the article – 7:9 – deals with perishable goods and is of particular relevance to the pharma industry. Based on a proposal first presented by Australia, Brazil and New Zealand [1], all WTO Members are mandated to give special treatment to this kind of merchandise, defined as "*goods that rapidly decay due to their natural characteristics, in particular in the absence of appropriate storage conditions*.[11]" In specific terms, Members are obliged to "*provide for the release of*

[8] There is a built-in qualification according to which this has to be done "*as appropriate*".

[9] The provision contains a qualification according to which this should be done "*to the extent possible*".

[10] The article states that this should be done for "*at least those goods entered through air cargo facilities to persons who apply for such treatment*".

[11] Article 7:9 of the TFA, footnote 10. Attempts to come up with a specific list of covered products failed to generate the necessary consensus. The implication for pharmaceutical goods is that some products will fall within the definition, while others will not.

perishable goods: (a) under normal circumstances within the shortest possible time; and (b) in exceptional circumstances where it would be appropriate to do so, outside the business hours of customs and other relevant authorities" [2]. Each Member is further requested to "*give appropriate priority to perishable goods when scheduling any examinations that may be required* [3]." There is also an obligation to "*either arrange or allow an importer to arrange for the proper storage of perishable goods pending their release.*"[12] In cases of significant delay in the release of perishable goods, the importing Member is required – upon written request – to provide a communication on the reasons for the delay. Flexibility with the execution of this obligation is provided by the qualification of that having to happen "*to the extent practicable* [4]".

This proposal had been introduced at a late stage of the negotiating process – indeed, it was one of the last provisions to be added to the text – but received a very positive response. Virtually all delegations supported the idea of special treatment for perishable goods. What took a few months to negotiate were the specifics of how that objective should best be secured. The consensus principle of the decision-making process required Members to find compromises. Several of the initial ideas had to be dropped,[13] but essential elements were retained and made it into the final text. The ultimately agreed language still reflects the different interests that had to be balanced. This can already been seen in the opening paragraph, which sets out the basic objective of the provision – the prevention of avoidable losses or deterioration of perishable goods – but then goes on to state that measures to achieve that end could only be introduced "*provided that all regulatory requirements have been met*." Nevertheless, the core of the original proposal survived and promises to improve trade in those goods noticeably.

Article 8 seeks to encourage border agency cooperation, both within a given country and in dealing with agencies of neighbouring Members with whom a common border is shared.

It is followed by a call to "*allow goods intended for import to be moved within a territory under customs control from a customs office of entry to anther office from where the goods would be released or cleared*" (**article 9**).

Article 10 sets out a series of measures to cut back on formalities connected with importation, exportation and transit of goods. It calls for such formalities – and documentation requirements – to be reviewed with a view to minimizing their incidence

[12] Article 7:9 of the TFA, paragraph 3. The Member may require that any storage facilities arranged by the importer have been approved or designated by its relevant authorities. The movement of the goods to those storage facilities, including authorizations for the operator moving the goods, may be subject to the approval, where required, of the relevant authorities. The Member shall, where practicable and consistent with domestic legislation, upon the request of the importer, provide for any procedures necessary for release to take place at those storage facilities.

[13] See, for instance, the suggestion to allow for consignments of perishable goods to be cleared at the premises of the importer or at the premises of a third party designated by the importer.

and complexity (article 10:1). Members are further asked to accept copies of documents required for import, export, or transit formalities (article 10:2) and encouraged to use international standards as a basis for those formalities and for related procedures (article 10:3). The Agreement also aims to establish 'single windows' in countries, although the related language had to be phrased in best endeavour terms (article 10:4). Practices like preshipment inspection and the mandatory use of customs brokers are subjected to disciplines (articles 10:5 and 10:6). Members are further obliged to apply common customs procedures and uniform documentation requirements for release and clearance of goods throughout their respective territories (article 10:7[14]). Where goods presented for import are rejected on account of their failure to meet prescribed sanitary or phytosanitary regulations or technical regulations, the Member shall, subject to and consistent with its laws and regulations, allow the importer to re-consign or to return the rejected goods to the exporter or another person designated by the exporter (article 10:8). The last component of the article calls for each Member to allow for the temporary admission of goods and for inward and outward processing (article 10:9).

Article 11 sets out a series of requirements to improve the conditions for free transit of goods. They include measures to reduce fees, charges and formalities, and to enhance non-discrimination.

The last article (**12**) prescribing TF reforms seeks to enhance the exchange of information between customs administrations for the purpose of verifying an import or export declaration.

5. Expected impact

Collectively, these measures are expected to have a considerable impact on several levels. Some effects were already being felt even before the negotiations had finished. The launch of the TF talks – and the resulting international focus on the issue – triggered an increase of facilitation reforms. An analysis of TF provisions in regional trade agreements (RTAs), for instance, showed a noticeable rise in their frequency after 2004 [5]. There was also a significant impact on the content side, with more and more TF measures being modelled on the TFA [5].

Most analyses of the benefits of the TFA start with the expected economic gains. A 2013 OECD report predicted that full implementation would result in a 13 to over 15 per cent reduction of total trade costs.[15] This was confirmed by a more recent WTO

[14]The article does allow the continuation of certain practices (specified in article 7:7:2).

[15]Trade Facilitation Indicators: The Potential Impact of Trade Facilitation on Developing Countries' Trade, OECD Trade Policy Working Paper, No. 144, 2013. The precise figures are 14.5% reduction of total trade costs for low income countries, 15.5% for lower middle income countries and 13.2% for upper middle income countries.

study[16] which showed that full implementation of the TFA can reduce Members' trade costs by an average of 14.3 per cent – greater than the trade cost reduction that would flow from the elimination of all remaining applied MFN tariffs. Both variable and fixed costs of exporting were predicted to fall. Over the 2015–30 horizon, implementation of the TFA could add up to 2.7 per cent a year to world export growth and more than half a per cent a year to world GDP growth.

Even larger reductions were anticipated with respect to import and export times. Full implementation of the TFA was projected to reduce time to import by over a day and a half (a 47 per cent reduction over the current average). Cuts in export time were even more dramatic – estimated to be shortened by almost two days (a 91 per cent reduction over the current average).

For time-sensitive goods – where the speed and predictability of delivery is critical – the report found that accelerated cross-border clearance under the FTA would provide an especially major boost to trade.

In addition to its own specific economic benefits, the TFA is also expected to give new impetus to deeper trade facilitation reforms globally. Indeed, it was already generating positive momentum in this direction even before the Agreement entered into force. In recent years, national and regional initiatives have increasingly been developed against the common TFA template and avoided piecemeal approaches that risked incompatibility and incoherence with corresponding reforms in other parts of the world. As economic interdependence deepens – and traders and investors increasingly seek harmonized rules and procedures – this informal 'coordinating' role of the TFA becomes especially significant.

In addition, the TFA offers a guarantee that the reforms it embodies are firmly locked in – giving traders and investors added assurances that the provisions of the new Agreement are permanent ones that cannot being altered by a change in administration. They can further rely on the provisions' enforceability. As WTO rules, the TFA articles are subject to the organization's dispute settlement mechanism, which substantially increases their chances of being effectively implemented and maintained 'on the ground'. The Agreement is further expected to create a culture of cooperation between government and business, and to secure political commitment for additional reforms.

6. What remains to be done?

With the adoption of the amendment protocol[17] (required to integrate the Trade Facilitation Agreement into the existing legal WTO framework), all decisions that

[16] WTO World Trade Report 2015: Speeding up trade: benefits and challenges of implementing the WTO Trade Facilitation Agreement. All subsequently referenced findings are based on this report.

[17] The decision was taken by the WTO's General Council on 27 November 2014. See WT/L/940.

Table 1
WTO Members which have already completed their TFA ratification process

WTO member	Date of deposit
Hong Kong, China	08.12.2014
Singapore	08.01.2015
United States of America	23.01.2015
Mauritius	05.03.2015
Malaysia	26.05.2015
Japan	01.06.2015
Australia	09.06.2015
Botswana	18.06.2015
Trinidad and Tobago	27.07.2015
Korea, Republic of	30.07.2015
Nicaragua	04.08.2015
Niger	06.08.2015
Chinese Taipei	17.08.2015
Belize	02.09.2015
Switzerland	02.09.2015
China	04.09.2015
Liechtenstein	18.09.2015
Lao People's Democratic Republic	29.09.2015
New Zealand	29.09.2015
Togo	01.10.2015
Austria	05.10.2015
Belgium	05.10.2015
Bulgaria	05.10.2015
Croatia	05.10.2015
Cyprus	05.10.2015
Czech Republic	05.10.2015
Denmark	05.10.2015
Estonia	05.10.2015
Finland	05.10.2015
France	05.10.2015
Germany	05.10.2015
Greece	05.10.2015
Hungary	05.10.2015
Ireland	05.10.2015
Italy	05.10.2015
Latvia	05.10.2015
Lithuania	05.10.2015
Luxembourg	05.10.2015
Malta	05.10.2015
Netherlands	05.10.2015
Poland	05.10.2015
Portugal	05.10.2015
Romania	05.10.2015
Slovak Republic	05.10.2015
Slovenia	05.10.2015
Spain	05.10.2015
Sweden	05.10.2015
Thailand	05.10.2015
United Kingdom	05.10.2015

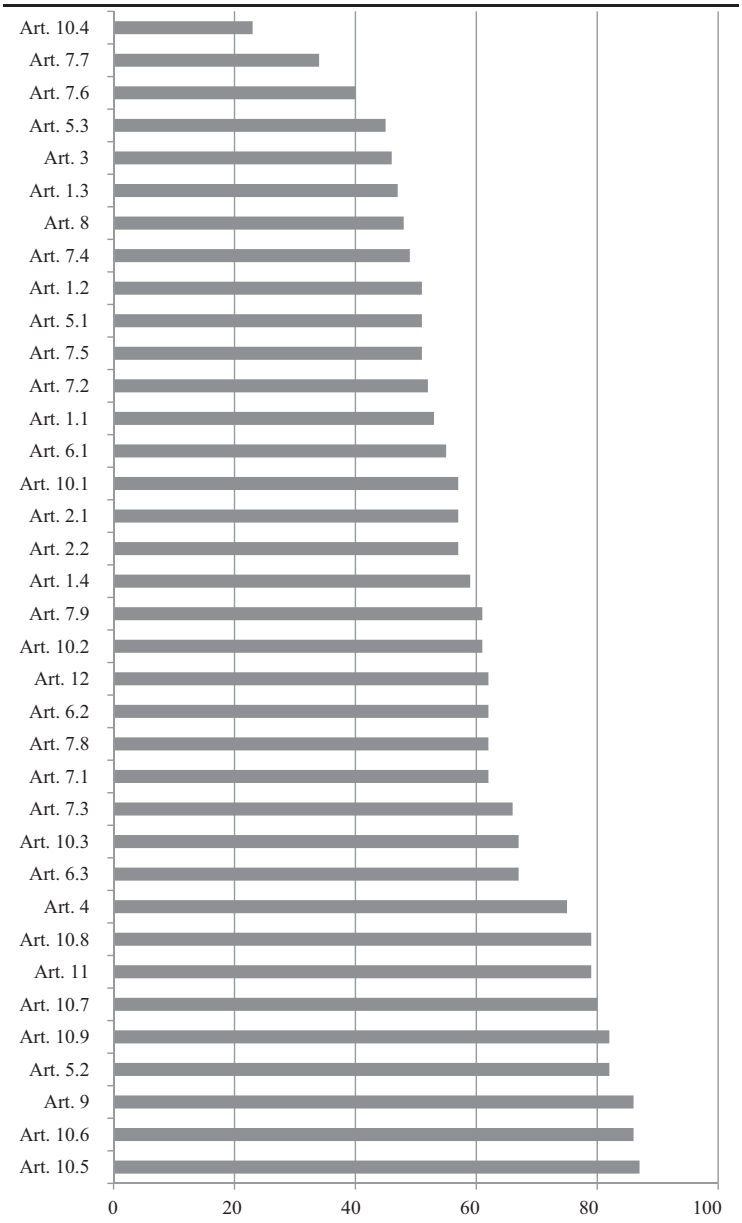
Table 1, continued

WTO member	Date of deposit
The former Yugoslav Republic of Macedonia	19.10.2015
Pakistan	27.10.2015
Panama	17.11.2015
Guyana	30.11.2015
Côte d'Ivoire	08.12.2015
Grenada	08.12.2015
Saint Lucia	08.12.2015
Kenya	10.12.2015
Brunei Darussalam	15.12.2015
Viet Nam	15.12.2015
Myanmar	16.12.2015
Norway	16.12.2015
Ukraine	16.12.2015
Zambia	16.12.2015
Georgia	04.01.2016
Lesotho	04.01.2016
Seychelles	11.01.2016
Jamaica	19.01.2016
Mali	20.01.2016
Cambodia	12.02.2016
Paraguay	01.03.2016
Turkey	16.03.2016
Brazil	29.03.2016
Macao, China	11.04.2016
United Arab Emirates	18.04.2016
Samoa	21.04.2016
India	22.04.2016
Russian Federation	22.04.2016
Albania	10.05.2016
Montenegro	10.05.2016
Kazakhstan	26.05.2016
Sri Lanka	31.05.2016
Saint Kitts and Nevis	17.06.2016
Madagascar	20.06.2016
Moldova, Republic of	24.06.2016
El Salvador	04.07.2016
Honduras	14.07.2016
Mexico	26.07.2016
Peru	27.07.2016
Saudi Arabia	28.07.2016
Afghanistan	29.07.2016
Senegal	24.08.2016
Uruguay	30.08.2016

required consensus by the entire membership were taken. This did not, however, mark the end of the road as it still left steps to be accomplished for the Agreement to enter into force.

At the 2013 Bali Conference, ministers had agreed on a specific ratification threshold for that to take place. By invoking article X:3 of the Marrakesh Agreement, it was

Table 2
Implementation priorities as expressed in category A notifications (percentage of overall category A notifications)



decided that two thirds of all WTO Members had to complete their respective domestic processes for the TFA to take effect. Work on ratification started immediately after the adoption of the amendment protocol, and acceptance instruments began to come in. As of 13 September 2016, their number had grown to 92, representing almost 85 per cent of what is needed for the Agreement to enter into force. More instruments are close to being submitted, creating reasonable hopes for the TFA to take effect soon.

Work on implementing the embodied reforms has already begun. Developed countries are getting ready to apply the entire Agreement as of day one. Developing and least-developed Members were allowed to design flexible implementation schedules. While equally obliged to implement the entire Agreement, they have the possibility to determine time frames and required capacity building support. The technical way of doing this is to group all measures into three categories:

- "A" containing provisions designated for implementation as of the day the Agreement enters into force,[18]
- "B" for provisions that require more time for their implementation and
- "C" for provisions whose implementation necessities both additional time and capacity building support.

Many such A, B and C notifications have already been submitted, especially with respect to category A. They give a good indication of when we can expect to see the TFA fully implemented, and which of its measures are considered to be a priority.

An analysis of how measures of particular interest to the pharmaceutical industry are classified reveals that most will be applied expeditiously (see Table 2).

Taken together, the state of the ratification and notification process to date paints a promising picture – and suggests that the Trade Facilitation Agreement is already starting to bring its many benefits to the business world.

Acknowledgements

I would like to thank WTO Deputy Director General Xiaozhun Yi for having taken the time for a review. Suja Rishikesh-Mavroidis provided very useful comments and suggestions. Thanks are also due to María Alvarez de Cozar who prepared the input used for the second table.

References

[1] TN/TF/W/184, submitted on 5 December 2012.

[18] Least-developed countries are given additional time to comply with all related category time-frames. For details, see articles 14 – 16 of the TFA.

[2] Article 7:9 of the TFA, paragraph 1.
[3] Article 7:9 of the TFA, paragraph 2.
[4] Article 7:9 of the TFA, paragraph 4.
[5] Neufeld Nora, Trade Facilitation under the Regional Trade Agreement Umbrella: Origins and Evolution, in: Regional Trade Agreements and the Multilateral Trading System, edited by Rohini Archaya, Cambridge University Press, 2016.