Pharmaceutical Manufacturing Resilience in EU

July 2020

teva

Executive Summary

Teva is **the world and European leader** in generic pharmaceutical manufacturing.

Teva's manufacturing facilities in Europe produce **93%** of its finished products sold on the continent.

Additionally, Teva api, one of its subsidiaries, produces **53%** of the active pharmaceutical ingredients (APIs) Teva uses in Europe, 40% of which are manufactured in its European facilities.

As a strategic partner, Teva provides an important contribution to the continent's manufacturing resilience. A resilient system is designed with the capability to suffer minimum production loss during disruptions. Manufacturing resilience relies on flexible and productive people and machines and requires investments to keep a healthy manufacturing network running at all time. However, until now, the European context has not been the most favourable for measures intended to secure supply, especially for commoditised products, such as generic or biosimilar medicines.

To guarantee the European continent's manufacturing resilience, autonomy and diversity, including security of supply, Teva believes that European manufacturers must have the means to financially sustain their manufacturing activities on the continent. Europe must move away from healthcare systems' unsustainable preference for the lowest cost generic option, which does not account for companies' investments to secure supply and/or comply with Europe's key transformative priorities.

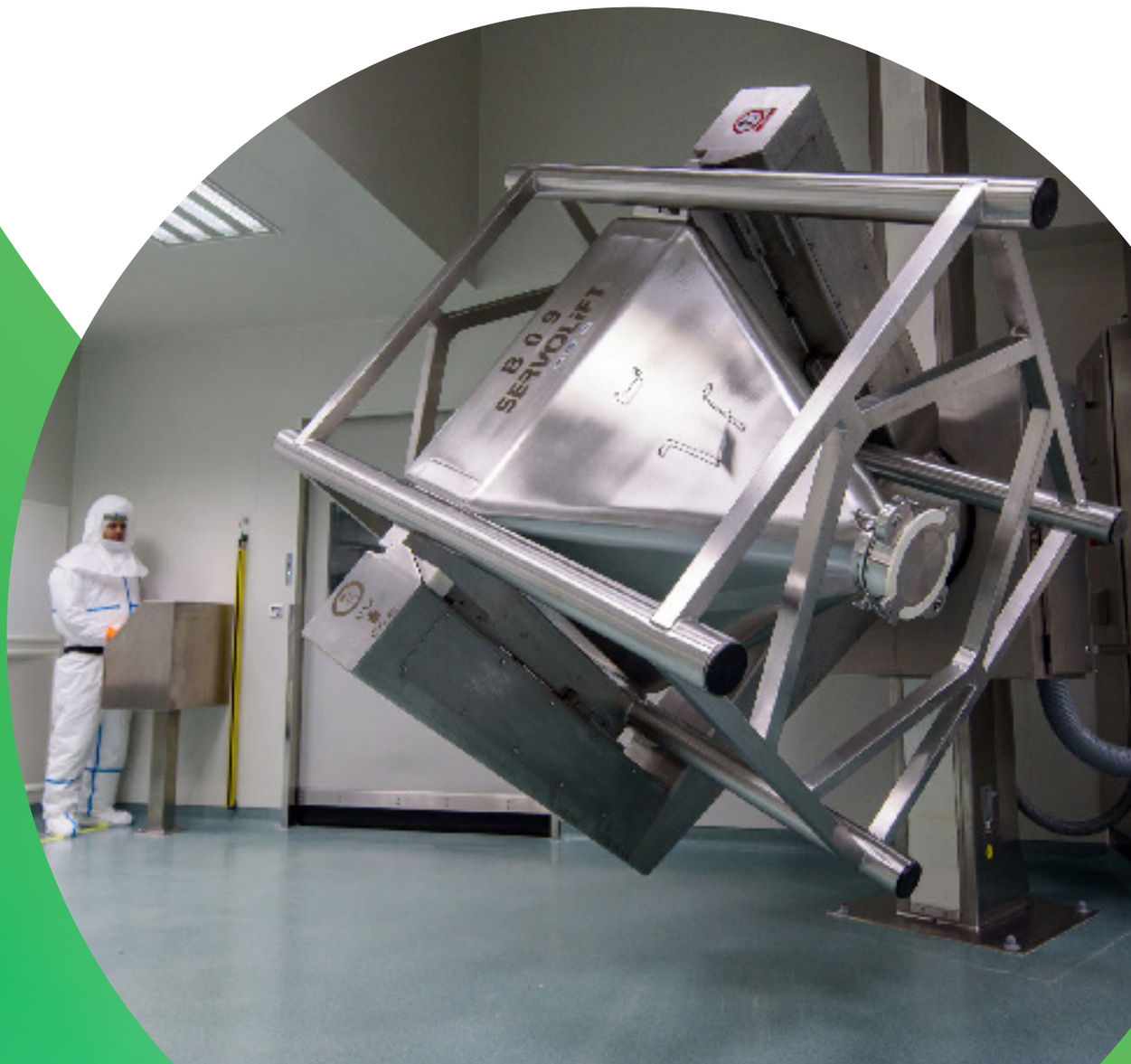
The time has come for the EU and member states to reform their procurement/tender rules to support manufacturers' efforts to secure supply and define new pricing models to secure resilience and ensure security of supply. Furthermore, API and finished product manufacturers should also be allowed to evolve in a modern, digitalised, reactive and cost-effective regulatory environment.

Teva supports a strategic dialogue between policy makers, regulators, payers, industry and any other key actors of the pharmaceutical value chain. It does so to best implement the above-mentioned key priorities in order to secure Europe's resilience and autonomy in pharmaceutical manufacturing and supply both API and finished goods.

Teva, therefore, calls for the following measures to be put in place:

National governments and payers should address the commoditisation of off-patent medicines and support the resilience and diversity of pharmaceutical manufacturers and production sites for both APIs and finished products, by:

- Taking into consideration EU API and intermediates' resilience when discussing pricing for the finished products;
- Designing new pricing models to address the (economic) causes responsible for medicines shortages and/or driving production out of the EU;
- Reforming tender practices by implementing MEAT (Most Economically Advantageous Tender) criteria and introducing critical changes to ensure the sustainability of tender practices for pharmaceutical products;
- Encouraging production of diversified products which deliver greater benefits to patients and healthcare systems, such as complex generics or medicines with a digital component;
- Providing financial subsidies to support manufacturing autonomy where urgently needed.



The EU and national government regulators should modernise and optimise the EU and national regulatory frameworks by:

- Expediting the inclusion of an API monograph in the European Pharmacopeia and attribution of the subsequent Certification of suitability to the monographs of the European Pharmacopoeia (CEP) once the API is commercialised;
- Modernising the EU regulatory framework to enable more electronic reporting/digital tools for finished products and API regulatory activities;
- Reducing onerous and cumbersome red tape, notably by reforming the EU variations directive;
- Support API and finished product manufacturers to secure high-level quality standards across the world, including better enforcement of Good Manufacturing Practices in less-regulated countries;
- Ensure regular and constructive dialogue with regulatory competent authorities across Europe.

Upgrading the single market IP Framework:
Broadening safe harbours and the Bolar exemption:

- Ensuring business incentives predictability and legal certainty in the EU;
- Fully implement the SPC (Supplementary Protection Certificates) manufacturing waiver;
- Implement a broad Bolar exemption, which extends to third-party API suppliers.

Ensure an international economic level playing field with third countries by establishing subsidies and supporting companies that produce critical APIs, raw materials and finished products in Europe **while respecting Europe's WTO commitments.**

Table of Contents

EU Pharmaceutical Manufacturing Resilience has become a **major strategic priority for the EU**

The European Commission wishes to encourage and support EU manufacturing capacity for APIs and pharmaceutical starting materials[1] – crucial elements of a single chemical-pharmaceutical strategic value chain, since they constitute the ingredients for the finished product.

As the coronavirus outbreak turned into a global pandemic, it demonstrated **the possible exposure of the EU pharmaceutical supply to manufacturing and sourcing from outside of the EU**, as well as its impact (e.g. the closure of Wuhan's API manufacturing site, the export ban of India's COVID-19 related API).

More structurally, the European Commission also believes that **the EU's growing dependency on medicine imports and APIs from outside of Europe may result in shortages** if it is not counterbalanced by a sufficient level of EU supply chain diversification.

This raises health security risks according to the Commission, and is a concern for the EU's strategic autonomy, especially during crises.

Following the announcements of both the EC strategic pharmaceutical roadmap on June 2nd, which highlights the above-mentioned issues, and the EU Financial Recovery Plan to re-launch the EU economy after the Coronavirus crisis, **the Commission should institute a number of programmes to address manufacturing resilience.**

Communication from the Commission so far seems to focus on the **EU's increasing dependence on non-EU countries** for the provision of intermediates and active ingredients for medicines and, to a lesser extent, of manufactured medicines.

From Teva's point of view, it is essential to ensure that all measures take into consideration the whole value chain from intermediate to finished goods, as it is not enough to target only part of the supply chain.

To increase the resilience of the supply chain, and reinforce the sector's global competitiveness, one must first understand that the pharmaceutical supply chain must be seen as a full, end-to-end process (backward integration), where the API, or any other element, cannot be taken in isolation.

[1] "European Commission Pharmaceutical Roadmap for a Pharmaceutical Strategy : Timely patient access to affordable medicines"

Teva's contribution to the European healthcare systems:

A strategic player to help secure the autonomy, and the resilience of Europe's healthcare systems and economies

Teva is the world and Europe's leading provider of generic medicines. It offers quality medicines and treatments to patients, as well as APIs for the pharmaceutical manufacturing industry.

Teva's mission is to be a global leader in generics and biopharmaceuticals, improving the lives of patients. The company has 3,500 products in its portfolio and serves around 200 million people each day.

Teva also has a growing portfolio of innovative specialty, or branded, medicines and biopharmaceutical products, with a promising pipeline focused on medicines for central nervous system disorders, oncology, and respiratory diseases.

In 2018, Teva's workforce consisted of 42,535 employees across 60 countries. Of these, 12 countries had more than 1,000 employees each, and over 30 countries had more than 200 employees each.

Teva manufacturing footprint in Europe

- Complex Manufacturing & Supply Operations
- Solids Manufacturing & Supply Operations
- Local Manufacturing & Supply Operations
- Teva api & Biologics

Teva's unique capabilities and domestic footprint allow us to be a major partner to European healthcare systems, most notably thanks to the following facts:

In Europe, Teva has
19,236 employees.
In 2018, it operated
31
manufacturing, research and development facilities.

Teva has a strong domestic manufacturing footprint in Europe, in both finished products and APIs

Finished product manufacturing sites in Bulgaria, Croatia, the Czech Republic, Germany, Hungary, Ireland, Italy, Lithuania, Netherlands, Poland, Spain and the UK, make up the majority of Teva's production capacity, driving massive investments in Europe.

In Germany, for example, Teva is making **a three-digit million-euro investment in the development of the company site in Ulm,** to become the hub of Teva's biotech activities.

Teva api is the world's leading international API manufacturer, with a portfolio of:

more than	nearly	in more than
400	**1,100**	**100**
high quality API products	customers	countries

Teva api facilities have **a large European footprint** and is present in Croatia (2), Czech Republic (1), Hungary (2), and Italy (5).

Teva api also produces in Israel and India. Besides supporting Teva's own manufacturing,

Teva api also supports 75% of the top 50 global pharmaceutical companies.

Teva manages its product supply through a **well-established supply chain organisation** which orchestrates supply and demand between the supplying sites/3rd parties, and the markets.

Every manufacturing site has its own supply chain team, supply from 3rd parties is being coordinated by a dedicated team.

In each of the countries, **a market supply chain team interacts with the commercial and finance teams.**

A regional function supervises regional activities in line with Teva's overall mission, i.e. to ensure supply to patients.

European Supply Chain Organisation

A diversified distribution centre network

Teva can leverage its 30 distribution centres, which ship over

1.2 billion

packs of medicines

each year across Europe, to ensure patients have access to their medicines. Teva has vast expertise in managing and sourcing shortage products and getting them to where they are most needed in an efficient manner.

Key Facts:

Thanks to Teva's European footprint, **a considerable majority of Teva's global portfolio is already manufactured in Europe (65% volume),** while for API it is equally split (≈40%-40%) between Europe and third-world countries (i.e. India and China).

Focusing on Europe, **93% of Teva's finished products supplied in Europe are currently being produced in Europe.** Furthermore, **Teva sources approximately 53% of its API needs in Europe through its subsidiary Teva api, 40% of which are produced within Europe.** This is slightly above the European average (according to a Charles River Associate Study, API supplies sourced from European countries accounted for 35% of generic API sales in Europe).

In terms of intermediates, or raw materials, necessary for the production of APIs, **Europe still represents the source for 22% of all of Teva's SKUs.**

In Europe, Teva already enjoys a strong regionally based supply chain, with a significant footprint in APIs and finished products manufactured in Europe. This makes **Teva a unique and resilient partner to Europe's healthcare systems.**

Below you will find a detailed description and contextualisation of Teva's requests to maintain Europe's autonomy and resilience regarding pharmaceutical value chains. →

Teva's priority recommendations to ensure Europe's manufacturing resilience and security of supply

A National governments and payers should address the commoditisation of off-patent medicines and APIs

Today, European healthcare systems are mainly focused on obtaining the lowest cost possible, forcing generic products' price down.

This has ultimately led to the commoditisation of generics, and **an increased dependence on third-world countries.**

A cost-based system is not compatible with the intent of ensuring Europe's pharmaceutical resilience and autonomy of manufacturing investments, especially for mature, essential medicines, as it does not recognise the associated additional value and expenses related to Europe's high production costs.

Although **Europe secures its competitiveness through its accumulation of innovative technology and expertise** that has not been transferred anywhere else, once the technology and know-how become globally available, Europe loses its competitive manufacturing advantage.

Indeed, **price commoditisation,** combined with the extensive reforms driving costs up in a cost-led, competitive market, **stimulates businesses to strive for cost leadership,** while maintaining high standards and a lean structure.

This has led the industry to move part of its supply chain outside of Europe, notably for commoditised, essential, lifesaving drugs, as other regions of the world offer a much more competitive cost base.

In spite of these challenges, Teva has maintained, as much as possible, its production footprint in Europe, often putting itself at a competitive disadvantage. Such a situation challenges Teva's ability to maintain its strong European footprint, notably on API and intermediates.

Despite applying the same high global regulatory and quality standards across the world, the differences between fixed and variable production costs in Europe and countries like India are so large that, **unless a thorough discussion on price takes place at national level, the EU's ambition to produce critical essential APIs and/or critical, essential medicines on its soil will not be sustainable.**

Therefore, as the EU seeks to encourage and support EU manufacturing capacity for medicines, APIs and pharmaceutical starting materials, **Teva would like to make the following recommendations:**

Take into consideration EU API and Intermediates' resilience when discussing **pricing for the finished products**

The decision to enhance the EU API and Intermediates' resilience should be embedded in the finished products' pricing discussion with payers, as it relates to their sustainability (especially when becoming commoditised).

In this approach, **the EU and member states should look at the entire pharmaceutical value chain,** and not just part of it in isolation, when thinking about backward integration in Europe.

For example, **this implies that the industry could maintain at least a second active manufacturing line for API** (maintaining a low level of production at all times) to be able to keep a manufacturing licence of this product.

This active second line **would allow switching from one operating production line to another,** in case of constraints.

However, maintaining a second manufacturing line active in Europe, especially when for very commoditised APIs/medicines and, even more so, if at low volumes of production, **represents a significant expense for the industry.**

It must therefore be compensated in the price of the finished product.

Design new pricing models to address systematically the economic root causes responsible for medicines shortages and/or for driving production out of the EU

For finished products, national pricing practices such as tender, clawback mechanisms or external reference pricing lead to the concentration of medicines supply, limiting the number of players and rationalising the supply chain.

Teva believes that **European healthcare systems should move away from the unsustainable preference for the lowest cost generic option,** which does not account for companies' investments to secure supply and/or comply with Europe's key transformative priorities.

Teva believes that **generic and biosimilar manufacturers should be exempt from payback/clawback mechanisms,** hence does not support such mechanisms.

The generic and biosimilar market competition already stimulates manufacturers to adopt competitive prices for a higher volume uptake, at the same time contributing to wider patient access for treatments and savings for the healthcare system.

Some reforms introduced in the midst of the 2009 financial crises have seriously impacted the economic viability of the sector and forced the industry to invest elsewhere to remain competitive.

Measures like clawback or external reference pricing are among the pricing models that need to be revisited urgently.

Teva strongly calls on national governments to define, with concerned stakeholders, **new pricing models to secure the financial stability of the healthcare systems and the industry's ability to invest to secure production and supply.**

In order to mitigate any potential impact of the post COVID-19 expected economic recession, Teva calls on national governments to **negotiate and implement stability pacts notably with the off patent pharmaceutical industry in order to secure the sustainability and the investment of the sector.**

Additionally, the industry's ability to cope with commoditisation lies in its ability to differentiate itself. Therefore, the EU and the member states should **encourage any investment efforts that aim at producing products that deliver greater benefits to patients and the healthcare systems,** including in the off-patent sector.

Encourage production of diversified products which deliver greater benefits to patients and healthcare systems, such as complex generics or medicines with a digital component

Reform tender practices by implementing MEAT criteria and introducing critical changes to ensure the sustainability of tender practices for pharmaceutical products

At national level, tender rules should be reformed to include MEAT criteria, and to adjust unsustainable conditions. Tender systems looking at price only, push the European industry to consolidate and rationalise its supply chain playing against a more resilient, diversified, and competitive manufacturing framework.

Beyond enforcing MEAT criteria in tender practices, **other changes in tender rules should be introduced as well, such as:**

- **Adjusting the number of tender winners** according to the market, product and country characteristics
- **Preventing disproportionate penalties**
- **Using lead times** that guarantee a steady supply of medicines
- **Rewarding multiple API sources** as part of security of supply.

At the EU level, in the context of the existing EU procurement directive, **the Commission should look at developing guidance to best implement MEAT criteria for pharmaceutical products** for the markets where tender practices are used, looking beyond the price-only criteria.

For critical and strategic essential medicines and API: a thorough discussion on economic sustainability should take place at national level between industry, payers, and regulators, aiming at anticipating the market gap and supporting the production of these critical, essential, and often commoditised, products.

Pharmaceutical and API manufacturing companies that intend to conduct domestic production of critical APIs, raw materials and finished products should be able to receive subsidies to enable an economic level playing field with lower income countries. These subsidies should cover the expenses for the establishment or the maintenance of a domestic plant or manufacturing line for APIs and raw materials that are highly dependent on foreign countries (ready-mixed) production facilities, etc.

To support the EU's competitiveness, resilience and green ambitions, **the EU and member states must reorient their funding policies to reward and support investment efforts** made in key strategic value chains, such as the pharmaceutical sector, thus enabling an international economic level playing field.

Provide financial subsidies to support manufacturing autonomy where urgently needed

To conclude this chapter, Teva highlights that in order to enable Europe to have a more resilient, autonomous, and diversified end-to-end value chain, **systemic, comprehensive pricing reforms need to be executed to ensure sustainable pricing for commoditised medicines** and to deliver investment stimulus packages rather than focusing on the lowest price only, which plays against the EU's ambitions.

If, in the short term, ensuring production of strategic essential API and medicine products on European soil is one of the COVID-19 lessons learned, member states and **the EU should perform a structural review of their pricing policy in order to systematically support manufacturers** to remain competitive while adapting/ upgrading their facilities and to accompany Europe's transformative ambition.

B Implement greater regulatory efficiency and cost-optimisation for both industry and competent authorities

There are **considerable and important barriers for the API industry in the current regulatory framework,** which are seriously impacting Europe's ability to attract API investment.

It needs to be simplified in order to optimise efficiency.

The current system is rife with bureaucracy and unnecessary processes, which add to the industry's costs and, therefore impact its competitiveness.

As such, Teva would like to make the following recommendations

The inclusion of an API monograph in the European Pharmacopeia and the attribution of the subsequent CEP must be done once the API is commercialised

A Certificate of suitability to the monographs of the European Pharmacopoeia (CEP) allows the producer of the respective API to have any possible changes (e.g. changes to the source of the intermediate) centrally reviewed (for EU countries as well as partnered third countries).

Without it, each API is reviewed based on an Active Substance Master File (ASMF), which requires changes to be requested individually, per country, not only for the API in question, but for all finished products which include this API.

Thus, **each review is conducted in a silo, representing a burdensome and costly process for industry,** but also for regulators.

Currently, an API must be included in the Pharmacopeia before the industry can require a CEP, being that **the whole process can take up to 9 years** (5-7 years until the monograph is included in the European Pharmacopeia after request by the industry, and another 1-2 years for attribution of the CEP).

This could be easily solved by de-linking the CEP from the European Pharmacopeia, or by creating a centralised certificate for APIs, which would be available from the start of the product's commercialisation, instead of only after the monograph is published in the European Pharmacopeia.

The EU regulatory framework needs to be modernised to enable more electronic reporting/digital tools in finished products and API regulatory activities

A related topic to the CEP and the efficiency in dealing with information in the regulatory dossier is **the need to include data regarding the API in the regulatory dossier for the finished product.** There has been a continued interest from authorities, namely the International Organisation for Standardisation (ISO)[1], to have more data transparency and more information included in the regulatory dossier.

The information currently required in the dossier is already complex, and is responsible for the high amount of variations the industry must file, not to mention that it is also something that discourages companies from including additional API manufacturers in the dossier, given the high unrecognised and uncompensated costs associated.

As such, Teva considers it beneficial to transfer the responsibility to provide information on the API in the regulatory dossier from the Marketing Authorisation Holder (MAH) of the finished product to the API supplier. The API supplier should be the one responsible for maintaining and updating data related to the API. This data should then be identified and linked in the regulatory dossier for the finished product, using the same telematics database and technologies that are used for the finished product.

This would allow for centralised access to all the relevant information for each product by the regulators, while reducing companies' expenses with variations. It will also help avoid competition issues, since having the MAH add more information on the API to the finished product's dossier could imply including confidential data from the API supplier.

[1] The ISO sets extremely stringent standards for the Identification of Medicinal Products (IDMP), which European Union (EU) Member States, the MAH and the EMA are obligated to use due to Commission Implementing Regulation (EU) No 520/2012 (articles 25 and 26).

The EU Variations system needs to be reformed

In addition, the previous chapter also highlights how measures to secure security of manufacturing and supply should include increasing flexibility to submit changes to the product dossier. Currently, the process to make some types of variations to a regulatory dossier is long and carries a considerable expense for industry or the regulatory competent authorities, with no scientific added value and could be automatized via a telematics based regulatory infrastructure.

Ensure regulatory stability and dialogue with competent authorities across Europe

It is also **extremely important for national competent authorities to facilitate the addition and maintenance of a second manufacturing site, as well as a second API supplier.** This last point can bolster and ensure supply, especially during moments of crisis or supply constraints.

However, in order to do so, regulatory authorities must also be more pragmatic and predictable in handling the authorisations for such sites and suppliers, recognising their essential role in ensuring the supply chain's resilience.

Moreover, **there must be an increase in collaboration between authorities and the industry.** The recent coronavirus epidemic has demonstrated the importance and effectiveness of clear and direct communication and cooperation between the different stakeholders.

API and finished products manufacturers should be supported to secure high-level quality standards across the world

Teva's medicines undergo exhaustive safety monitoring and quality assurance measures at every stage of the process: from R&D, to clinical trials, to the sourcing of raw materials, to production, all the way through to delivery and patient use.

Teva's robust safety and quality monitoring systems help detect and manage safety issues, prevent future concerns, and ensure appropriate reporting to applicable regulatory agencies, in accordance with their guidelines.

For imported medicines or ingredients, **Teva conducts a wide array of good practice audits for manufacturing, laboratories, and testing** (GMP, GCP, GLP), as well as testing procedures for imports to ensure compliance.

To enhance and support Teva's efforts, as well as to secure a level playing field on enforcement, **regulatory agencies should devote more resources to GMP inspections in less regulated countries.**

This level playing field should focus on guaranteeing and enforcing equal GMP standards in third, less-regulated countries. **By levelling the conditions in which companies operate around the world, European sites' competitiveness will increase.**

C Upgrading the single market IP Framework: Broadening safe harbours and the Bolar exemption

Ensuring business incentives predictability, and legal certainty, in the EU

Teva believes that **a strong, stable and predictable IP system is important to support the research and the development of new innovative medicines for patients.** At the same time, it is crucial to ensure that the current IP system remains balanced and does not lead to delayed market entry and delayed patient access to off-patent medicines.

Fully implement the SPC manufacturing waiver

Under the SPC Regulation, **SPCs confer the same rights as patents and therefore extend to the importation and manufacturing of products within their scope of protection.** This has had the unintended consequence of preventing generic and biosimilar manufacturers from both stockpiling in Europe for Day 1 launch and producing products in Europe with the intention to supply ex-EU markets with shorter effective patent protection.

To address this issue and strengthen EU-based manufacturing and competitiveness (and avoid further relocation of both R&D and manufacturing sites outside the EU to countries where no such protection exist), in 2019 the EU introduced an amendment to the SPC Regulation which created a new exemption to SPC rights, namely the stockpiling of API and medicines for Day 1 launch at SPC expiry in the EU and the production of the API and medicines for export outside the EU.

However, these exemptions are subject to very strict conditions. For instance, any generic or biosimilar company that intends to rely on the SPC manufacturing waiver has to send a notice to both the SPC holder and the relevant IP office(s) with information that is normally considered confidential and commercially sensitive, such as the identity of the manufacturer, the Member State where the manufacturing site is located or a list of countries where the product is to be exported. IP office(s) are then requested to publish the information contained in such notices.

Whilst the SPC manufacturing waiver has the potential to increase investments in development and manufacturing of generic and biosimilar medicines, and their APIs, in the EU and could lead to the creation of around 25,000 new high skilled jobs (according to the European Commission - http://europa.eu/rapid/press-release_IP-18-3907_en.htm), it will only achieve such potential if the EU and Member States (as well as their national courts) ensure that it is fully implemented in accordance with the intention of the legislation.

A full implementation will require applying and interpreting the SPC manufacturing waiver in accordance with its rationale and dismissing any attempts to misuse the sensitive information that generic and biosimilar companies will have to disclose.

It may also require the EU to consider **amending the conditions of the SPC manufacturing waiver** if, following the initial five years review, it appears that such conditions are not fit for their purpose and are preventing an effective use of the waiver (with companies continuing to prefer the option of manufacturing outside of the EU where they have that choice).

Finally, the UK Intellectual Property Office has suggested administrative variations to ensure that an equivalent SPC manufacturing waiver continues and can function properly post Brexit and transition period. However, there is the potential for divergence over time between the UK and the EU in terms of how such a waiver will operate because, for example, questions referred to the CJEU for interpretation of the SPC manufacturing waiver regulation by EU Member States will not have direct effect in the UK after Brexit.

Implement a broad Bolar exemption, which extends to third-party API suppliers

The so-called Bolar exemption was introduced in EU law by the Directive 2001/83/EC (the Human Medicines Directive) as amended in 2004. The rationale behind the Bolar exemption was to **allow generic and biosimilar manufacturers to conduct studies and trials with a view to obtain marketing approval before patent expiry** and thus be in a position to effectively enter the market upon expiry.

Unfortunately, the Human Medicines Directive only set a minimum standard and **EU Member States and national courts have adopted different approaches** – some narrow, some broader - when implementing the exemption.

Moreover, an uncertainty remains in relation to whether the supply of API to a third-party (which will conduct studies and trials considered exempt by Bolar) is itself covered by the Bolar exemption.

This fragmented implementation and the unclear situation in relation to third-party API suppliers have **led to decisions to reduce or cut entirely the launch of new API products in European countries.** This affects the sourcing of API in Europe for both trials and subsequent commercial scale manufacturing, and thus more generally the position of the API industry in Europe.

The Bolar exemption should be further harmonised with a broader EU standard, should extend to API supplied by third-parties for the purpose of clinical trials and studies and acknowledge that EU based API suppliers can commence development of API prior to a specific request from a supplied party.

Key Facts:

In *Astellas v. Polpharma*, Polish and German courts have come to different conclusions on the issue of whether third-party API suppliers are exempted under Bolar.

In Poland, the Supreme Court considered in 2013 that an API supplier could not rely on the Bolar exemption even though the studies and trials undertaken by the supplied party fell into the scope of the exemption. Polish law has now been changed to overturn this narrow interpretation.

In Germany, the Düsseldorf Court of Appeal challenged this conclusion in 2014 and, having doubts about the correct interpretation, referred the issue to the CJEU. The case was eventually settled before the CJEU issued a ruling.

In *Boehringer v. Teva*, in 2018, the Milan Court found that Teva api had infringed the SPC on tiotropium bromide by offering for sale API to other companies for marketing approval.

The Italian court adopted a restrictive view and said that the supply of API to third parties may only be exempted when it follows a request from the supplied party, such as a generic manufacturer, for a specific purpose and not when it is proactively offered by the API manufacturer.

D European and national-level incentives to support manufacturers' "green transition"

As a global company with 65 manufacturing facilities around the world, **Teva works to continuously improve the impact of its manufacturing and daily operations on the environment.**

Recognising the potential impact its facilities and medicines can have, **Teva implements measures to avoid, reduce, or control pollution** and promote the responsible and efficient use of energy and natural resources across the company and its supply chain.

Key Facts:

In 2019, Teva reduced:

- **Greenhouse gas emissions** by **17%** from 2017
- Its **total waste** by **13%** from 2018
- Its **energy consumption** by **6%** from 2018.

As part of the circularity approach, **Teva looks towards a true zero waste model** that ensures both a customer and a use for the waste it generates; i.e. zero landfill and zero incineration without energy recovery. Simultaneously, **Teva is also implementing a solvent recovery project** to reduce the amount of fresh solvent procured and/or to be sold to the market as a usable product.

One of the European Commission's main priorities for the next five years is the European Green Deal and the move towards a "greener" society. Europe already enforces extremely strict and demanding regulatory requirements and Teva makes sure to comply with all national requirements in the countries where it is present.

In Europe, the production of APIs falls under the industrial emissions directive (Directive 2010/75/EU), the main EU instrument regulating pollutant emissions from industrial installations. **This framework is very onerous and requires the implementation of the most advanced technology to reduce environmental risk,** as well as specific permits and licenses, since it takes an integrated approach.

As such, the permits must take into account the whole environmental performance of the plant, covering emissions to air, water and land, the generation of waste, the use of raw materials, energy efficiency, noise, the prevention of accidents, and the restoration of the site upon closure.

Key Facts:

This framework requires a technology investment to clear solvents from emissions. This end-of-pipe treatment can take the form of **cryogenic condensation** or **thermal-oxidation** (the cost for implementing this last method alone is, approximately, one and a half million euros for each site).

Another costly requirement is effluent management: wastewater treatment technology costs half a million euros, on average, per site.

Given the urgency of tackling environmental issues, and the fact that the manufacturing process can be extremely prejudicial for the environment, due to the high-energy requirements and the amount of pollutants generated in the process, **all efforts going into the direction of making a greener production or transport system should be supported and encouraged via state financial aid.**

Thus, policy makers should focus on rewarding manufacturers, to help them transition to "greener" practices where possible.

European and national-level incentives supporting the "green transition", be it for innovation or in compliance with updated regulatory requirements, could take various shapes and forms (state aid – direct financing incentives, grants – or fiscal policies, such as tax reductions or exemptions, etc.).

Teva's additional recommendations

Make financial aid accessible

Europe, both at national and supra-national level, must be responsible for making the changes it wants to see in the rest of the world. As such, **European institutions and countries should ensure that companies actually have access to programmes that aid them in improving efficiency** (e.g. conversion of manufacturing facilities to take advantage of idle capacity and transitioning to more digitally integrated facilities) **and reducing negative externalities** (e.g. "green transition" investments).

Many programmes are stifled due to the amount of "red tape" associated with them, effectively preventing companies from using them and forcing them to foot the bill entirely on their own.

Financial aid would enable API and finished products manufacturers to benefit from subsidies, enabling them to invest in otherwise unsustainable areas and/or expensive advanced manufacturing technologies, including technologies that are consistent with GMP.

Europe needs to continue to stand for an open international trade and against protectionism

No country/region is self-sustainable, therefore, an open trade system is key. Europe's fight against protectionist measures which may impact the import of key intermediates/raw materials/ finished products is critical. **Protectionist measures endanger supply and lead to a slowdown in industry output.**

Free trade agreements offer a venue to support industry and address market barriers. For example, if Europe seeks mutual recognition in third countries, in particular for GMP, it must be included and leveraged in open and free trade agreements. This would ultimately facilitate inspections and enforce EU-level standards.

Teva Europe Government Affairs Team & Contact Points

G. Pinto Mendes – VIE, EU Policy Analyst

E. Tyssier – Senior Director, Head of Government Affairs Europe

A. Zanaglio – Associate Director Government Affairs Europe