

# Competition: Commission report finds active competition enforcement contributes to affordable and innovative medicines

Margrethe **Vestager**, Commissioner in charge of competition policy, said *“Giving European patients and healthcare systems access to affordable and innovative medicines is one of Europe’s main challenges and objectives. The report published today provides key insights into the valuable work that competition authorities across Europe are doing to ensure that pharmaceutical markets help achieve this goal. It is important that we continue giving a high priority to our work in this area.”*

The report provides an overview on the enforcement of antitrust and merger rules in the pharmaceutical sector and describes how competition law enforcement has contributed to improving European patients’ access to affordable and innovative essential medicines. It focuses on the period since 2009, when the Commission carried out an [inquiry into competition in the pharmaceutical sector](#).

The Commission drafted the report in close cooperation with the national competition authorities of the 28 EU Member States, with which the Commission works in the European Competition Network.

On the basis of the insights gained from the report, the Commission and the national competition authorities will continue their enforcement efforts in the pharmaceutical sector, which remains a matter of high priority taking into account the importance of the sector both economically and in terms of impact on peoples’ well-being and lives.

## **Main findings of the report**

### *Fair prices for medicines*

With respect to **anti-competitive agreements and cases of abuse of a dominant position**, the Commission and national competition authorities have investigated well over 100 cases and have adopted **29 decisions** against unlawful practices in the supply of medicines since 2009:

- In these cases, the competition authorities have investigated and sanctioned anti-competitive practices that lead to **higher prices of medicines**.
- The **anticompetitive practices** ranged from (i) exclusionary conduct to delay the entry of generic medicines into the market, to (ii) market sharing/price fixing practices and (iii) pay-for-delay agreements, where originator and generic companies colluded to keep the generics off the market and shared the originator’s profits from doing so. Several

investigations concerned (iv) excessive prices charged for off-patent medicines.

- These decisions imposed **finances totalling over €1 billion**, or made binding companies' commitments to remedy their anti-competitive behaviour.

Higher prices may also result from **mergers of pharmaceutical companies** where the pricing power of the merged company is strengthened. To prevent pharmaceutical markets from becoming overly concentrated, **the Commission reviewed more than 80 mergers** in the pharmaceutical sector. Competition concerns were detected in 19 cases, where mergers could have led to price increases, in particular for generic products or biosimilar products. The Commission cleared these mergers only after the companies committed to divest parts of their businesses in order to preserve the existing degree of price competition.

In addition, the competition authorities undertook more than **100 market monitoring and advocacy activities**. These offered insight into the functioning of the markets, provided guidance to market participants, and triggered antitrust investigations in some individual cases. Advocacy activities influenced the design of regulation and legislation and helped to create or restore conditions more conducive to effective and fair competition.

#### *More innovation and choice*

The report found that competition enforcers helped **maintain the level of innovation** in the sector by intervening, using antitrust rules, against practices that could have distorted the incentives to innovate. This relates in particular to attempts to delay the entry of generic medicines into the market, which can allow companies to unduly draw profits from older products instead of having to compete with new, innovative medicines.

The Commission's merger control activity also contributed to **innovation and increased choice** of medicines, by preventing transactions that could have compromised research and development efforts to launch new medicines or to extend the therapeutic use of existing medicines.

#### *Scope for further enforcement action*

The antitrust and merger cases cited in the report show that the pharmaceutical sector requires close scrutiny by competition authorities. The enforcement record of the Commission and the national competition authorities provides a solid basis for competition authorities to continue working and focusing their enforcement efforts in the sector.

However, while the cases discussed in the report show that competition law enforcement helps to safeguard competition on prices and to stimulate innovation, there are limits to what competition law can do. In particular, continuous efforts by all stakeholders are needed to address the societal challenge of ensuring sustainable access to affordable and innovative

medicines.

The executive summary and the report are available in all official EU languages on the [Commission's competition website](#).

## Background

In its [Conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States](#) of 17 June 2016, the Council expressed several concerns regarding patients' access to affordable medicines. Referring to the Commission's [2009 Pharmaceutical Sector Inquiry Report](#), which stressed that a competitive market for medicinal products benefits from vigilant competition law scrutiny, the Council invited the Commission to prepare a report on competition cases following this sector inquiry.

The European Parliament, in its [Resolution on EU options for improving access to medicines](#) of 2 March 2017 also expressed concerns about insufficient access to essential medicinal products and high prices of innovative medicines, recognising the importance and effectiveness of antitrust tools against anti-competitive behaviour such as the abuse or misuse of patent systems and of the system for authorisation of medicines.

The report published today was drafted to describe, in response to the concerns raised separately by the Council and the European Parliament, the contribution that competition law enforcement can make to achieving the objectives of affordable and innovative medicines.

The Commission and Member States' competition authorities co-operate closely within the European Competition Network. National competition authorities are fully empowered to apply [Articles 101 and 102](#) of the Treaty of the Functioning of the European Union (TFEU). If a certain conduct does not affect cross-border trade, the national competition authorities apply their national antitrust laws, which are often a reflection of EU law. The Commission is entrusted with reviewing mergers with an EU dimension, i.e. where the merging companies' turnovers meet the thresholds laid out in the [EU Merger Regulation](#). If these thresholds are not met, a merger can be caught by national jurisdictions and reviewed by one or several national competition authorities.

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## [\*\*Safeguards in free trade agreements: Council adopts horizontal framework for bilateral measures\*\*](#)

The EU will soon have in place an overall framework for ensuring consistency of safeguard measures included in free trade agreements.

The Council today adopted a regulation streamlining **the inclusion of safeguard measures in trade agreements** so that they are applied effectively and consistently across the board.

Bilateral safeguard measures linked to trade agreements (allowing for the temporary withdrawal of tariff preferences) are intended to **protect a particular domestic industry** from an increase in imports of any product which is causing, or which risks causing, serious injury to that industry.

The EU regularly concludes trade agreements with third countries, most of which include bilateral safeguard clauses or other mechanisms for the temporary withdrawal of tariff preferences or preferential treatment. Up to now, the bilateral safeguard mechanism has been proposed **separately** in conjunction with each trade agreement.

At this stage, the regulation covers the **implementation of the EU-Japan, EU-Singapore and EU-Vietnam free trade agreements**. Further trade agreements might be added to the scope of the regulation in the future by means of delegated acts.

## **Next steps**

The regulation should be signed on 13 February in Strasbourg. It will then be published in the Official Journal and enter into force 20 days later.

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**[Mario Draghi: Hearing of the Committee on Economic and Monetary Affairs of the European Parliament](#)**



**EUROPEAN CENTRAL BANK**  
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## **Introductory Statement by Mario Draghi, President of the ECB, at the ECON committee of the European Parliament, Brussels, 28 January 2019**

Mr Chairman,

Honourable members of the Economic and Monetary Affairs Committee,

Ladies and gentlemen,

It is a pleasure to be back at the European Parliament and to appear before your Committee.

I am happy that you have chosen the euro project and its achievements over the past 20 years as the topic for our discussion today. I will start on the substance without further ado, discussing in turn the internal and external dimensions of the euro area. I will then argue that, building on what we have already achieved, our duty today is to continue to make progress in ensuring that all of the euro's benefits are realised in full.

### **The euro's internal dimension**

The euro was introduced to deepen the Single Market and safeguard its integrity. It continued the European project of reducing cross-border barriers through common endeavours and common policies. It followed the spirit that was already imbued in the Schuman declaration in 1950: building Europe "through concrete achievements". As a result, our economies are now integrated to a point that was unimaginable not so long ago.

The euro was designed to be a trusted and stable currency. And the euro has indeed provided two decades of price stability, thereby upholding people's

confidence in the value of their savings. Stable prices also facilitated firm investment and the creation of new jobs. Today, there are 20 million more Europeans in employment than 20 years ago in the 19 countries that currently make up the euro area. And since the creation of the euro, the labour force participation rate has risen from 59% to 67%, its highest level ever.

The two decades in which the euro has existed have been exceptional. The first decade was the culmination of a 30-year period of macroeconomic stability, also known as the Great Moderation. Inflation averaged close to 2% and the ECB ensured price stability mainly by adjusting its key interest rates.

The second decade produced the worst economic and financial crisis since the Great Depression. As I had the opportunity to discuss at length in my remarks at the Parliament's plenary debate two weeks ago, as a response to the crisis we had to deploy new instruments to safeguard the effectiveness of our monetary policy and stabilise the euro area economy.<sup>[1]</sup>

Thanks to the collective efforts of all European citizens, the euro area has emerged from this crisis. The results of their and their representatives' determination have been tangible: 22 consecutive quarters of economic growth, the unemployment rate at its lowest level since October 2008, and wages and incomes on the rise.

However, over the past few months, incoming information has continued to be weaker than expected on account of softer external demand and some country and sector-specific factors. The persistence of uncertainties in particular relating to geopolitical factors and the threat of protectionism is weighing on economic sentiment.

At the same time, supportive financing conditions, favourable labour market dynamics and rising wage growth continue to underpin the euro area expansion and gradually rising inflation pressures. This supports our confidence in the continued sustained convergence of inflation to levels that are below, but close to, 2% over the medium term. Significant monetary policy stimulus remains essential to support the further build-up of domestic price pressures and headline inflation developments over the medium term. This will be provided by our forward guidance on the key ECB interest rates, reinforced by the reinvestments of the sizeable stock of acquired assets. In any event, the Governing Council stands ready to adjust all of its instruments, as appropriate, to ensure that inflation continues to move towards the Governing Council's inflation aim in a sustained manner.

## **The euro's external dimension**

The benefits of the euro have not been limited to the European internal dimension. Standing together within the Economic and Monetary Union (EMU) allowed us to retain sovereignty that would otherwise be lost by individual countries in a highly integrated world economy.

As already envisaged at the time of its creation, the euro symbolises the unity of a European continent that is better able to exert global influence.

Our togetherness in the EMU gives us “a greater say in international negotiation” and enhances our “capacity to influence economic relations” – to quote the Delors Report.<sup>[2]</sup>

Over the past 20 years, the euro has become the second most important currency in the international monetary system. Somewhere between 20% and 40% of global foreign reserves, foreign exchange transactions, international debt and international trade transactions are denominated in euro. And over 50 countries or territories use or link their currency to the euro.<sup>[3]</sup>

This global standing brings benefits. For one, it lowers the transaction costs of trading internationally, making euro area firms more competitive. It also adds breadth and liquidity to euro area financial markets, allowing domestic and international investors to allocate economic resources more efficiently. And it lowers the cost of global capital market financing for euro area borrowers, including corporations, financial institutions and public entities, thus benefiting firms, households and taxpayers. Of course, the international role of the euro also brings challenges, such as greater exposure to global foreign financial developments and potential changes to the monetary policy transmission process.

The international benefits of sharing a currency go beyond the monetary sphere. In a world with deep economic and financial interlinkages, international cooperation is essential and we can more effectively promote European ideas and interests by speaking together. Indeed, the euro area’s voice has been crucial in strengthening the international financial regulatory framework after the global financial crisis. Today, the Single Supervisory Mechanism is the largest banking supervisor globally and successfully contributes to shaping the international supervisory framework.

Since the global financial and euro area debt crises, however, the euro’s international role seems to have gradually eroded. While its importance as the currency of invoice for international trade transactions has remained broadly stable, its role in global foreign reserves and global debt markets has declined.

This decline is a symptom of the fault lines in EMU exposed by the crises. Concerns about the resilience of the EMU architecture and about financial fragmentation underpinned this erosion. Indeed, stability, financial depth and liquidity are among the key determinants of an international currency.

European policymakers are now paying closer attention and various calls have been made in recent months for the euro to assume a stronger international role. The Euro Summit of December 2018 encouraged work to be taken forward to this end.

The international role of the euro is supported by the pursuit of sound economic policies in the euro area and a deeper and more complete EMU. And this requires further efforts along the path of deeper integration.

# Completing the Economic and Monetary Union

The past 20 years have revealed beyond doubt how challenging ensuring economic prosperity and stability can be. This was true both inside and outside the euro area.

Nonetheless, these years also demonstrated that such a shared challenge is best faced collectively. To realise in full the benefits of the euro, we need to have the same components that made the euro a reality in 1999.

On the one hand, we need national reforms to promote sustainable economic convergence. Under any monetary system, higher growth potential can only be achieved through continuous reform efforts. As the convergence process is primarily driven by structural factors, this is a key responsibility of Member States.

On the other hand, Europe can make a difference by supporting and facilitating such reform efforts. Our togetherness represents a unique competitive advantage, and we should capitalise on this.

First, we can build on the synergies between EMU and the Single Market. The Single Market is indeed one of the most powerful tools we have to unlock the mechanisms that will raise productivity. In particular, a genuine capital markets union (CMU) would not only ease and diversify access to funds for households and firms, thus fostering investment and innovation. It would also enable risk diversification and thus compensate for temporary drops in activity locally – the so called private risk-sharing –, thereby reinforcing the overall resilience of EMU.

Second, it is essential to complete the projects that we initiated during the crisis, namely the banking union. Together with CMU, a complete banking union would deliver meaningful private risk sharing that is currently lacking in the euro area in comparison to the US.

But private risk sharing, to be effective, needs to be supported by other policies.

We should thus rekindle trust in our economic and fiscal framework, by making it more effective in ensuring sound policy making at national level. These actions can also be further supported at the European level by the recent decisions to launch an instrument for convergence and competitiveness for the euro area.

To tackle future cyclical crises, the two layers of protection against shocks – the diversification of risk through the private financial system on the one hand, and public countercyclical support through fiscal instruments at the national and European levels on the other – need to interact in a complete and efficient manner.

Achieving these reforms is not idealistic, nor utopian if we work together. And at the Euro Summit in December, leaders renewed their political commitment to strengthen EMU. If we want to realise in full the benefits of

the euro, we need to capitalise on this commitment and translate it into concrete policy actions.

## **Conclusion**

Mr Chairman,

Honourable members of the Economic and Monetary Affairs Committee,

I have used the word “together” several times today. As this is the last time that we will be together in this legislative term, let me add a few words to you personally.

I would like to thank you all for the role that this Committee has played over the past years.

In my first hearing here, I remember saying that was my first exercise in democratic accountability with the European Parliament and how grateful I was for it. Many more would follow and you effectively ensured that the ECB would be accountable and therefore could legitimately be independent in carrying out its monetary policy. But I am also grateful for the support that this Committee always expressed for the actions of the ECB, a sincere support because it built on the voice of European citizens and an important support that helped the ECB through the many difficult times of the past years.

As co-legislators your role was also essential in delivering reforms that further strengthened our Union.

This Committee, and the European Parliament more generally, has been in my experience an attentive interpreter of the demands of European citizens. It is only by doing so that the trust in the legitimacy of the EU’s institutions and policies is built, making it possible to achieve a more effective and inclusive Union.

As I have argued elsewhere, citizens demand, and Parliament may help in achieving, a “more perfect Union”. A Union that will continue providing its citizens with physical and economic security, while also promoting the values of an open, democratic and peaceful society.

Thank you for your attention. I am now at your disposal for questions.

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**Declaration by the High Representative on behalf of the EU on the situation**

## [in Venezuela](#)

The massive, popular demonstrations which have taken place in Venezuela over the last days have been met with indiscriminate violence from the authorities, leading to the tragic death of numerous people and many more injured and arrested.

The European Union firmly condemns these actions and offers its deep condolences to the families of the deceased.

The EU reiterates that the presidential elections last May in Venezuela were neither free, fair, nor credible, lacking democratic legitimacy. The country urgently needs a government that truly represents the will of the Venezuelan people.

The EU reiterates its full support to the National Assembly, which is the democratic legitimate body of Venezuela, and whose powers need to be restored and respected, including the prerogatives and safety of its members. We reaffirm our deep belief that a peaceful and inclusive democratic solution is the only sustainable way out of the current political impasse and the severe social crisis it has provoked.

The EU strongly calls for the urgent holding of free, transparent and credible presidential elections in accordance with internationally democratic standards and the Venezuelan constitutional order. In the absence of an announcement on the organisation of fresh elections with the necessary guarantees over the next days, the EU will take further actions, including on the issue of recognition of the country's leadership in line with article 233 of the Venezuelan constitution.

The EU stands with the Venezuelan people in this critical hour, and will continue follow events closely, including at the next Foreign Ministers meeting next Thursday. The EU stands ready to act in support of an immediate and credible process of engagement, including through the immediate establishment of an International Contact Group. Contacts and coordination with regional and international partners are ongoing, and will be intensified in the coming hours.

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