How the EU regulates medicines

11/09/2017

Awareness session for international regulators and NGOs on the work of EMA and European medicines regulatory system

The European Medicines Agency (EMA) will host an <u>awareness session to present</u> the European Union's (EU) medicines regulatory system and EMA's role in it to <u>international regulators and non-governmental organisations</u>.

A clear understanding of how medicines are regulated in different parts of the word is of prime importance in an increasingly globalised world where regulators rely on close cooperation. Speakers from across the Agency will present on the European medicines regulatory network and the various activities carried out by EMA as part of it. Topics include European Union (EU) marketing authorisation procedures, support to innovation, benefit/risk assessment of new medicines, pharmacovigilance activities, and stakeholder engagement, among others. The event will be held on 18–19 September 2017. A link to the live broadcast will be freely accessible on EMA's homepage on the day of the event. For more information, please see the programme.

The European medicines regulatory system is based on a network of regulatory authorities from the 31 European Economic Area countries (28 EU Member States plus Iceland, Liechtenstein and Norway), the European Commission and EMA. EMA and the Member States cooperate and share expertise in the assessment of new medicines and of new safety information. They also rely on each other for exchange of information in the regulation of medicines, for example regarding the reporting of side effects of medicines, the oversight of clinical trials and the conduct of inspections of medicines' manufacturers.

Benoît Cœuré: The transmission of the ECB's monetary policy in standard and non-standard times

Speech by Benoît Cœuré, Member of the Executive Board of the ECB, at the workshop "Monetary policy in non-standard times", Frankfurt am Main, 11

September 2017

Monetary policy has had a powerful impact on financial markets in recent years. There is compelling international evidence that non-standard policy measures, such as asset purchases, forward guidance and negative interest rates, have been successful in altering relative asset prices in a way that is consistent with the predictions of portfolio rebalancing theory and the signalling channel of monetary policy. Few therefore dispute that the first stage of transmission of non-standard policy measures to the financing conditions of the private sector has been effective. Since the effective lower bound on nominal interest rates is expected to prevail more often in the future, this is undoubtedly good news.

The situation is less clear, however, when it comes to the second and third stages of transmission — that is, from easier financial conditions to economic activity and from economic activity to prices. Many central bank observers point to continued anaemic growth and low inflation across the globe and conclude that unconventional policy measures have failed to stimulate the economy. If this were the case, it would place a question mark over the use of such measures.

In my remarks this morning I would like to examine this claim more closely. In doing so, I will focus on two prime channels underlying the second stage of transmission: the exchange rate channel and the real interest rate channel. My remarks will therefore be neither exhaustive nor complete, given that monetary policy can affect the economy through many other channels as well, such as its impact on the valuation of equities and, hence, on firms' cost of capital and investment decisions, Tobin's q in short. [3] Another channel of relevance is the bank lending channel as formalised by Bernanke and Gertler (1995).

But by focusing on the exchange rate and interest rate channels, we can get a good understanding of how effective recent policy measures have been. In particular, I will show that monetary policy-induced exchange rate movements may have considerable impact on consumer prices, but that this relationship depends on the state of the economy and the shocks driving it, much in line with the recent literature in this field. And I will show that the New Keynesian Investment and Savings (IS) curve is alive and well in the euro area — that is, aggregate demand responds to changes in real ex ante interest rates, and can also be shown to have done so in recent times, provided it is measured properly.

A state-dependent exchange rate pass-through

Let me start with the exchange rate channel — a channel that has been heavily debated in recent months in the light of the large movements that we have observed in the foreign exchange market. For example, since the beginning of April the euro has appreciated by around 13% against the US dollar and 7% in nominal effective terms. Textbook economics would suggest that such sizeable changes ought to lower the prices of imported goods and thereby put downward pressure on producer and consumer prices.

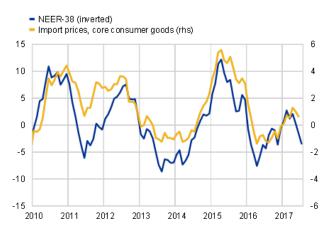
Transmission of exchange rate movements along the pricing chain

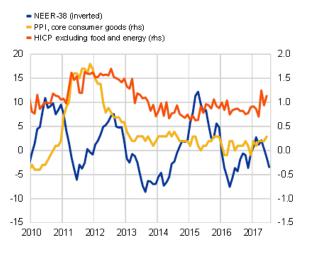
Import price inflation and the nominal effective exchange rate

(annual percentage points)

Core HICP and PPI inflation and the nominal effective exchange rate

(annual percentage points)





Sources: Haver Analytics and ECB staff calculations. Latest observation: June 2017, NEER-38: July 2017.

Sources: Haver Analytics and ECB staff calculations. Latest observation: June 2017, NEER-38: July 2017.

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On the left-hand side of slide 1 you can see that there is indeed a strong correlation between annual changes in the euro's nominal effective exchange rate and annual extra-euro area import price inflation, here shown for consumer goods excluding food, beverages and tobacco. Simple eyeballing would suggest a pass-through of around 40%, at least following depreciations, a point I will return to later. On the right-hand side you can see that the correlation is already much weaker in the case of the pass-through to producer and consumer prices. No discernible pattern emerges over the past seven years or so.

Of course, the reduced responsiveness at higher stages of the pricing chain in part reflects the fact that imports only account for a fraction of both producers' overall input costs and final consumption. But the seemingly stubborn resilience of consumer and producer price inflation to the sharp depreciation of the euro in 2014, and the subsequent appreciation in 2015, is nevertheless surprising. After all, based on prevailing estimates in the literature, the net effect of these two opposing exchange rate movements could have lifted HICP excluding energy and unprocessed food inflation — I will refer to this as core inflation from now on — by up to 0.5 percentage point over the course of last year. [4] In other words, such estimates suggest that euro area core inflation in 2016 would have been less than half its actual level if it had not been for the euro's depreciation in the preceding years.

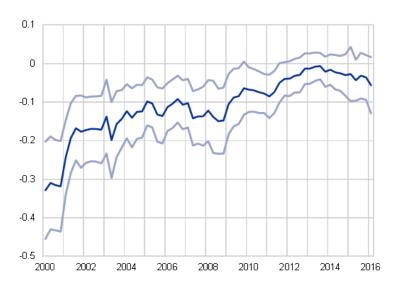
While this cannot be ruled out in the absence of a reliable counterfactual, it at least invites suspicion, not least as producer price inflation proved equally resilient lately. Recent price developments therefore raise two important questions. First, has the exchange rate pass-through declined over time and, if so, is it a temporary or a more permanent phenomenon. And, second, if it has declined, is this related to the use of non-standard monetary policy measures?

My answer to the first question is that, yes, the pass-through is likely to have been lower in recent years, mainly for two reasons.

The first, and more permanent, reason has to do with structural factors unrelated to monetary policy. A large body of the literature illustrates that the exchange rate pass-through depends on factors such as the monetary policy framework, import composition, trade integration, currency invoicing and the rise of global value chains. Broadly speaking, as globalisation has advanced and inflation and inflation volatility have declined, these factors have contributed to progressively reduce the exchange rate pass-through in most developed economies. For example, in the case of the euro area, it has been found that a growing share of local currency pricing has mechanically reduced the pass-through. You can see this on slide 2 for the euro area. Today the pass-through to final consumer price inflation may be less than a third of what it was at the beginning of the century.

Slide 2

Exchange rate pass-through to HICP inflation over time



Sources: Eurostat and ECB staff calculations.

Notes: The chart shows the cumulated impulse response (dark blue line) of HICP inflation to a 1% appreciation in the NEER after three years over time and the respective 95% confidence bands (light blue lines). The cumulated impulse response is based on the updated estimation of Hahn (2003) over a 20-year rolling window from the first quarter of 1980 to the first quarter of 2016. Each point on the dark blue line refers to the end point of each 20-year rolling sample, with the first sample referring to the period from the second quarter of 1981 to the first quarter of 2000 and the last sample to the period from the second quarter of 1981 to the first quarter of 2000 and the last sample to the period from the second quarter of 1981 to the first quarter of 2000 and the last sample to the period from the second quarter of 1981 to the first quarter of 2000 and the last sample to the period from the second quarter of 1981 to the first quarter of 2000 and the last sample to the period from the second quarter of 1981 to the first quarter of 2000 and the last sample to the period from the second quarter of 1981 to the first quarter of 2000 and the last sample to the period from the second quarter of 1981 to the first quarter of 2000 and the last sample to the period from the second quarter of 2000 and the last sample to the period from the second quarter of 2000 and the last sample to the first quarter of 2000 and the last sample to the period from the second quarter of 2000 and the last sample to the period from the second quarter of 2000 and the last sample to the period from the second quarter of 2000 and the last sample to the period from the second quarter of 2000 and the last sample to the period from the second quarter of 2000 and the last sample to the period from the second quarter of 2000 and the last sample to the period from the second quarter of 2000 and the last sample to the period from the second quarter of 2000 and the last sample to the period from the seco

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The second reason is more cyclical in nature. It relates to the state of the economy and the response of monetary policy to it. The theory is that exporters will not set their prices as a constant mark-up over costs, but will adjust them to expected changes in their future marginal costs and demand prospects. The implication is that what ultimately matters for the exchange rate pass-through is the type of shock that is hitting the economy. This notion goes back at least to Corsetti and Dedola (2005) but has received more prominence lately following the work of Kristin Forbes and co-authors (2015).^[7]

Slide 3

A state-dependent exchange rate pass-through

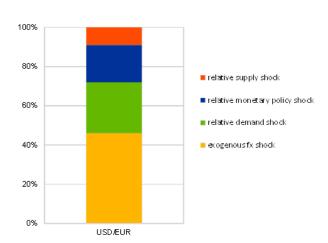
Historical variance decomposition of USD/EUR: 1999Q1-2017Q3

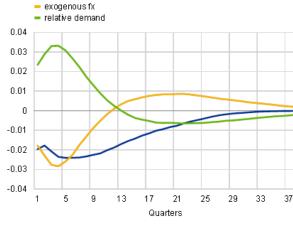
(percentage share)

Response of core HICP to different shocks normalized to a 1% appreciation of USD/EUR

(yoy percentage changes, not cumulated)

relative monetary policy





Source: ECB staff calculations.

Notes: Estimates are based on a quarterly BVAR model of the USD/EUR exchange rate, relative euro area - US GDP, relative euro area - US CPI and relative shadow interest rates, identified via sign restrictions over the period 1999Q1-2017Q3 (with 2017Q3 proxied by July data and nowcast estimates of GDP).

Source: ECB staff calculations.

Notes: Estimates are based on a quarterly BVAR model of the USD/EUR exchange rate, relative euro area - US CPI, relative shadow interest rates and core EA HICP, identified via sign restrictions over the period 1999Q1-2017Q2.

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On the left-hand side of slide 3 you can see initial evidence to support this claim. ECB staff find that less than half of the euro's exchange rate variations vis-à-vis the US dollar over the past almost 20 years was purely exogenous. [8] More often than not, exchange rates move in response to changes in relative demand, supply or monetary policy. And each of these shocks might entail a different response from domestic prices.

This you can see on the right-hand side. What this chart shows you is that there are occasions when euro area core inflation rises, rather than falls, following an exchange rate appreciation — which is entirely at odds with our traditional thinking on the pass-through. Perhaps unsurprisingly, this is typically the case when the exchange rate appreciates in response to a favourable demand shock. The logic is as follows: as the economy operates above capacity, inflationary pressures emerge that are sufficient to fully offset the disinflationary effects coming from the exchange rate channel.

The chart also shows that changes in the relative monetary policy stance have, on average, the expected impact on consumer prices: if euro area policy tightens, the exchange rate appreciates and inflation falls. In other words, there is no empirical evidence that the exchange rate channel of monetary policy is inactive.

But its strength will critically depend on the overall state of the economy, and not on the type of policy measure, standard or non-standard. This is my

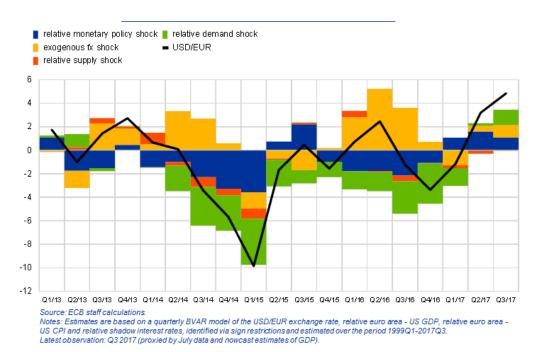
answer to the second question and can best be seen by looking at two concrete examples.

Slide 4

Exchange rate movements reflect a combination of shocks

Historical decomposition of euro exchange rate against the US dollar

(percentage quarterly contributions, not cumulated)



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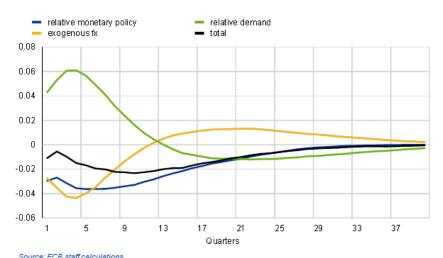
The first one relates to the sharp depreciation of the euro in the run-up to the announcement of the APP. As you can see on slide 4, a simple model-based analysis suggests that a large fraction of the decline in the euro's external value reflected the worsening economic outlook, to which we ultimately reacted. It is likely that exporters to the euro area, faced with falling euro area demand, absorbed part of the exchange rate movement in their markups to protect their market shares, thereby mitigating the upward pressure on prices stemming from a weaker currency.

The second example relates to the current situation. Slide 4 shows that there are three forces, of roughly equal strength, that help to explain the euro's marked appreciation in recent months: improved euro area growth prospects, an exogenous component and a tightening in the relative monetary policy stance vis-à-vis the United States.

Slide 5

Response of core HICP following the 2017Q3 appreciation of USD/EUR

(yoy percentage changes, not cumulated)



Notes: ELB static calculations.

Notes: Estimates are based on a quarterly BVAR model of the USD/EUR exchange rate, relative euro area - US GDP, relative euro area - US CPI, relative shadow interest rates and core EA HICP, identified via sign restrictions over the period 1999Q1-2017Q2. The impulse response functions are rescaled to reflect the appreciation of the euro exchange rate on impact by a magnitude consistent with the contribution of the specific shocks in driving the euro appreciation in 2017Q3 based on the historical decomposition estimates for that quarter. The '2017Q3 appreciation' refers to the change in the USD/EUR from July 2017 compared to its average in 2017Q2.

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Slide 5 illustrates the implications of this shock decomposition for the assessment of the exchange rate pass-through. The black line, which is the net effect, suggests relatively mild downward pressure on core inflation, much below what the rule of thumb would tend to suggest, despite the sizeable appreciation.

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The reason is simple. The current solid economic expansion in the euro area allows firms that export to the euro area to increase prices in their currency without losing market share, thereby mitigating, once again, the pass-through. So, exporters to the euro area are now able to recoup part of the margins they compressed during the downturn. The extent to which they are able to do so also depends on the degree of competition, a point made by Rudi Dornbusch back in 1987. The more concentrated market power is, and the less substitutable products are, the more likely firms are to increase their margins following exchange rate appreciations. This also means that the pass-through may well differ across industries. [9]

These examples demonstrate that it is by and large the state of the economy that will determine the strength of the pass-through. Monetary policy, for its part, is likely to influence the pass-through predominantly through its impact on the economy itself.

And at the moment this support from monetary policy may be even more powerful than in the past. The reason is that, in the class of models used here,

positive demand shocks are normally identified by assuming that short-term interest rates rise in response to higher growth and inflation.

At the current juncture, however, the policy-relevant horizon — the "medium term" concept in our monetary policy strategy — is likely to be longer given the persistence of subdued inflationary pressures. Our forward guidance on both policy rates and the APP, as reiterated by the Governing Council last Thursday, reflects this assessment. This means that, compared with past demand shocks, policy will remain more accommodative for longer, thereby likely muting further the pass-through of any growth-driven exchange rate appreciation. And with the current recovery in the euro area being largely driven by domestic demand, euro strength may also have less of an impact on growth than, for example, after the Great Financial Crisis.

All of this suggests, therefore, that monetary policy never acts in isolation on the exchange rate and that, in periods of recovery, the positive confidence and stimulus effects of monetary policy are likely to offset, at least in part, the disinflationary effects of a stronger currency coming from expectations of tighter policy.

Slide 6

Disconnect emerging between long-term interest rate differential and USD/EUR

US Treasury and Bund yield differential (inverted) and USD/EUR



Latest observation: 01/09/2017.

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Of course, this also means that should the contributions of the different shocks driving the exchange rate change over time, then also our assessment of the impact on inflation will have to change — expansion or not. Exogenous

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shocks to the exchange rate, if persistent, can lead to an unwarranted tightening of financial conditions with undesirable consequences for the inflation outlook. As shown on slide 6, the emerging disconnect between the euro's exchange rate vis-à-vis the US dollar and the long term interest rate differential between the US and Germany may suggest that we are entering such a situation. Against this background, the recent volatility in the exchange rate represents a source of uncertainty which requires monitoring.

The New Keynesian IS curve in the euro area

This brings me to the second channel I would like to discuss this morning: the effects of monetary policy on real economic activity.

Much of our attention recently has been focused on the properties of the Phillips curve — that it may be flatter, non-linear or mis-specified in terms of the relevant economic slack. By now, we are fairly confident that non-linearities and broader labour market slack are likely to explain much of the weakness in inflation as of late. [10]

Some observers have interpreted the lack of stronger price pressures as a failure of monetary policy to stimulate the economy. They argue that persistently low inflation is testimony to the ineffectiveness of non-standard policy measures. If this were true, then also the reasoning behind the shock-based exchange rate pass-through would in part be misguided.

I would argue, however, that such claims reflect a serious misunderstanding and simplification of how monetary policy works. There are very few instances, such as through the exchange rate, where policy can directly affect prices. In most cases monetary policy transmits to prices through its impact on the intertemporal allocation of consumption, savings and investment. If prices are slow to adjust, a cut in the key policy rate lowers the real interest rate, which, in turn, stimulates interest-sensitive spending. In other words, if we want to see if policy works or not, or if the economy has become less sensitive to changes in interest rates, then we should examine the slope of the IS curve, and not only of the Phillips curve. [11]

Empirical research on the IS curve is scarce, however. And the few studies available are generally not encouraging from a monetary policy perspective. They typically find that output does not respond, in a statistically significant way, to the real interest rate. [12] Often they even find a positive relationship between real interest rates and output. These findings are at best disturbing given that much of mainstream monetary thinking is built on the idea that firms and households take the level of the interest rate into account when making economic decisions.

Slide 7

Estimated coefficients of a euro area New Keynesian IS curve

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(40)
	· ` ′	· · ·	· · ·	` ′	` ′	` ′	\- /	` '	` '	(10)
Lagged output	0.98***	0.96***	0.97***	0.98***	0.96***	0.96***	0.96***	0.91***	0.98***	0.98***
	(0.04)	(0.03)	(0.07)	(0.04)	(0.05)	(0.03)	(0.03)	(0.07)	(0.04)	(0.04)
Output expectations							0.11**	0.07		
							(0.04)	(0.08)		
Real ex ante interest rate gap	-0.06			-0.02						
	(0.07)			(0.08)						
Real ex post interest rate gap		-0.01								
		(0.06)								
Real ex ante interest rate			-0.01							
			(0.11)							
Real ex ante shadow rate gap					0.00					
					(0.04)					
Real ex ante bank rate gap						-0.13*	-0.31***	-0.31**		
						(0.07)	(0.10)	(0.13)		
FCI									0.19***	0.09*
									(0.05)	(0.05)

Source: ECB staff calculations.

Notes: Standard errors in parentheses. ***p<0.01, **p<0.05, *p<0.1

Sample: 1999Q1 to 2017Q2 except specifications (4) and (8), which are 1999Q1-2008Q2 and 2010Q1-2017Q2 respectively and specifications (9) and (10), which are 2005Q1 to 2017Q2 due to data availability.

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To illustrate the empirical failure of the IS curve, slide 7, column 1, shows the estimated coefficients of a regression of the euro area output gap on its own lag and a measure of the real "interest rate gap", i.e. the difference between the real ex ante interest rate and the time-varying natural rate. Except for the fact that output is not forward-looking — I will come to this in a minute — this is a standard New Keynesian IS curve where the output gap is based on estimates by the European Commission, the short-term interest rate is the three-month Euribor, expected inflation is taken from the ECB's Survey of Professional Forecasters (SPF) and the natural rate is taken from the euro area estimates by Holston, Laubach and Williams (2016).

Clearly, the real interest rate gap is not statistically significant at any reasonable confidence level. This finding holds true if we use actual ex post inflation — specification 2 — instead of expected inflation, or if we include the real interest rate *per se*, and not as a deviation from the natural rate, as is sometimes suggested, as in specification 3.

The financial crisis and the use of non-standard policy measures do not seem to explain the puzzle either: the real interest rate remains insignificant if we restrict the sample to the period before the outbreak of the crisis, specification 4, or if we take the euro area shadow rate as estimated by Wu and Xia (2016) — specification 5 — a measure that attempts to mimic the joint effects of unconventional policy measures at the zero-lower bound.

What I would argue, however, is that the short-term interest rate is not the appropriate measure to use in an empirical IS curve. In a bank-based economy, such as the euro area, the short-term interest rate may simply not be sufficient to characterise the monetary policy stance and, hence, the financial conditions ultimately determining the decisions by households and firms. The imperfect substitutability between market-based financing and bank loans was already recognised by Modigliani (1963) and later refined by Bernanke and Blinder (1988).

Indeed, it is enough to recall the period after the outbreak of the sovereign debt crisis, and the associated financial fragmentation, to see that the interbank market rate is a biased measure of the financing conditions facing the private sector. [13] In other words, unless there is a perfect transmission from changes in short-term rates to the ultimately relevant borrowing rates, estimates using the former will yield inconclusive results.

This conjecture is also supported by the data. In specification 6 we replaced the short-term interest rate with a measure of the composite bank-based cost of borrowing for non-financial firms. If we use this measure instead, the real ex ante interest gap in our IS curve has the expected sign and becomes statistically significant at the 10% level: a 1 percentage point reduction in the gap increases output by 0.13 percentage point.

The interest rate channel becomes even more powerful once we estimate a New Keynesian IS-curve that is closer to first principles — that is, one that is also forward-looking in output, as in specification 7. For this purpose, we add to the equation the expected real GDP growth rate six quarters ahead, as collected by the ECB's SPF.

As in previous findings in the literature, output appears to be strongly forward-looking. But the thing to note is that the real interest rate gap is now significant at the 1% level, suggesting an increase in output by 0.3 percentage point following a 1 percentage point drop in the real rate gap. There is also no evidence that output might have become less sensitive to changes in real bank lending rates with the advent of non-standard measures: although the sample is naturally small, and estimates might therefore be biased, specification 8 illustrates that the coefficients remain unchanged when we estimate the same forward-looking IS curve for a sample starting with the outbreak of the sovereign debt crisis in 2010.

In other words, these estimates would suggest that about a quarter of the reduction in the output gap that we have observed since the introduction of our credit easing measures in June 2014 can be directly explained by the impact of our measures on bank lending rates, even after controlling for the indirect positive impact on expected inflation. These estimates are very close to other internal ECB staff estimates, using more sophisticated term structure and general equilibrium models, of the impact of our measures on economic growth. [15]

So, monetary policy is far from being ineffective in stimulating aggregate demand, also when approaching the effective lower bound. The fact that inflation remains subdued rather reflects constraints operating at the third

stage of transmission — from activity to prices — that are often outside the control of monetary policy.

Before I conclude I would like to illustrate one last point. Bank lending rates are without doubt a key variable in explaining output movements in the euro area. The evidence I provided today further emphasises this point. At the same time, the financial conditions that are ultimately relevant for firms and households may be broader than that. One of them — the exchange rate — I discussed in more detail earlier in my remarks. [16] Other factors may include equity prices or long-term interest rates that are often relevant for household mortgages. [17]

One way to summarise these factors is to use financial conditions indexes (FCIs). My colleague Peter Praet gave a detailed speech on such indices earlier this year, which I strongly recommend reading. [18] Here I would like to focus on the relevance of these broad measures for economic activity.

As you can see in column 9 of slide 7, FCIs are highly statistically significant when used in a New Keynesian IS curve. This is unlikely to be a statistical artefact. It is rather further evidence that we cannot reduce our analysis of the impact of monetary policy to a simple short-term rate as has typically been done in the academic literature so far. [19]

The question then is no longer which financial variable to use in estimations, but how to weigh them to reflect any varying impact they may have on output and, ultimately, inflation. For example, my last specification on slide 7 uses an FCI that attributes a much larger weight to the exchange rate, in line with the rule of thumb I mentioned earlier, which suggested a strong pass-through to inflation. Interestingly, this FCI fits the data less well, and is just about significant at the 10% level, which might support the view that the exchange rate pass-through could be lower than what such a rule of thumb would suggest.

But as I explained earlier, even a lower weight on the exchange rate would likely not fully capture the relative importance of the various financial variables at *each* point in time. That is, if the impact of changes in financial conditions on inflation depends on the state of the economy, then ideally FCIs would be based on time-varying weights. This is food for thought for future research.

Conclusion

With this in mind, let me conclude.

The negative relationship between the real interest rate gap and economic activity as posited by Wicksell back in 1898 is a mainstay of modern central banking. This relationship has not been lost with the advent of unconventional monetary policy measures. By easing market-based financial conditions, and by putting downward pressure on the real interest rate that banks charge to borrowers, central banks can stimulate aggregate demand, even when short-term interest rates approach the effective lower bound.

The validity of this relationship is also crucial for assessing the price effects of monetary policy-induced movements of the exchange rate. With policy being effective in boosting growth, any disinflationary effect of a stronger currency arising from expectations of a tighter future monetary policy stance might be mitigated, or offset, by the ensuing improvement in the economic outlook. However, exogenous shocks to the exchange rate, if persistent, can lead to an unwarranted tightening of financial conditions with undesirable consequences for the inflation outlook.

Thank you.

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EIB provides USD 15 million for Egypt Mid-Cap fund

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Daily News 08 / 09 / 2017

Juncker Plan: Investment Plan finances innovative medical research with a €75 million loan to Evotec

The Investment Plan for Europe continues to support innovative projects in the health sector. The European Investment Bank (EIB) is providing €75 million to Evotec to invest in research and development of treatments for serious illnesses. The loan is guaranteed by the European Fund for Strategic Investments (EFSI), the central element of the Investment Plan for Europe, the so-called Juncker Plan. Evotec will use this long-term financing boost to finance drug discovery and the development of new treatments for serious illnesses and diseases. The type of financing is also novel: it is the first large equity-type investment under EFSI in any industry anywhere in Europe. It also EFSI's first contingent investment, meaning the bank shares the risk of Evotec's research & development (R&D) success. Speaking at the signing event, Commission Vice-President Jyrki Katainen, responsible for Jobs, Growth, Investment and Competitiveness, said: "The development of innovative treatments is a process which requires sustained investment. This is where the Investment Plan can play a role. I am glad that, with today's agreement,

the Plan is supporting research which aims to tackle serious illnesses and diseases." This agreement with Evotec comes days after agreements were finalised with MagForce to develop new treatments for brain cancer as well as Apeiron which also develops cancer treatment, particularly a rare type affecting children. Also today the European Investment Fund signed a deal with ACT Ventures to provide €20 million in financing to small tech businesses in Ireland. For the latest EFSI figures country-by-country, see here. A full press release on today's agreement is available here. (For more information: Annika Breidthardt — Tel.: +32 229 56153; Siobhán Millbright — Tel.: +32 229 57361)

La Commission fournit une aide supplémentaire aux producteurs européens de pêches et nectarines

Les producteurs européens de pêches et nectarines recevront une aide supplémentaire à celle déjà annoncée <u>en juin</u> au vu des difficultés de marchés auxquelles ils ont fait face cet été. €12,8 millions viendront donc compléter l'aide déjà fournie au début de la saison qui se montait alors à €70 millions. Cela financera le retrait du marché de 35 020 tonnes de nectarines et pêches. Cette compensation financière s'adressant aux producteurs grecs, italiens et espagnols qui n'auraient pas trouvé de débouchés sur les marchés sera rétroactive au 3 août. Le Commissaire à l'agriculture, Phil Hogan a dit: "Nous restons évidemment attentifs et vigilants quant à la situation des producteurs européens qui exercent leur travail dans un contexte volatile. La Politique Agricole Commune dispose de nombreux moyens pour les soutenir lors de difficultés et nous démontrons encore une fois que la Commission reste aux côtés des agriculteurs." Cette décision, adoptée aujourd'hui, sera publiée demain, samedi 9 septembre, au <u>Journal Officiel</u>. Les producteurs de fruits et légumes européens continueront à bénéficier d'autres mesures au titre de la politique agricole commune de l'UE, telles que les paiements directs, le financement du développement rural et le soutien financier aux organisations de producteurs, représentant un total d'environ €700 millions par an. (Pour plus d'informations: Daniel Rosario - Tel.: +32 229 56185; Clémence Robin -Tel: +32 229 52509)

STATEMENTS

Bringing back hope to patients on waiting lists all over Europe: Statement by Vytenis Andriukaitis on the occasion of European Day for Organ Donation and Transplantation

"On 9 September we celebrate the 18th European Day for Organ Donation and Transplantation. I am in Lithuania at an event marking the 30th anniversary of the first heart transplant in the country. It is an emotional moment for me because 30 years ago, as a young surgeon, I had the privilege to take part in that operation. Since then, the number of transplantations, of all types, has increased a lot in the EU and worldwide, only between 2010 and 2015 the increase was 14 per cent... A large part of this is thanks to higher donation rates. Therefore we should honour the contribution of the countless everyday heroes in the EU who have helped extend and save hundreds of thousands of lives. Improvements are also due to surgical advances, better coordination between clinical teams, improved transport and safety standards for organs,

and an increase in the cross-border exchange of organs. [...] In just two years, almost 90 transplants have taken place, mainly for children, which would not have been possible without this. We will soon publish a report that will clearly illustrate that pooling resources and knowledge across the EU can significantly improve clinical outcomes.[...] Unfortunately, nevertheless 16 patients die every day waiting for an organ in the EU; thousands of patients remain on transplant waiting lists. As a doctor, I know exactly how far we have come, medically speaking. As a European Commissioner I know the fundamental importance of coordination at a European level when we're talking about organ donation and transplantation. I believe that together with our Member States we can do more. Where there is a will there is a way." The full statement in all linguistic versions is available online. (For more information: Anca Paduraru — Tel.: +32 229 91269; Aikaterini Apostola — Tel.: +32 229 87624)

Calendar

The Commissioners' Weekly Activities

Upcoming events of the European Commission (ex-Top News)

<u>CALENDRIER du 11 septembre au 17 septembre 2017</u>

(Susceptible de modifications en cours de semaine)

Déplacements et visites

Lundi 11 septembre 2017

Informal meeting of ministers responsible for development (FAC), in Tallinn

11-14/09 European Parliament plenary session, in Strasbourg

President Jean-Claude **Juncker** receives Mr Joseph Daul, President of the European People's Party (EPP); and Mr Manfred Weber, Chairman of the EPP Group in the European Parliament.

Ms Federica **Mogherini** and Mr Neven **Mimica** in Tallinn, Estonia: attend the Informal meeting of ministers responsible for development.

Mr Andrus **Ansip** in Tallinn, Estonia: attends the Informal meeting of ministers responsible for development, the Digital for Development session.

Mr Maroš **Šefčovič** delivers a keynote speech at "European Energy Policy"

symposium, organised by the Economic Council of Germany, in Brussels.

Mr Miguel **Arias Cañete** in Valladolid, Spain: delivers a keynote speech at the VIII Agrarian Cooperativism Days.

Mr Vytenis Andriukaitis receives representatives of ReAct Europe.

M. Pierre **Moscovici** à Paris (jusqu'à 14/09): rencontre les membres du Haut Conseil des Finances publiques; M. Luc Carvounas, Député et Membre de la Commission de la Défense Nationale et des Forces Armées de l'Assemblée Nationale et Maire d'Alfortville; et M. Jean-Yves Le Drian, Ministre de l'Europe et des Affaires étrangères de la France.

Mr Carlos Moedas receives directors from Microsoft.

Mr Carlos **Moedas** receives Mr Massimo Busuoli, Head of the Norwegian University of Science and Technology (NTNU) Brussels Office.

Mr Julian **King** delivers a speech at the High-Level Commission Expert Group on Radicalisation, in Brussels.

Mardi 12 septembre 2017

College meeting

European Parliament plenary session, in Strasbourg

Mr Günther H. **Oettinger** meets members of the ALDE group of the European Parliament to discuss the next multiannual financial framework of the European Union following the presentation of the Reflection Paper on the Future of EU finance, in Brussels.

Ms Mariya **Gabriel** Strasbourg, France: participates in a working dinner with the European Newspaper Publishers' Association.

Mercredi 13 septembre 2017

European Parliament plenary session, in Strasbourg

President Jean-Claude **Juncker** delivers his 2017 State of the Union address to the Plenary of the European Parliament.

Mr Carlos **Moedas** in France (until 14/09): in Strasbourg: attends breakfast roundtable on the state of play of innovation in Europe at the European Forum for Renewable Energy Sources (EUFORES).

Mr Carlos **Moedas** à Orléans, France: participe à une rencontre des scientifiques de la région d'Orléans; rencontre M. Jean-Marc Falcone, Préfet de la région Centre-Val de Loire; et participe à une réception officielle en Préfecture d'Orléans.

Ms Mariya **Gabriel** in Luxembourg (until 14/09): visits the European Commission's Datacentre in Betzdorf.

Jeudi 14 septembre 2017

European Parliament plenary session, in Strasbourg

Justice and Home Affairs Council (JHA), in Brussels

Mr Valdis **Dombrovskis** in Tallinn, Estonia (until 16/09): delivers a speech on the "Future of global regulatory coordination in the financial sector and implications for the EU financial sector and economy" at Eurofi Financial Forum 2017; meets Mr Vittorio Grilli, Chairman of the Corporate and Investment Bank, EMEA at J.P. Morgan; Mr Richard Gnodde, Vice-Chairman of The Goldman Sachs Group, Inc. and CEO of Goldman Sachs International; and Mr Massimiliano Alvisini, Senior Vice-President Europe and CIS of Western Union.

Mr Johannes **Hahn** receives the observers from the International Monitoring Operations to Albania, in Brussels.

Ms Marianne **Thyssen** in Mannheim, Germany: visits "Förderband Mannheim e.V.", EU-funded projects aiming at supporting young people during the transition from school to apprenticeship, and into work.

- M. Pierre **Moscovici** à Paris: rencontre M. Gilles Finchelstein, Directeur général de la <u>Fondation Jean-Jaurès</u>; et M. Laurent Cohen, Directeur général adjoint de la Fondation Jean-Jaurès; et M. Nicolas Hulot, Ministre d'État, Ministre de la Transition Écologique et Solidaire de la France.
- M. Pierre **Moscovici** reçoit M. Jean-Yves Le Gall, Président du <u>Centre National</u> <u>d'Etudes Spatiales</u> (CNES), à Bruxelles.

Ms Violeta **Bulc** in Frankfurt, Germany: attends the opening ceremony of the <u>International Motor Show (IAA)</u>; and participates in the Second High-Level Dialogue on Automated and Connected Driving.

Ms Elżbieta **Bieńkowska** receives Mr Harry Ilan Laufer, Minister for SMEs, Trade and Entrepreneurship of Romania.

Ms Věra **Jourová** in the Czech Republic: attends a meeting of the Committee of Agriculture of the Chamber of Deputies of Parliament, on dual food quality.

Ms Margrethe **Vestager** receives Mr Álvaro Nadal Belda, Minister for Energy, Tourism and Digital Agenda of Spain.

Mr Carlos **Moedas** à Paris, France: rencontre Mme Nathalie Loiseau, Ministre auprès du ministre de l'Europe et des Affaires étrangères, chargée des Affaires européennes.

Mr Carlos **Moedas** receives representatives of Abengoa S.A. (company providing innovative technology solutions in the energy and environment sectors).

Mr Carlos **Moedas** receives Mr Jean-Bernard Lévy, Chairman and CEO of EDF Group.

Mr Carlos **Moedas** delivers a keynote speech at the "ENI after 6" — a series of conferences organised by the EU Government Affairs of ENI, in Brussels.

Ms Mariya **Gabriel** in Luxembourg: meets Mr Xavier Bettel, Prime Minister of Luxembourg, Minister of State, Minister for Communications and the Media, Minister for Religious Affairs, Minister for Culture.

Ms Mariya **Gabriel** in Frankfurt, Germany (until 15/09): participates in the <u>International Motor Show (IAA)</u>; in the Second High-Level Dialogue on Automated and Connected Driving; and in a dinner hosted by Mr Alexander Dobrindt, Federal Minister for Transport and Digital Infrastructure of Germany.

Vendredi 15 septembre 2017

Eurogroup, in Tallinn

15-16/09 Informal meeting of economic and financial affairs ministers, in Tallinn

Mr Maroš **Šefčovič** in Frankfurt, Germany: attends the opening ceremony of the International Motor Show (IAA).

Mr Johannes Hahn Belgrade, Serbia: on official mission.

Mr Miguel **Arias Cañete** in Montreal, Canada (until 16/06): participates in the Ministerial on Climate Action (MOCA).

Mr Christos **Stylianides** receives Mr Wolfgang Jamann, Secretary General and CEO of CARE International.

Mr Christos **Stylianides** receives Mr Rodrigo Rivera, High Commissioner for Peace of Colombia.

Ms Violeta **Bulc** in Ljubljana, Slovenia: presents the 'State of the Union' to the Slovenian National Assembly.

Ms Elżbieta **Bieńkowska** in Poland (until 16/09): delivers a speech on the occasion of the 15th anniversary of the Polish Union of Cosmetics Industries.

Ms Věra **Jourová** in Austria: meets Mr Wolfgang Brandstetter, Vice-Chancellor and Federal Minister for Justice of Austria; visits a Youth Detention Centre; and the Lower Austrian Provincial Exhibition 2017: "Alles was Recht ist".

Ms Corina **Creţu** in Valencia, Spain: participates in an <u>event</u> organised by the European Committee of the Regions (CoR) on the future of the European Cohesion policy.

Ms Margrethe **Vestager** in Denmark (until 16/09): delivers a keynote speech on "Competition as seen from Brussels" at the Northern Jutland Business

Development Forum.

Mr Carlos Moedas meets CEOs of research funding foundations, in Brussels.

Mr Julian **King** in Tallinn, Estonia: delivers a speech at the <u>EU Cyber</u> <u>Security Conference "Digital Single Market, Common Digital Security 2017"</u>.

Ms Mariya **Gabriel** in Frankfurt, Germany: participates in a breakfast talk with Mr Anton Losinger, Auxiliary Bishop of Augsburg.

Samedi 16 septembre 2017

Informal meeting of economic and financial affairs ministers, in Tallinn

Mr Miguel **Arias Cañete** in Montreal, Canada: participates in the Ministerial on Climate Action (MOCA).

Ms Elżbieta **Bieńkowska** in Warsaw, Poland: participates in the 60^{th} Anniversary event of the Association of International Road Transport Carriers in Poland (ZMPD).

Ms Margrethe **Vestager** in Denmark: delivers a speech at the Social Liberals convention.

Dimanche 17 septembre 2017

Mr Andrus **Ansip** in New York, the United States: attends the Annual Meeting of the Broadband Commission for Sustainable Development.

Mr Pierre **Moscovici** à Washington, les États-Unis (jusqu'à 22/09): participe à un dîner du travail offert par M. David O'Sullivan, Ambassadeur et Chef de la délégation de l'Union européenne aux États-Unis.

Ms Mariya **Gabriel** in Rome, Italy: participates in the European People's Party (EPP) conference and the roundtable on "Europe, Growth, Digital Society and Business".

Prévisions du mois de septembre:

19-21/09 Informal meeting of energy and transport ministers (TTE), in Tallinn.

25/09 General Affairs Council (GAC), in Brussels.

26/09 General Affairs Council (Art. 50), in Brussels.

29/09 Tallinn Digital Summit, in Tallinn.

Prévisions du mois d'octobre:

- 02-05/10 European Parliament plenary session, in Strasbourg.
- 09/10 Eurogroup, in Luxembourg.
- 09-10/10 Agriculture and Fisheries Council (AGRIFISH), in Luxembourg.
- 10/10 Economic and Financial Affairs Council (ECOFIN), in Luxembourg.
- 12-13/10 Justice and Home Affairs Council (JHA), in Luxembourg.
- 13/10 Environment Council (ENVI), in Luxembourg.
- 16/10 Foreign Affairs Council (FAC), in Luxembourg.
- 17/10 General Affairs Council (GAC), in Luxembourg.
- 17/10 General Affairs Council (Art. 50), in Luxembourg.
- 17/10 Competitiveness Council (COMPET), in Luxembourg.
- 18/10 Tripartite Social Summit, in Brussels.
- 19-20/10 European Council, in Brussels.
- 23/10 Employment, Social Policy, Health and Consumer Affairs Council (EPSCO), in Luxembourg.
- 23-26/10 European Parliament plenary session, in Strasbourg.
- 24/10 Transport, Telecommunications and Energy Council (TTE), in Luxembourg.

Prévisons du mois de novembre:

- 06/11 Eurogroup, in Brussels.
- 06-07/11 Agriculture and Fisheries Council (AGRIFISH), in Brussels.
- 07/11 Economic and Financial Affairs Council (ECOFIN), in Brussels.
- 09/11 Justice and Home Affairs Council (JHA), in Brussels.
- 10/11 Foreign Affairs Council (FAC), in Brussels.
- 13-14/11 Foreign Affairs Council (FAC), in Brussels.
- 13-16/11 European Parliament plenary session, in Strasbourg.
- 15/11 General Affairs Council (GAC), in Brussels.
- 17/11 Economic and Financial Affairs Council (ECOFIN), in Brussels.

- 17/11 Social Summit for Fair Jobs and Growth, in Gothenburg.
- 20/11 General Affairs Council (GAC), in Brussels.
- 20-21/11 Education, Youth, Culture and Sports Council (EYCS), in Brussels.
- 24/11 Eastern Partnership summit, in Brussels.
- 27/11 Foreign Affairs Council (FAC), in Brussels.
- 29-30/11 European Parliament plenary session, in Brussels.
- 30/11 01/12 Competitiveness Council (COMPET), in Brussels.

Prévisions du mois de décembre:

- 30/11 01/12 Competitiveness Council (COMPET), in Brussels.
- 04/12 Eurogroup, in Brussels.
- 04-05/12 Transport, Telecommunications and Energy Council (TTE), in Brussels.
- 05/12 Economic and Financial Affairs Council (ECOFIN), in Brussels.
- 07-08/12 Justice and Home Affairs Council (JHA), in Brussels.
- 07-08/12 Employment, Social Policy, Health and Consumer Affairs Council (EPSCO), in Brussels.
- 11/12 Foreign Affairs Council (FAC), in Brussels.
- 11-12/12 Agriculture and Fisheries Council (AGRIFISH), in Brussels.
- 11-14/12 European Parliament plenary session, in Strasbourg.
- 12/12 General Affairs Council (GAC), in Brussels.
- 12/12 General Affairs Council (Art. 50), in Brussels
- 14-15/12 European Council, in Brussels.
- 18/12 Transport, Telecommunications and Energy Council (TTE), in Brussels.
- 19/12 Environment Council (ENVI), in Brussels.

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