

Conclusions of the 50th meeting of the EEA Council

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The fiftieth meeting of the EEA Council took place in Brussels on 20 November 2018 under the Presidency of Ms Ine Eriksen Søreide, Minister of Foreign Affairs of Norway. The meeting was attended by Ms Karin Kneissl, Minister of Foreign Affairs of Austria, representing the Presidency of the Council of the European Union, Ms Aurelia Frick, Minister of Foreign Affairs of Liechtenstein, and Mr Guðlaugur Þór Þórðarson, Minister for Foreign Affairs of Iceland, as well as by Members of the Council of the European Union and representatives of the European Commission and the European External Action Service. The EEA Council discussed the overall functioning of the Agreement on the European Economic Area (EEA Agreement) and held an orientation debate on the European Pillar of Social Rights in the context of the EEA Agreement.

Political Dialogue

1. The EEA Council recognised that the close partnership between the EU and the EEA EFTA States was the best guarantee of long-term shared prosperity and stability. In this context, the EEA Council noted that, within the framework of the Political Dialogue, the Ministers had discussed the implications for the EEA Agreement and the EEA EFTA States of the UK's withdrawal from the EU, and multilateralism. The EEA Council underlined the importance of continuing the practice of inviting officials from the EEA EFTA States to political dialogues held at the level of the relevant EU Council working parties.

2. With regard to the UK's withdrawal from the EU, the EEA Council underlined the importance of safeguarding the EEA Agreement, ensuring the continuation of a well-functioning, homogenous EEA and preserving the integrity of the Internal Market. The EEA Council welcomed the close dialogue and continuous exchange of information that has been established between the EU and the EEA EFTA States on the negotiations between the EU and the UK under Article 50 of the Treaty on European Union regarding the withdrawal of the UK from the EU. The EEA Council, aware of the EEA dimension of the UK's withdrawal from the EU, called for a continuation of the dialogue between the EU and the EEA EFTA States to ensure continued homogeneity in the EEA. Cooperation in the EEA

3. On 1 January 2019 the EEA Agreement will have been into force for 25 years. It has closely linked our societies and economies and has ensured that a high level of norms and social standards is applicable to all our citizens

and workers. The EEA Agreement has been a solid basis for broad and strong relations. The positive spirit of cooperation has allowed for adaptations and solutions to be found, in a world of constant change. The EEA Council confirmed its support for the EEA agreement as the continued basis for future relations between the EU and EEA EFTA States. The EEA Council recognised the positive contributions made by the EEA EFTA States to the decision-shaping process of EEA-relevant EU legislation and programmes through their participation in the relevant committees, expert groups, studies and agencies, as well as through the submission of EEA EFTA Comments. The EEA Council underlined the importance of inviting EEA EFTA Ministers to informal EU Ministerial meetings and Ministerial conferences relevant to EEA EFTA participation in the Internal Market, and expressed its appreciation to the current Austrian and incoming Romanian Presidencies for the continuation of this practice. The EEA Council recognized the important role of parliamentary cooperation and cooperation between economic and social partners through the EEA Joint Parliamentary Committee and the EEA Consultative Committee, respectively.

4. Welcoming the recovery of the European economy, the EEA Council emphasised the importance of a well-functioning Internal Market as a driver in boosting economic growth and creating new jobs throughout Europe. It underlined the indivisibility and importance of the four freedoms for the well-functioning of the Internal Market, which is in the common interest of all Contracting Parties. The EEA Council agreed that a holistic approach was required to tackle some of the main challenges facing the Internal Market, and stressed the importance of the close involvement of the EEA EFTA States in the further design and development of Internal Market policies and initiatives. It furthermore stressed the importance of the two-pillar structure of the EEA Agreement. Emphasising the fact that greater knowledge of the EEA Agreement throughout the EEA was in the interest of all Contracting Parties, the EEA Council urged the EU and the EEA EFTA States to ensure that information on the EEA Agreement was made readily and easily available.

5. The EEA Council acknowledged the importance of predictable trade conditions for economic operators within the EEA. In this regard, the EEA Council welcomed the exemption of Iceland, Liechtenstein and Norway from the EU's provisional safeguard measures concerning imports of a number of steel products, which came into effect on 19 July 2018. These exemptions are compatible with both the EU's bilateral and multilateral World Trade Organisation (WTO) obligations.

Energy and climate change

6. The EEA Council placed great importance on continued close cooperation between the EU and the EEA EFTA States in environmental, energy and climate change policies, particularly in light of the 2030 Framework for Climate and Energy and the Framework Strategy for a Resilient Energy Union with a Forward-Looking Climate Change Policy. The EU and the EEA EFTA States took note of the latest Intergovernmental Panel on Climate Change (IPCC) special report, which unequivocally confirmed the negative impacts of climate change,

including its conclusions indicating that global emission reductions in all sectors were crucial and that further action was needed in mitigation and adaptation, notably to reach the temperature goal as set out in the Paris Agreement and expressed their commitment to the transition to low greenhouse gas emission, sustainable and climate-resilient economies and societies. They also expressed their commitment to reaching a successful outcome under the Paris Agreement work programme at the 24th Conference of the Parties of the United Nations Framework Convention on Climate Change in Poland this December and to actively participate in the Talanoa Dialogue, enabling the effective implementation of the Paris Agreement.

7. While respecting the Contracting Parties' right to determine the conditions for exploiting their energy resources, their choice between different energy sources and the general structure of their energy supply, the EEA Council noted that the EEA EFTA States remain a key partner of the EU as a reliable supplier of energy and underlined that the close cooperation should continue in the areas of the Internal Energy Market, in addition to cooperation in the fields of energy security, emissions trading, the promotion of competitive, climate-resilient, safe and sustainable low carbon energy, energy efficiency, renewable energy resources, and carbon capture, utilisation and storage (CCUS), circular economy, as well as other environmental issues, such as chemicals, water resource management, biodiversity and pollution.

Digital Single Market

8. The EEA Council noted that extending the Digital Single Market to the EEA EFTA States is an important step towards completing the Internal Market. In this context, the EEA Council welcomed the steps taken to incorporate new legislation connected to the Digital Single Market Strategy. In view of the importance of the free flow of data in the European digital economy, the EEA Council welcomed in particular the incorporation of the General Data Protection Regulation into the EEA Agreement. The EEA Council also took note of important legislative proposals currently under consideration, including the revision of the regulatory framework in telecommunication, and on cybersecurity.

Capital controls

9. The EEA Council noted that the free movement of capital is a fundamental Internal Market freedom and an integral part of the EEA acquis and acknowledged that restrictions can be implemented only temporarily, on the basis of the provisions of Article 43 of the EEA Agreement. The EEA Council welcomed the progress of the comprehensive plan of the Icelandic Government for removal of capital controls without threatening economic and financial stability of the country, particularly the lifting of capital controls on individuals, companies and pensions funds. The EEA Council further welcomed the progress made towards the removal of capital controls in Greece.

Incorporation of EEA-relevant EU acts

10. Noting the Progress Report of the EEA Joint Committee, the EEA Council expressed its appreciation for the work of the Joint Committee in ensuring

the continued successful operation and good functioning of the EEA Agreement.

11. The EEA Council welcomed the ongoing efforts to reduce the number of EU acts awaiting incorporation into the EEA Agreement and to accelerate the incorporation process. While commending all the steps undertaken in the course of the last years, the EEA Council noted that the number of acts awaiting incorporation was still too high. The EEA Council called for continued work in order to significantly and durably reduce the number of acts awaiting incorporation and thereby continue to ensure legal certainty and homogeneity in the EEA. This common goal can be achieved through political will and enhanced dialogue among the relevant experts and organs. The EEA Council urged all parties to engage constructively to find solution to pending difficult issues. Furthermore the EEA Council looked forward to reaching a conclusion as soon as possible on the incorporation of the Third Postal Directive and Genetically Modified Organisms.

12. While welcoming the recent progress made at expert level, the EEA Council highlighted the importance of promptly incorporating outstanding legislation in the field of financial services – representing about half of the total backlog – in order to ensure a level playing field throughout the EEA in this important sector. The EEA Council recalled its continuous commitment to the conclusions approved by EU and EEA EFTA Ministers of Finance and Economy on 14 October 2014, in particular to the two-pillar solution set out therein.

13. The EEA Council further noted that there were a number of Joint Committee Decisions where the six-month deadline provided for in the EEA Agreement with regard to constitutional clearance had been exceeded. It encouraged the EEA EFTA States to strengthen their efforts to resolve the pending cases as soon as possible and to avoid such delays in the future.

Agricultural trade

14. The EEA Council welcomed the entry into force of the Agreement between the European Union and Norway on 1 October 2018 concerning additional trade preferences in agricultural products, reached on the basis of Article 19 of the EEA Agreement. The EEA Council noted the suspension of negotiations between the EU and Norway on the protection of geographical indications.

15. The EEA Council acknowledged that the Contracting Parties had reaffirmed their commitment, in accordance with Article 19 of the EEA Agreement, to continue their efforts with a view to achieving the progressive liberalisation of agricultural trade. The EEA Council encouraged them to continue the dialogue on the review of the trade regime for processed agricultural products within the framework of Article 2(2) and Article 6 of Protocol 3 to the EEA Agreement, in order to further promote trade in this area.

EU programmes

16. Acknowledging the contribution made by EU programmes to building a more competitive, innovative and social Europe, the EEA Council welcomed the

participation of the EEA EFTA States in EEA-relevant programmes to which they contributed financially under the current Multiannual Financial Framework (MFF) for 2014-2020. The EEA Council recognised in particular the active participation and full integration of the EEA EFTA States in the European Research Area and the successful association of Norway and Iceland in Horizon 2020, the EU's flagship programme for Research and Innovation, as well as in Erasmus+ in the field of education, youth and sport, and Creative Europe for the cultural and audiovisual sectors. The EEA Council would continue to place high importance on the integration and policy alignment of EEA EFTA States with the EU in the area of research and innovation and in education and culture.

17. The EEA Council took note of the preparations for the next MFF for 2021-2027, including the European Commission's proposals for individual programmes for the new period. It duly noted the contributions from the EEA EFTA States and encouraged them to take an active part in EU programmes foreseen under the new financial framework. This participation is a means towards developing, strengthening and broadening cooperation on matters falling outside of the four freedoms, as provided for in the EEA Agreement. The modalities for the EEA EFTA States participation in the future EU programmes for 2021-2027 shall remain unchanged and based on the relevant provisions of the EEA Agreement.

Financial Mechanism

18. The EEA Council emphasised the importance of solidarity among the countries of Europe to overcome social and economic challenges within the EEA, which is in the common interest of all Contracting Parties. In this sense, it expressed concern regarding the continued high level of youth unemployment in some EEA Member States. The EEA Council commended the positive contribution made by the EEA and Norway Financial Mechanisms in reducing economic and social disparities throughout the EEA.

19. With regard to the agreements on an EEA and a Norwegian Financial Mechanism for the 2014-2021 period, the EEA Council welcomed the conclusion of Memoranda of Understanding between the EEA EFTA States and most of the Beneficiary States in the EU. The EEA Council looked forward to projects commencing under the new mechanisms.

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Mergers: Commission approves acquisition of Shire by Takeda, subject to conditions

Commissioner Margrethe **Vestager**, responsible for competition policy, said: *"There are many diseases with only a limited number of effective and safe treatments. Inflammatory bowel disease is one such case. It is a lifelong condition with devastating effects on people's lives. Therefore, it is essential that companies continue developing promising new products to treat it. We can today approve the merger between Shire and Takeda, but only subject to the divestment of the product that Shire is developing to treat the disease and which could have been lost through the merger. This will preserve innovation in this market and, importantly, increase the choice of*

treatments for patients.”

The Commission’s investigation

The Commission’s investigation focused on treatments for **inflammatory bowel disease** (IBD), and in particular on **biologic treatments** for the disease, where Shire’s and Takeda’s activities overlap.

IBD is a lifelong disease, with patients often being diagnosed at a young age. Conventional treatments, such as anti-inflammatory drugs and corticosteroids, have limited effect and patients are therefore prescribed biologic treatments when the disease becomes more severe.

Takeda already offers a biologic treatment for IBD, called **Entyvio**, which belongs to a class of biologic treatments called “anti-integrins”. This type of treatment has the advantage of being safer to use, by elderly or very young patients and patients with existing medical issues or that have reacted badly to medication in the past. For some IBD patients, anti-integrins are the only type of biologic that can be prescribed.

Shire is currently developing a biologic treatment belonging to the same class of biologics, anti-integrins. It would therefore be expected to compete closely with Entyvio once it reaches the market.

The Commission was concerned that the takeover, as originally notified, would lead to a **loss of innovation** and a **reduction in potential future competition**.

In particular, the Commission’s market investigation found that Takeda would be unlikely to continue developing Shire’s new anti-integrin treatment. This would have meant a serious loss of innovation on a market where patients currently have few treatment options available to them. It would have also prevented a product from reaching the market that could compete with Entyvio and reduce prices for this type of biologic treatment.

The proposed remedies

To address the Commission’s competition concerns, Takeda offered to divest Shire’s pipeline product that is expected to compete with Entyvio, including the rights to its development, manufacturing and marketing, to a purchaser that would have an incentive to develop the drug.

The commitments thus **fully remove the overlap between Takeda’s and Shire’s activities on the market** where the Commission had identified competition concerns.

Therefore, the Commission concluded that the proposed transaction, as modified by the commitments, would no longer raise competition concerns. The decision is conditional upon full compliance with the commitments.

Companies involved

Takeda Pharmaceutical Company Limited, headquartered in Japan, is a global pharmaceutical company active in four main therapeutic areas: oncology,

gastroenterology, neuroscience and vaccines.

Shire plc, headquartered in Ireland, is a global biopharmaceutical company, which specialises in developing treatments for rare diseases across a range of therapeutic areas including immunology, haematology, neuroscience, gastroenterology and genetic diseases.

Merger control rules and procedures

The transaction was notified to the Commission on 28 September 2018.

The Commission has the duty to assess mergers and acquisitions involving companies with a turnover above certain thresholds (see Article 1 of the [Merger Regulation](#)) and to prevent concentrations that would significantly impede effective competition in the EEA or any substantial part of it.

The vast majority of notified mergers do not pose competition problems and are cleared after a routine review. From the moment a transaction is notified, the Commission generally has a total of 25 working days to decide whether to grant approval (Phase I) or to start an in-depth investigation (Phase II). This deadline is extended to 35 working days in cases where remedies are submitted by the parties, such as in this case.

More information will be available on the Commission's [competition](#) website, in the Commission's [public case register](#) under the case number [M.8955](#).

Fusionskontrolle: Kommission genehmigt Übernahme von Shire durch Takeda unter Auflagen

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[Concentrations: la Commission autorise, sous conditions, l'acquisition de Shire par Takeda](#)

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