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Pressemitteilung: EU-Prüfer untersuchen Wirksamkeit des EFSI

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State of children's medicines in the EU

Today, the Commission presents a report to the European Parliament and the Council, on progress made in children's medicines since the Paediatric Regulation[1] came into force 10 years ago. It concludes that positive advances in the development of medicines for children could not have been achieved without specific EU legislation – e.g. the authorisation of 260 new medicines. The Paediatric Regulation also gives a good return on investment. However, the report acknowledges that more effort is needed to combine the effects of the Paediatric with those of the Orphan medicines Regulation to address shortcomings in treating rare diseases in children.

Commenting on the report, Vytenis **Andriukaitis**, Commissioner for Health and Food Safety, said: *"Whereas I am pleased with the overall progress made in improving children's access to safe, tailored medicines, I am committed to extending these positive gains to children with rare diseases. When we consider the advances in adult oncology, it upsets me deeply that we have not made the same progress in treating the cancers that affect children. In the next 10 years we must focus on making similar breakthroughs for children, by combining the incentives under the Orphans and the Paediatric Regulations, and by ensuring that the European Reference Networks[2] – in particular 'ERN PaedCan'[3] on paediatric cancer, reach full capacity".*

Key findings:

- The number of agreed paediatric investigation plans (PIPs)[4] – the first step in developing medicines for children, surpassed 1 000 in 2017. Of these, 131 were completed by the end of 2016.
- There is a clear upward trend in the number of completed PIPs, with over

60 % finalised in the last three years.
- The conditions with the highest number of completed PIPs are immunology/rheumatology (14 %), infectious diseases (14 %), cardiovascular diseases and vaccines (each 10 %).
- Due to the Regulation there has been a significant surge in new treatments for children with rheumatologic diseases, and area where there were very limited therapeutic options before 2007.
- Oncology (childhood cancer) is at the lower end of the agreed paediatric investigation plans, representing only 7% of completed PIPs.
- The report shows that the Regulation works best in areas where the needs of adult and paediatric patients overlap.
- There is also more research into paediatric medicines. The proportion of clinical trials that include children increased by 50 % between 2007 and 2016 from 8.25 % to 12.4 %, leading to more evidence-based information when medicines are used in children.

Next steps

As an integral part of its assessment of the impact of the Paediatric Regulation, the Commission held a targeted stakeholder consultation which ran from November 2016 to February 2017. Following its adoption, Commissioner **Andriukaitis** will present the report's findings to people working in regulatory affairs, patients' groups and other stakeholders at a conference in Brussels on 21 November 2017.

This report is an essential intermediate step in the debate on a joint vision about the future parameters for paediatric and orphan medicines. Before proposing any amendments, the Commission will evaluate – in consultation with stakeholders and experts, how the combined effects of the Orphan and Paediatric Regulation can support medicine development in subpopulations of particular need, e.g. children with cancer. Results of this reflection will be presented by 2019 to allow the next Commission to take informed decision about possible policy options.

Further information

Children's medicines report

Questions and Answers on 10 years of the EU Paediatric Regulation

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[1] Regulation (EC) 1901/2006

[2] European Reference Networks for rare or low prevalence complex diseases

[3] ERN PaedCan Factsheet

[4] A Paediatric Investigation Plan (PIP) is a research and development programme that aims to ensure that a new product is tested for its potential use in children and that such tests become an integral part of the overall product development.

Questions and Answers on 10 years of the EU Paediatric Regulation

Why does the EU need special legislation for children's medicines?

Before the Paediatric Regulation came into force there was a very serious gap in the development and testing of medicines for children. Many products used in children were prescribed and administered based on physicians' own experience rather than on the results of clinical research. Medicines were often not available in a form suitable to children. Doctors had to do their best to adapt adult medicines and get the dosage right for children, e.g. by crushing adult tablets and using only a portion depending on a child's weight. This off-label use of adult medicines was widespread – estimated at more than 50%. Such practice comes with the risk of inefficacy as well as serious side effects.

What are the main aims of the Paediatric Regulation?

The Regulation is structured around three main objectives:

- More medicines for children
- Better product information
- More paediatric research

How does the Regulation set out to meet these objectives?

The Regulationsets up a system of obligations, rewards and incentives to encourage manufacturers to research and develop medicines for children's specific therapeutic needs. It obliges companies to screen every new product they develop for its potential use in children, to progressively increase the number of products with paediatric indications. This is done at the earliest stage of development through the 'Paediatric Investigation Plan' (PIP) which is an obligatory part of overall product development.

In addition, the Regulation promotes high-quality information and high-quality research into medicines for children through measures, such as:

- an EU network of networks of investigators and trial centres carrying out paediatric research;
- an EU inventory of paediatric needs;
- a public database of paediatric studies; and
- a requirement for companies to submit any existing paediatric studies on authorised medicinal products for scrutiny by regulatory authorities.

Is progress in children's medicines really thanks to EU legislation?

A comparison of the situation before and after the Regulation demonstrates a

clear positive effect in terms of new authorised medicines. During the period the Regulation has been in force (2007-2016) over 260 new medicines (new marketing authorisations and new indications) for use by children were authorised, most linked to the Regulation's requirements. The number of agreed paediatric investigation plans (PIPs) surpassed 1 000 in 2017, of which 131 were completed at the end of 2016. There is a clear upward trend in the number of completed PIPs, with over 60 % finalised in the last three years. This quantitative analysis shows clear progress. The figures are also in line with expectations taking into account the time it takes to bring a new medicine to the market – up to 10 years.

Are these new medicines actually reaching children?

Issuing a marketing authorisation or adding paediatric information to existing ones does not necessarily mean that children will immediately benefit from these products. Reimbursement considerations at national level may slow down the roll-out, and Paediatricians may not immediately switch to newly authorised products. In a survey that provided input to this report[1], respondents estimated that the increase in available medicines is in the range of 5-10%. On prescribing habits, 58 % of respondents agreed that doctors increasingly prescribe approved medicines according to their licensed indication for children, as a result of the Regulation. This demonstrates a positive trend, but also underlines certain inertia. Reducing off-label use in children depends not only on the number of authorised paediatric medicines, but on real availability and use at bed-side.

What are the costs vs benefits of the Regulation?

On the one hand the legislation obliges pharmaceutical companies to carry out paediatric research, requiring additional investment. On the other hand this obligation is linked with a reward system that allows companies to recuperate the additional upfront costs. The report concludes that in economic terms, the Regulation provides overall positive results from a socioeconomic perspective demonstrating the appropriateness of this direct investment in improving the availability of paediatric medicines. The combination of obligations and rewards seems effective to shift focus to paediatric product development. Still a considerable number of completed PIPs (45%) failed to obtain a reward and there are instances of over- or under compensation pointing to certain limitations of the current system.

Where are the biggest advances seen, and why?

In the last 10 years we have seen an increase in medicines for children in many therapeutic areas, the most notable being Rheumatology and infectious diseases. Indeed, the significant surge of new treatments for children with rheumatologic diseases following the completion of PIPs has transformed a sector which was previously neglected.

The areas with the biggest advances are those where the greatest strides are being made in the adult market. As the starting point for most PIPs is a research and development programme for adults, progress in children's medicines depends on companies' adult product pipeline and is influenced by

specific market segments that make the biggest profits. Where the adult needs or market expectations overlap with paediatric needs, children will benefit directly.

In which areas is progress considered insufficient?

The least progress is being made in diseases that are biologically different in adults and children, where the disease burden differs, or when it only affects children. This is often the case with rare diseases, including childhood cancers. Considering the progress made in treating cancer in adults in the last decade, this is a very serious shortcoming. Although cancer in children is rare, it is still the leading cause of death in children past the age of infancy.

How can we make progress in rare diseases in children?

The Commission, needs to scrutinise with regulatory authorities and stakeholders, how to combine the effects of the Paediatric Regulation and the Orphans Regulation[2] to increase the number and quality of medicines that treat rare diseases – including rare cancers, in children. On the one hand, the Paediatric Regulation provides the rewards, incentives and obligations described above. In parallel, the Orphans legislation – which aims to increase the treatment options available for rare diseases patients, sets out other incentives such as a 10 year market exclusivity or fee waivers for the regulatory procedure. The Commission needs to – and will by 2019 – conclude a joint evaluation of the Paediatric and Orphan Medicines legislation to allow the next Commission to take an informed decision about possible policy options.

What can be done in the shorter term?

In the meantime, the Commission will, together with the European Medicines Agency, take positive actions to streamline the current application and implementation of the Regulation wherever needed. This includes, for example, looking at ways to ensure speedier completion of PIPs, considering whether the Commission's guidelines for handling PIP applications should be adapted, discussing paediatric needs in an open and transparent dialogue involving all relevant stakeholders, and fostering international cooperation and harmonisation.

Additionally, the European Reference Networks for rare and complex diseases, which started their work in March 2017, have the potential of significantly improving diagnosis and treatment and of influencing prescribing practices. The Commission will help ensure that these Networks have access to sustainable funding and the necessary IT tools so that they reach their full capacity.

For more information

Children's medicines report

Press release

European Commission:https://ec.europa.eu/health/human-use/paediatric-medicines_en

European Medicines Agency

[1] Technopolis study, chapter 5.

[2] Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products, OJ L 18, 22.1.2000, p. 1.

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Europe de l'espace: le président Juncker visite le Centre Spatial Guyanais

Demain, le président **Juncker** et le président de la République française Emmanuel Macron visiteront le Centre Spatial Guyanais à Kourou. Cette visite du "port spatial" de l'Europe, une infrastructure unique pour l'Europe qui assure un accès autonome à l'espace, intervient un an après la présentation de la Stratégie Spatiale pour l'Europe et s'inscrit dans la promotion d'une ambitieuse politique industrielle au service des intérêts stratégiques de l'Union européenne. L'engagement de la Commission se caractérise par le développement de projets spatiaux de grande envergure tels que les programmes d'observation de la Terre Copernicus et de navigation par satellite Galileo et EGNOS pour un investissement de plus de 12 milliards d'euros sur la période 2014-2020. Ces programmes spatiaux européens fournissent d'ors et déjà des services dont bénéficient des millions de personnes: grâce à l'utilisation des données spatiales, les services d'urgence et de secours, les réponses face aux catastrophes naturelles, l'aviation ou encore l'agriculture voient leur efficacité améliorée. De nombreuses entreprises utilisent également ces données pour des applications toujours plus innovantes. Une vidéo et une fiche FR et EN détaillent les produits et services fournis par les programmes spatiaux de l'UE. Vous pouvez suivre la visite du Président Juncker en Guyane sur le portail audiovisuel de la Commission européenne. *(Pour plus d'informations: Lucía Caudet – Tel.: +32 229 56182; Maud Noyon – Tel. +32 229-80379; Victoria von Hammerstein – Tel.: +32 229 55040*)

Banking Reform: EU reaches agreement on first key measures

On Wednesday, the European Parliament, the Council and the Commission agreed on elements of the review of the Bank Recovery and Resolution Directive (BRRD) and of the Capital Requirements Regulation (CRR) and Directive (CRD) proposed in November 2016, an important piece of the Commission's ongoing work to reduce risk in the banking sector and in line with the efforts to complete the Banking Union, as set out in the Commission's Communication of 11 October 2017. The agreement on the BRRD creates a new category of

unsecured debt in bank creditors' insolvency ranking. It establishes an EU harmonised approach on the priority ranking of bank bond holders in insolvency and in resolution. The agreement on the CRR/CRD implements the new International Financial Reporting Standard (IFRS 9). This will help mitigate the impact of IFRS 9 standards on EU banks' capital and ability to lend. It will also avoid potential disruptions in government bond markets that would result from rules limiting large exposures to a single counterparty. Valdis **Dombrovskis**, Vice-President responsible for Financial Stability, Financial Services and Capital Markets Union said: *"Today's agreements are the first deliverables of our banking risk reduction package. First, harmonised rules for bank bond holders in a situation of insolvency gives banks clarity for building up buffers to absorb losses and protect taxpayers. It is a key step towards complying with the global standard on Total Loss-Absorbing Capacity (TLAC). This measure will also enhance the effectiveness of bank resolution processes. The second agreement gives banks more time to adjust to the introduction of the new accounting standard IFRS 9 and to the expiry of certain exemptions from the large exposure limits, thereby avoiding disruption in lending and in government bond markets."* Wednesday's political agreements will be followed by further technical talks to finalise the text. A full press release is available online. *(For more information: Annika Breidthardt – Tel.: +32 229 56153; Letizia Lupini – Tel.: +32 229 51958)*

MiFID II: EU issues guidance on obtaining brokerage and research services from non-EU brokers

Today, the European Commission has issued guidance in the form of Frequently Asked Questions to clarify how EU investment firms should interact when they seek out brokerage and research services from broker-dealers in non-EU countries. Valdis **Dombrovskis**, Vice-President in charge of Financial Stability, Financial Services and Capital Markets Union, said *"With the issued guidance EU firms will have greater clarity on how to deal with non-EU brokers that provide research. In this context, we welcome the decision of the staff of the U.S. Securities and Exchange Commission to simultaneously agree to relief for US brokers supplying research to EU firms. Our coordinated action again shows the excellent EU-US cooperation in international financial regulatory matters."* The Commission recognised the need to clarify how firms subject to the Markets in Financial Instruments Directive (MiFID II) can obtain such services from other jurisdictions. The Commission FAQ notes the relevant provisions and explains how EU firms can procure international research and brokerage services in full compliance with their obligations. MiFID II is a cornerstone of the reforms we put in place following the financial crisis to improve investor protection and the transparency and oversight of financial markets. Today's initiative will contribute to ensure that research budgets are decoupled from brokerage, in compliance with the requirements laid out in MiFID II. *(For more information Annika Breidthardt – Tel.: +32 229 56153; Letizia Lupini – Tel.: +32 229 51958)*

State of children's medicines in the EU

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State aid: Commission opens in-depth investigation into UK tax scheme for multinationals

The European Commission has opened an in-depth investigation into a UK scheme that exempts certain transactions by multinational groups from the application of UK rules targeting tax avoidance (the UK CFC rules). It will investigate if the scheme allows these multinationals to pay less UK tax, in breach of EU State aid rules. Commissioner Margrethe **Vestager** in charge of competition policy said: "*All companies must pay their fair share of tax. Anti-tax avoidance rules play an important role to achieve this goal. But rules targeting tax avoidance cannot go against their purpose and treat some companies better than others. This is why we will carefully look at an exemption to the UK's anti–tax avoidance rules for certain transactions by multinationals, to make sure it does not breach EU State aid rules*." The general purpose of the UK CFC rules is to prevent UK companies from using a subsidiary, based in a low or no tax jurisdiction, to avoid taxation in the UK. They reallocate income artificially shifted to offshore subsidiaries of UK parent companies to the UK for taxation. CFC rules in general are an effective and important feature of many tax systems to address tax avoidance. However, since 2013, the UK CFC rules include an exception for certain financing income (i.e. interest payments received from loans) of multinational groups active in the UK – the *Group Financing Exemption*. At this stage, the Commission has doubts whether this exemption complies with EU State aid rules. In particular, the Commission has doubts whether this exemption is consistent with the overall objective of the UK CFC rules. The Commission's State aid investigation does not call into question the UK's right to introduce CFC rules or to determine the appropriate level of taxation. The role of EU State aid control is to ensure Member States do not give some companies a better tax treatment than others. The opening of an in-depth investigation gives the UK and interested third parties an opportunity to submit comments. It does not prejudge the outcome of the investigation.

The full press release is available online in EN, FR, DE. *(For more information: Ricardo Cardoso – Tel.: +32 229 80100; Yizhou Ren – Tel.: +32 229 94889)*

Mergers: Commission clears the creation of a joint venture by GETEC and Briva

The European Commission has approved, under the EU Merger Regulation, the creation of a joint venture between GETEC Wärme und Effizienz AG ('GETEC') of Germany and Briva Group B.V of the Netherlands. The joint venture will be active in the conception, development, operation and maintenance of energy generation and distribution systems, the provision of energy contracting services for buildings, as well as in measures to increase energy efficiency and development of new business models. GETEC is active in energy contracting in Germany. It is a subsidiary of EQT Fund Management S.à.r.l of Luxembourg and GETEC Energy Holding GmbH of Germany. Briva, ultimately controlled by the Ten Brinke Group B.V. of the Netherlands, is active in project development, construction, sale or lease of residential, commercial and industrial real estate, mainly to strategic investors in Germany and the Netherlands. The Commission concluded that the proposed acquisition would raise no competition concerns given the joint venture's limited activities in the EEA. The transaction was examined under the simplified merger review procedure. More information is available on the Commission's competition website, in the public case register under the case number M.8627. *(For more information: Ricardo Cardoso – Tel.: +32 229 80100; Maria Sarantopoulou – Tel.: +32 229 13740)*

Mergers: Commission clears acquisition of US engineering company CH2M by Jacobs Engineering Group

The European Commission has approved, under the EU Merger Regulation, the acquisition of CH2M HILL Companies, Ltd. by Jacobs Engineering Group Inc., both of the US. CH2M is a professional consulting services provider across a full spectrum of technical topics such as engineering, construction management and operations as well as maintenance projects. Jacobs Engineering Group is a technical professional services firm providing a range of technical, professional, and construction services to a large number of industrial, commercial and governmental clients. The Commission concluded that the proposed acquisition would raise no competition concerns given the transaction's limited impact on the market structure within the European Economic Area. The transaction was examined under the simplified merger review procedure. More information is available on the Commission's competition website, in the public case register under the case number M.8641. *(For more information: Ricardo Cardoso – Tel.: +32 229 80100; Maria Sarantopoulou – Tel.: +32 229 13740)*

Mergers: Commission clears acquisition of Irish wind farms by Fixarra, Luricawne, Sojitz and Kansai Electric Power

The European Commission has approved under the EU Merger Regulation the acquisition of joint control over Evalair Limited and Plum Wind Farm Holdings Limited ("Plum") , both of Ireland, by Fixarra Limited, also of Ireland, as well as Luricawne Wind S.a.r.l. of Luxembourg, Sojitz Corporation and Kansai Electric Power Co. Inc. ("KEPCO") both of Japan. Evalair owns and operates four wind farms in Ireland. Plum owns a wind farm in Ireland that is currently in development. Fixarra is owned by the Craydel Group of Ireland, an engineering provider. Luricawne is owned by HgCapital of the UK, which is a private equity firm. Sojitz is a conglomerate primarily active in the area of trading goods and services, including in the energy sector. KEPCO is active in several businesses including electrical power and gas supply. The Commission concluded that the proposed acquisition would raise no competition concerns because the acquisition does not give rise to an overlap between the companies' activities. The transaction was examined under the simplified merger review procedure. More information is available on the Commission's competition website, in the public case register under the case number M. 8635. *(For more information: Ricardo Cardoso – Tel.: +32 229 80100; Maria Sarantopoulou – Tel.: +32 229 13740)*

ANNOUNCEMENTS

Vice-President Dombrovskis in Bucharest, Romania

Valdis **Dombrovskis**, Vice-President for the Euro and Social Dialogue, also in charge of Financial Stability, Financial Services and Capital Markets Union, is in Bucharest for a European Semester visit from 26 to 27 October. Vice-President Dombrovskis' visit also includes several bilateral meetings, including with Klaus Iohannis, President of Romania, Ionuţ Misa, Minister of Public Finance of Romania, Mugur Isărescu, Governor of the National Bank of Romania, as well as meetings with social partners. On Thursday, the Vice-President will deliver a closing speech at a conference entitled "10 years of EU membership: from cohesion to convergence", organised by the National Bank of Romania. On Friday, Vice-President **Dombrovskis** will deliver an opening speech at a Commission event entitled "Inclusive growth in Romania – Challenges and opportunities", organised within the framework of the European Semester. *(For more information: Annika Breidthardt – Tel.: +32 229 56153; Juliana Dahl – Tel.: +32 229 64976)*

Commissioner Arias Cañete opens European Electric Vehicle Congress in Madrid

On Friday 27 October, Commissioner for Energy and Climate Action Miguel **Arias Cañete** will open today the IV European Electric Vehicle Congress in Madrid. In his speech he will underline the crucial importance of zero- and low-emission mobility for the future of the European transport sector. Ahead of the conference, the Commissioner said: "*Europe has fallen behind in the clean vehicle race. We could lose technological leadership in clean vehicles if others keep accelerating away from us. Our upcoming standards for cars and vans will be a fundamental tool to push for innovation and investments in*

*clean vehicles in Europe. We want all European manufacturers to invest and innovate, to succeed in this key new market."*The second delivery of the mobility package scheduled for adoption in the coming weeks will comprise legislative proposals and initiatives to deliver on the European Strategy for low-emission mobility from June 2016. It will include proposals to decarbonise the transport sectors, the revision of the clean vehicles directive and CO_2 standards for new cars and vans for the period after 2020, an Action Plan for alternative fuel infrastructures with dedicated measures including new funding opportunities as well as a flagship initiative on batteries. The upcoming package will be part of the wider political context to make European industry stronger and more competitive as outlined by Commission President Jean-Claude **Juncker** in his State of the European Union speech in September this year. Following up on this, the Renewed EU Industrial Policy Strategy will help the EU industries to stay or become the world leader in innovation, digitisation and decarbonisation. Building on Europe's leadership in a low-carbon and circular economy, this helps the EU to implement its Paris Agreement commitments. More information about the conference here. (*For more information: Anna-Kaisa Itkonen – Tel.: +32 229 56186; Nicole Bockstaller – Tel.: +32 229 52589)*

Commissioner Vella on official visit to Sweden to discuss circular economy and UN development goals

On 26 – 27 October, Commissioner for Environment, Maritime affairs and Fisheries, Karmenu **Vella**, will be in Sweden for an official visit. The Commissioner will speak before the Swedish Parliament at the Committee on Environment and Agriculture and the Committee on EU Affairs. He will also meet with Minister of the Environment, Karolina Skog and Minister for Rural Affairs, Karl-Erik Bucht. A roundtable discussion is planned with participants from the business, public and non-governmental sectors on the Commission's Circular Economy package and the upcoming EU Plastics Strategy. The Commissioner is also invited to speak at a public seminar on the UN Sustainable Development Goals, together with Professor Johan Rockström of the Stockholm Resilience Centre and founder of the Planetary Boundaries concept. Finally, a visit is planned to the world's first Marine Stewardship Council certified fisheries in Lake Mälaren, a project supported by the European Maritime and Fisheries Fund. *(For more information: Enrico Brivio – Tel.: +32 229 56172; Iris Petsa – Tel.: +32 229 93321)*

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