

Science and innovation for better medicines

10/08/2017

EMA leaflet shows how work of the Agency benefits patients

As authoritative regulator for medicines in Europe, the European Medicines Agency (EMA) ensures that medicines which are prescribed and used across the European Union (EU) are safe, effective and of good quality. The best scientific experts made available through the European regulatory network for medicines carefully evaluate each new medicine and only recommend its authorisation if the benefits for the patients outweigh the risks of possible side effects.

The leaflet, entitled '[Enabling science that works for patients](#)', explains that the Agency promotes science and innovation to find better medicines. EMA collaborates closely with patients to understand their point of view and to make sure that new medicines address their needs. The Agency provides scientific advice and guidance to encourage the development of new and innovative medicines, especially in areas with limited treatment options such as rare diseases and illnesses in children.

Patients and their needs are at the centre of all activities of the Agency. EMA involves patients, consumers and their representative organisations in all decisions made during the lifecycle of a medicine – in the development of policies, regulatory guidance, and the evaluation and safety monitoring of medicines. Patients provide valuable 'real-life' insights on the impact of regulatory decisions as members of the Agency's management board, scientific committees and working parties.

Press Release:EASO and the Italian Ombudsperson for Children and Adolescents are working together to strengthen the protection system for unaccompanied minors

At the end of July 2017, the European Asylum Support Office and the Italian authorities signed the Amendment to the EASO Operating Plan to Italy. EASO has started cooperating with the Italian Ombudsperson for Children and

Adolescents (Autorità garante per l'infanzia e l'adolescenza) implementing further support measures related to the guardianship system in Italy.

Italy is one of the main receiving countries for unaccompanied children in Europe. More than 12 500 children have arrived to Italy via the Central Mediterranean route in the first seven months of 2017, following a total of almost 26 000 arrivals of unaccompanied minors registered in 2016.

In order to address the needs of this particularly vulnerable group and to secure their best interest as a guiding principle in all procedures including asylum and reception system, a new law (Law 47/2017 on protection measures for unaccompanied children) entered into force in May 2017. One of the main changes is the introduction of the possibility for private citizens, selected and duly trained, to become volunteer guardians.

EASO will work together with the Italian Ombudsperson for Children and Adolescents in order to strengthen the implementation of these protection measures of unaccompanied children. The areas of cooperation will include a national awareness-raising campaign aimed at recruitment of volunteer guardians, providing support in their selection and training in some targeted regions, as well as development of relevant practical tools and counselling. The exchange of best practices will be also part of this cooperation.

Background

The Italian Ombudsperson for Children and Adolescents is an independent institution introduced by Law 112/2011 aiming at protecting and promoting children's rights. According to the Law 47/2017, this authority is in charge of the selection and training of the volunteer guardians in those regions where a Regional Ombudsperson has not yet been appointed.

EASO's support granted to the Italian authorities is foreseen and regulated by the single Operating Plan for 2017, including support to the relocation procedure and family reunification under Dublin Regulation (by pre-identification, information provision, registration and handling of Dublin request) and activities related to country of origin information.

Download press release here: [\[EN\]](#) [\[IT\]](#)

Useful Links:

[Italian Ombudsperson for Children and Adolescents](#)
[EASO](#)

EASO's Operating plan to Italy – Amendment No.1 (2017) [\[EN\]](#)

EASO Operating Plan to Italy (2017) [\[EN\]](#)

Any further information may be obtained by contacting:

– on the Italian Ombudsperson: segreteria@garanteinfanzia.org (Facebook e Twitter @aginfaanzia)

– on EASO, Mr. Jean-Pierre Schembri: jean-pierre.schembri@easo.europa.eu (Facebook and Twitter @EASO)

Daily News 10 / 08 / 2017

Feux de forêt: l'UE mobilise plus d'avions pour l'Albanie et travaille 24h/24 pour soutenir d'autres pays en Europe

La Commission européenne a contribué à mobiliser deux avions supplémentaires de la Grèce par le biais du mécanisme de protection civile de l'UE, suite à une nouvelle demande d'assistance de l'Albanie pour lutter contre les incendies de forêt dans le sud du pays. Le [Centre de coordination de la réaction d'urgence](#) de la Commission surveille 24h/24 et 7j/7 les risques d'incendie de forêt à travers l'Europe et a déjà apporté son soutien au Portugal, à la France, l'Italie, le Monténégro et l'Albanie depuis cet été. *«Lors de cette saison de feux de forêt très intense, de nombreux pays ont demandé l'aide européenne qui a pu être rapidement fournie. Aujourd'hui, je voudrais remercier la Grèce pour sa générosité dans son soutien à l'Albanie pour la seconde fois, en envoyant 2 avions en aide à son voisin, en ces temps de grand besoin d'assistance. Voici un exemple très concret de la solidarité européenne et de l'appui inestimable apporté par le mécanisme de protection civile de l'UE»*, a déclaré le commissaire à l'aide humanitaire et de la gestion des crises Christos **Stylianides**. L'Albanie a tout d'abord requis de l'assistance pour lutter contre les incendies de forêt le 2 août. La Grèce a alors envoyé 2 avions qui ont opéré dans le sud de l'Albanie entre le 3 et le 6 août. Le [système de cartographie par satellite d'urgence](#) de l'UE Copernicus a fourni 8 cartes satellites aux autorités albanaises. Dans cette période critique pour le bassin méditerranéen et compte tenu des capacités limitées de ces pays pour lutter contre les incendies, la Commission propose de cofinancer 85% des frais de transport pour les pays offrant leur soutien via le mécanisme de protection civile. Des banques [d'images](#) et de [vidéos](#) du Centre d'urgence sont disponibles, ainsi qu'une [fiche technique](#) sur « La lutte contre les incendies de forêt en Europe – comment cela fonctionne ». *(For more information: Carlos Martin Ruiz De Gordejuela – Tel.: +32 229 65322; Daniel Puglisi – Tel.: +32 229 69140)*

Rapid Alert System for Food and Feed (RASFF)

The Commission continues to follow the latest developments on fipronil finding in eggs very closely. For this Commission public health and issues related to food safety are always considered a priority and are treated as such. The Rapid Alert System for Food and Feed (RASFF) is a tool designed to swiftly exchange information between national authorities on health risks related to food and feed. A member country of the network that identifies a health hazard informs the rest of the system's network on the product concerned and the measures taken to address the risk. Measures include: withholding, recalling, seizing or rejecting products. This rapid exchange of information allows all RASFF members to check in real time whether they are also affected and if urgent action is needed. The authorities of affected countries have the responsibility to take the necessary emergency measures,

including giving direct information to the public, withdrawing products from the market, and making controls on the ground. Member States have the primary responsibility for conducting the investigations and taking the appropriate measures. The Commission has taken and continues to take all available measures to assist them in this task. A comprehensive overview of the RASFF is available in this [memo](#), which will be available in all languages online. (For more information: Daniel Rosario – Tel.: + 32 229 56185; Aikaterini Apostola – Tel.: +32 229-87624)

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

10 years since the start of the crisis: back to recovery thanks to decisive EU action

The global financial crisis began 10 years ago and led to the European Union's worst recession in its six-decade history. The crisis did not start in Europe but EU institutions and Member States needed to act resolutely to counter its impact and address the shortcomings of the initial set-up of the Economic and Monetary Union. Decisive action has paid off: today, the EU economy is expanding for the fifth year in a row. Unemployment is at its lowest since 2008, banks are stronger, investment is picking up, and public finances are in better shape. Recent economic developments are encouraging but a lot remains to be done to overcome the legacy of the crisis years. The European Commission is fully mobilised to deliver on its agenda for jobs, growth and social fairness.

Vice-President Valdis **Dombrovskis**, responsible for the Euro and Social Dialogue, said: *"Thanks to the determined policy response to the crisis the EU economy is now firmly recovering and the Economic and Monetary Union is stronger than before. We need to build on this progress, completing the financial union, reforming our economies to foster convergence, inclusiveness and resilience, and maintaining sustainable public finances. In doing so, we should pursue a balanced approach where risk reduction and risk sharing go hand-in-hand and the unity of the single market is preserved."*

Commissioner Pierre **Moscovici**, responsible for Economic Affairs, Taxation and Customs, said: *"Ten years after the global crisis began, the recovery of the European economy has firmed and broadened. We must use this positive momentum to complete the reform of our Economic and Monetary Union. Not all legacies from the past correct automatically. We have seen greater social and economic divergences develop in and among Member States. It is essential that our work going forward contributes to the real and sustained convergence of our economies."*

Ten years ago today, on 9 August 2007, BNP Paribas became the first major bank to acknowledge the impact of its exposure to sub-prime mortgage markets in the United States, having to freeze exposed funds. In the years that followed, what was initially a financial crisis turned into a banking crisis and a crisis of sovereign debt, soon affecting the real economy. The European Union fell into the worst recession in its history, which left deep marks on our citizens, companies and Member States' economies.

In this adversity, EU institutions and Member States took strong political decisions to contain the crisis, preserve the integrity of the euro and to avoid worse possible outcomes. The EU has worked to regulate the financial sector and improve economic governance; bolster new and common institutional and legal frameworks; establish a financial firewall for the euro area; support countries in financial distress; improve Member States' public finances; pursue structural reforms and encourage investment; fight youth unemployment; improve banking sector supervision; increase the ability of financial institutions to cope with future challenges; and establish ways to manage and better prevent possible crises.

As a result of these actions, Europe's Economic and Monetary Union has been significantly overhauled and the European economy – and notably the euro area economy – is back in shape. The European recovery is sustained and unemployment is steadily going down. The number of Member States belonging to the euro has increased from 12 to 19 and the euro is now the second-most important currency in the world. Out of the eight EU Member States that received financial assistance, only Greece is still under a programme and is due to exit it in mid-2018. Only three Member States are now subject to the corrective arm of the Stability and Growth Pact, the so-called Excessive Deficit Procedure, down from 24 Member States at the height of the crisis. The [Juncker Plan](#), or Investment Plan for Europe, launched in November 2014, is now set to trigger more than €225 billion across all Member States.

As robust as it is today, the EMU remains incomplete and the journey of the euro has just started. From the Five Presidents' Report of June 2015 to the reflection paper on the Deepening of the Economic and Monetary Union of May 2017, a lot of initiatives were taken in recent years to draw the lessons from the crisis and prepare the EU even better for future challenges.

For More Information

[Reflection Paper on Deepening the Economic and Monetary Union](#)

[The Five Presidents' Report](#)

[The White Paper on the Future of Europe](#)

Reflection paper on the [social dimension](#) of Europe

Reflection paper on [harnessing globalisation](#)

Follow Vice-President Dombrovskis on Twitter: [@VDombrovskis](#)

Follow Commissioner Moscovici on Twitter: [@Pierremoscovici](#)

Daily News 09 / 08 / 2017

10 years since the start of the crisis: back to recovery thanks to decisive EU action

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Le Plan Juncker soutient le traitement contre le cancer du cerveau

Les patients atteints du cancer du cerveau le plus agressif, le glioblastome, bénéficieront prochainement d'un accès plus large à une nouvelle forme de traitement, grâce au Plan Juncker. La Banque européenne d'investissement (BEI) et MagForce, une entreprise allemande spécialisée dans des dispositifs médicaux, ont signé un accord de financement de 35 millions d'euros pour développer une nouvelle méthode de traitement local des tumeurs solides. Cette méthode permet de combattre la tumeur de l'intérieur, tout en épargnant les tissus sains qui l'entourent. Des patients sont déjà traités avec succès en Allemagne et l'accord de financement signé aujourd'hui permettra que la nouvelle méthode puisse être offerte à l'échelle de l'Europe. Sans l'intervention du Fonds européen pour les investissements stratégiques (FEIS), cette opération conclue avec MagForce n'aurait pas été

possible. Jyrki Katainen, vice-président de la Commission européenne chargé de l'emploi, de la croissance, de l'investissement et de la compétitivité, a indiqué : « *La Commission européenne s'attache à promouvoir les investissements dans la recherche et l'innovation. Je suis ravi que, via l'accord d'aujourd'hui, le Plan d'investissement pour l'Europe contribue à la mise au point de nouveaux traitements complexes pour les patients atteints d'un cancer. Il s'agit d'un exemple très tangible du puissant impact que peut générer le soutien de l'UE à l'appui d'investissements.* » Les [projets et accords](#) qui ont été approuvés pour un financement au titre du Plan Juncker jusqu'à présent devraient permettre de mobiliser 225 milliards d'euros d'investissements dans les 28 États membres. Un communiqué de presse se trouve [ici](#). (Pour plus d'informations: Annika Breidhardt – Tel.: +32 229 56153; Siobhán Millbright – Tel.: +32 229 57361)

State aid: Commission approves €15.5 million aid for Aarhus Airport in Denmark

The European Commission found that public support to sustainably secure the functioning of a commercial airport in Aarhus, Denmark, is in line with EU State aid rules. The investment plan foresees the renovation of the terminal, of a number of operating facilities and the access area. It aims to allow the airport to serve its maximum capacity of 800,000 passengers per year. The aid amount is approximately €15.5 million. The rest of the project cost will be funded by private investors. The project contributes to improving connections in the Jutland region whilst limiting distortions of competition in the Single Market. The Commission concluded that the project complies with EU State aid rules, in particular the criteria under the Commission's 2014 [Aviation Guidelines](#). More information will be available on the Commission's [competition](#) website, in the public [case register](#) under the case number SA.44377 once confidentiality issues have been resolved. (For more information: Ricardo Cardoso – Tel.: +32 229 80100; Maria Sarantopoulou – Tel.: +32 229 13740)

Concentrations: la Commission autorise la prise de contrôle conjoint des activités de financement de véhicules Opel/Vauxhall de GM par Peugeot et BNP Paribas

La Commission européenne a approuvé, en vertu du règlement européen sur les concentrations, la prise de contrôle conjoint des filiales de General Motors chargées du financement de véhicules automobiles Opel/Vauxhall (les "Fincos"), actives à travers l'Europe, par les sociétés Peugeot S.A. et BNP Paribas, toutes deux basées en France. Les Fincos offrent divers produits de financement de véhicules automobiles pour les marques Opel/Vauxhall. Peugeot construit et vend des véhicules particuliers et des véhicules utilitaires légers dans le monde entier. A travers sa filiale Banque PSA Finance, Peugeot offre des solutions de financement pour les véhicules automobiles des marques Peugeot, Citroën et DS. BNP Paribas est également active dans le financement automobile, sans distinction de marques toutefois. La Commission a conclu que la concentration envisagée ne soulevait pas de problème de concurrence compte tenu du caractère limité des parts de marché des sociétés, ainsi que de la faible augmentation de ces parts de marchés à la suite de la transaction. En outre, il existe un nombre conséquent de concurrents présents sur les marchés

concernés. De plus amples informations sont disponibles sur le site [internet concurrence de la Commission](#), dans [le registre public](#) des affaires de concurrence de la Commission, sous le numéro [M.8460](#). *(Pour plus d'informations: Ricardo Cardoso – Tel.: +32 229 80100; Maria Sarantopoulou – Tel.: +32 229 13740)*

Mergers: Commission approves acquisition of Banco Popular Español S.A. by Banco Santander

The European Commission has approved, under the EU Merger Regulation, Banco Santander's proposed acquisition of Banco Popular Español, S.A. Banco Santander and Banco Popular are universal banks, providing commercial, retail investment and wholesale banking services as well as insurance services in Spain and Portugal. The Commission investigated the transaction's impact on the markets for retail and corporate banking, leasing, factoring and the provision of ATM services in the Portuguese and Spanish national and regional markets. Its investigation concluded that the transaction would raise no competition concerns. The parties' combined market shares are generally limited (below 25%) and strong competitors will remain in all affected markets. Today's decision is the final step by the Commission clearing the acquisition. It follows the Commission's [approval on 7 June 2017](#) of the resolution scheme of Banco Popular under EU bank recovery and resolution rules, which was based on a proposed resolution scheme by the [Single Resolution Board](#) (SRB). A full Press Release is available in [EN](#), [ES](#), [DE](#) and [FR](#). *(For more information: Ricardo Cardoso – Tel.: +32 229 80100; Maria Sarantopoulou – Tel.: +32 229 13740)*

Mergers: Commission clears acquisition of London City Airport by OTPP, AIMCo, Borealis and the Kuwait Investment Authority

The European Commission has approved, under the EU Merger Regulation, the acquisition of the London City Airport (LCY) of the UK by Ontario Teachers' Pension Plan Board (OTPP) and Alberta Investment Management Corporation (AIMCo) both of Canada, Borealis European Holdings (Borealis) of the Netherlands, and the Kuwait Investment Authority (KIA) of Kuwait. LCY is a commercial airport in the City of London. OTPP administers pension benefits and investments of pension plan assets on behalf of teachers in the Canadian province of Ontario. AIMCo is an institutional investment manager and KIA a global investor, with investments in all main geographical areas and asset classes, covering equities, fixed income, treasury, private equity and property. Borealis is an exclusive infrastructure manager for the Ontario Municipal Employees Retirement System Administration Corporation (OMERS) and manages a diversified global portfolio of stocks and bonds. The Commission concluded that the proposed acquisition would raise no competition concerns, because of its limited impact on the market structure. 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.8575](#). *(For more information: Ricardo Cardoso – Tel.: +32 229 80100; Maria Sarantopoulou – Tel.: +32 229 13740)*

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