### **Daily News 10 / 08 / 2018**

### European Solidarity Corps: Commission opens new call for project proposals

The European Commission is calling on interested parties to put forward ideas for projects under the European Solidarity Corps. A total of €44 million has been set aside from the EU budget for selected projects that will be open to all young people across Europe and beyond. This is the first of a series of calls that will allow at least 100,000 young people to take part in the Corps until the end of 2020. Commissioner for Budget and Human Resources, Günther H. Oettinger, said: "With the launch of this new call under the European Solidarity Corps, we are delivering on our commitment to create more opportunities for young people to engage in solidarity activities. Funded by the EU budget, the European Solidarity Corps is the best framework for young people to learn, share and use their energy for the common good." Tibor Navracsics, Commissioner for Education, Culture, Youth and Sport said: "Solidarity is one of the key values of the European Union. Time and again, young people across the EU have shown their willingness to help those in need. By creating a dedicated framework and making available the necessary funding for the period 2018-2020, we want to give them more opportunities to engage, including the possibility to form a group of volunteers and come up with their own ideas for solidarity projects." Commissioner for Employment, Social Affairs, Skills and Labour Mobility, Marianne Thyssen, added: "The European Solidarity Corps helps young people in their professional development and their integration into the labour market. With its strong European dimension of solidarity, the Corps is an extraordinary opportunity for young people to develop interpersonal skills and acquire new knowledge, all of these bringing an added value to them and society in general." More information is available in this <u>press release</u> and <u>memo</u>. A factsheet with the latest figures is available here. (For more information: Nathalie Vandystadt - Tel.: +32 229 67083; Sara Soumillion - Tel.: + 32 229 67094)

## Juncker Plan supports Bavarian Nordic's vaccine production with €30 million EIB loan

The European Union is supporting biotech company Bavarian Nordic with a €30 million loan from the European Investment Bank (EIB) which is guaranteed under the Juncker Plan's European Fund for Strategic Investments (EFSI). Bavarian Nordic will use the funding to build and furnish a production facility on its existing site in Kvistgård, Denmark, where it uses advanced biotechnological manufacturing processes and technologies for the production of vaccines. Bavarian Nordic has played a pivotal role in the fight against communicable diseases — notably Ebola — and by developing defence mechanisms against potential bioterrorism threats, such as smallpox, the biotech firm is a key contributor to the European Security Initiative. Commissioner Vytenis Andriukaitis, responsible for Health and Food Safety, said: "Global health security is a matter of universal concern and key priority for the European Commission. The Ebola crisis showed that very clearly and gave us an important lesson on the necessity to work together to prevent new types of threats. The EIB loan allocated today under the Juncker Plan shows once again

a joint commitment to support the EU's capacity to deal with health threats by encouraging the research and development of innovative therapies against infectious diseases, cancer and other threats." (Full press release can be found <a href="here">here</a>. For more information: Christian Spahr — Tel.: +32 229 50055; Siobhán Millbright — Tel.: +32 229 57361)

# La Commission aide cinq régions à utiliser des procédures de passation des marchés publics plus innovantes et responsables avec les fonds européens

La Commission, en partenariat avec l'Organisation de coopération et de développement économiques (OCDE), va fournir un soutien personnalisé au comité de coordination et de développement de la région portugaise du Centre, à l'autorité athénienne pour le transport urbain, à la région italienne des Pouilles et aux régions grecques de Grèce Centrale et de Macédoine-Orientaleet-Thrace, afin de les aider à utiliser des procédures de passation de marchés publics plus innovantes pour des projets cofinancés par l'UE. Ce soutien vise à promouvoir des critères de durabilité environnementale, d'impact social et d'innovation, au-delà du simple critère du coût. "La Commission va aider les autorités gérant les fonds européens à en avoir plus pour leur argent," a commenté la Commissaire à la politique régionale Corina Cretu, "Des procédures de marchés publics plus innovantes et responsables pour un meilleur rapport qualité-prix, voilà un exemple concret d'un budget de l'UE résolument axé sur les résultats." Elżbieta Bieńkowska, commissaire en charge du marché intérieur, de l'industrie, de l'entrepreneuriat et des PME, a ajouté: "La Commission veut aider les autorités publiques à maximiser l'impact des achats publics, en termes d'objectifs sociaux, d'innovation et de durabilité, notamment via la recommandation de l'UE sur la professionnalisation des acheteurs publics". Les autorités locales et régionales sélectionnées vont bénéficier du soutien de la Commission pour les projets suivants: Centre, Portugal: projets de recherche et innovation en lien avec <u>la stratégie régionale de spécialisation intelligente</u>; Athènes, Grèce: achat de véhicules plus respectueux de l'environnement pour le transport urbain; dans les Pouilles italiennes: nouvelles technologies et services administratifs innovants dans le domaine de la gestion de l'eau; Grèce Centrale: un système moderne et respectueux de l'environnement pour l'épuration des eaux près de la rivière Asopos; Macédoine-Orientale-et-Thrace: projets liés à la stratégie de développement territoriale des zones montagneuses de Rodopi et Nestos. Ce soutien s'inscrit dans le cadre du <u>Plan</u> d'Action de la Commission pour les marchés publics et correspond aux orientations politiques du <u>Paquet Marchés Publics</u> de 2017. (Pour plus d'informations: Johannes Bahrke - Tel.: +32 229 58615; Sophie Dupin de Saint-Cyr - Tel.: +32 229 56169)

## EU supports Bosnia and Herzegovina in managing the migration flows with additional €6 million

Today the European Commission adopted a special measure for an amount of €6 million to support Bosnia and Herzegovina in managing the migration flows. The EU funds will improve the capacity of Bosnia and Herzegovina for identification, registration and referral of third-country nationals crossing the border, provide accommodation and basic services for refugees, asylum seekers and migrants and strengthen the capacity for border control and

surveillance, hence also contributing to the prevention of and fight against the trafficking of human beings. These funds complement the €1.5 million already made available to Bosnia and Herzegovina in June to address the immediate humanitarian needs of refugees and migrants. In addition to humanitarian assistance, since 2007 the European Commission has been providing assistance to Bosnia and Herzegovina in the area of migration and border management for an amount of € 24.6 million. Since January 2016 Bosnia and Herzegovina also benefits from the regional programme 'Support to Protection-Sensitive Migration Management' worth €8 million. (For more information: Carlos Martin Ruiz de Gordejuela — Tel.: +32 229 65322; Alceo Smerilli — Tel.:+32 229 64887)

### State aid: Commission approves new Slovenian commitment package for Nova Ljubljanska Banka

Following an in-depth State aid investigation opened on 26 January 2018, the European Commission has concluded that Slovenia's aid for Nova Ljubljanska Banka (NLB) remains compatible with EU State aid rules on the basis of a new commitment package submitted by the Slovenian authorities on 13 July 2018. Slovenia has firmly committed to an ambitious time schedule for NLB's sale a first sale tranche of at least 50% plus one share will be sold by the end of 2018 and the Slovenian government will reduce its stake in NLB to 25% plus one share by the end of 2019. Furthermore, Slovenia prolonged key commitments and also offered new commitments to compensate for the delayed sale and restructuring process of NLB. Commissioner Margrethe Vestager, in charge of competition policy, said: "The sale of NLB was an important remaining milestone of NLB's restructuring plan, which allowed us to approve over €2 billion of State aid to the bank in 2013. Therefore, I welcome Slovenia's commitment to a clear time path to achieve this sale. Thanks to this, the Commission can today approve Slovenia's new commitment package for NLB, ensuring that the bank will be a viable long-term player in the Slovenian banking market." A full press release is available in EN, SL, FR and DE. (For more information: Ricardo Cardoso - Tel.: +32 229 80100; Giulia Astuti - Tel: +32 229 55344).

# State aid: Commission approves prolongation of the Polish resolution scheme for cooperative and small commercial banks

The European Commission has approved, under EU State aid rules, the prolongation of the Polish resolution scheme for twelve months. The scheme was initially approved in December 2016. The measure will continue to be available for cooperative banks and small commercial banks with total assets below €3 billion, only if they are found to be in distress by the competent national authorities. The objective of the scheme is to facilitate the work of the Polish resolution authorities, should a concrete case and need arise for it. The Commission found the prolongation of the scheme to be in line with EU State aid rules, in particular the 2013 Banking Communication and EU banking rules. More information will be available on the Commission's competition website in the case register under the case number SA.51403 once any confidentiality issues have been resolved. (For more

information: Ricardo Cardoso — Tel.: +32 229 80100; Giulia Astuti — Tel: +32 229 55344).

### Mergers: Commission clears acquisition of Pibinew by SL04 and Ambienta

The European Commission has approved, under the EU Merger Regulation, the acquisition of Pibinew S.r.l. of Italy by S.L.04 S.à. r. ("SL04") of Luxembourg and Ambienta Sgr S.p.A. of Italy. Pibinew designs, manufactures, decorates and sells plastic packaging for the cosmetic industry. SL04 is a private equity firm indirectly controlled by L Catterton Partners of the US whose portfolio includes companies active in the production and sale of cosmetics and fragrance products. Ambienta is a private equity firm whose portfolio companies are not active in the cosmetic sector. Pibinew and L Catterton's portfolio companies are active in vertically related markets, namely the production and sale of cosmetic packaging, and the supply of cosmetic and fragrance products, respectively. However, the companies' individual market shares in these vertically related markets are modest and a number of strong players would remain post-transaction in both markets. Therefore, the Commission concluded that the proposed acquisition would raise no competition concerns. 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.9004. (For more information: Ricardo Cardoso - Tel.: +32 229 80100; Giulia Astuti - Tel: +32 229 55344).

# Concentrations: la Commission autorise l'acquisition de XL Group par le groupe AXA

La Commission européenne a approuvé, en vertu du règlement européen sur les concentrations, l'acquisition de XL Group Ltd, basé en Bermuda, par le groupe AXA, basé en France. XL Group est actif dans la fourniture d'assurances et de réassurance à des entreprises industrielles, commerciales et professionnelles et aux sociétés d'assurance. AXA est actif dans l'assurance et la gestion d'actifs dans le monde entier. La Commission a conclu que l'opération envisagée ne soulèverait pas de problème de concurrence, compte tenu de son impact très limité sur la structure du marché. La transaction a été examinée dans le cadre de la procédure simplifiée de contrôle des concentrations. De plus amples informations sont disponibles sur le site internet concurrence de la Commission dans le registre public des affaires sous le numéro M.8908. (Pour plus d'informations: Ricardo Cardoso — Tel.: +32 229 80100; Giulia Astuti — +32 229 55344)

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

# State aid: Commission approves new Slovenian commitment package for Nova Ljubljanska Banka

Slovenia has firmly committed to an ambitious time schedule for NLB's sale with a first sale tranche of at least 50% plus one share by the end of 2018. Slovenia prolonged key commitments and also offered new commitments to compensate for the delayed sale and restructuring process of NLB.

Commissioner Margrethe Vestager, in charge of competition policy, said: "The sale of NLB was an important remaining milestone of NLB's restructuring plan, which allowed us to approve over €2 billion of State aid to the bank in 2013. Therefore, I welcome Slovenia's commitment to a clear time path to achieve this sale. Thanks to this, the Commission can today approve Slovenia's new commitment package for NLB, ensuring that the bank will be a viable long-term player in the Slovenian banking market."

The Commission opened an in-depth State aid investigation on 26 January 2018, to assess whether new measures proposed by the Slovenian authorities regarding the restructuring of NLB sufficiently compensated for delaying the bank's sale. In particular, the Commission was concerned that Slovenia had not sold a first tranche of NLB before the end of 2017, in line with the commitments originally proposed by Slovenia to ensure NLB's long-term viability.

The sale of NLB was a crucial element of the Commission's viability assessment in the NLB State aid decision of <a href="December 2013">December 2013</a>, allowing the Commission to approve the granting of significant State aid of up to €2.32 billion to NLB. Slovenia committed in 2013 and again in 2017 to this sale to ensure that it would no longer unduly influence NLB's daily business operations. A change in ownership will allow the bank — at all its levels — to operate solely for commercial objectives.

The Commission can exceptionally accept modifications to existing State aid commitments if the new commitments are equivalent to the original ones. In the case at hand, the new commitments should ensure NLB's viability to the same extent as the original commitments and address any additional competition distortions resulting from the delayed sale.

Slovenia first notified amended commitments to the Commission in December 2017. In its opening Decision of <u>26 January 2018</u>, the Commission doubted whether these amended commitments were equivalent to the original ones. On 13 July 2018, Slovenia submitted another amendment commitment package, now with an ambitious schedule to sell NLB.

### The new proposed commitments

The new commitment package proposed by Slovenia includes strict deadlines to

complete the sale of 75% minus one share of NLB. A first significant sale tranche of at least 50% plus one share will be sold by the end of 2018 and the Slovenian government will reduce its stake in NLB to 25% plus one share by the end of 2019.

If Slovenia does not respect the deadlines foreseen, a divestiture trustee will be appointed to take over the sales process. This commitment is important, as the Commission in the January 2018 decision already suggested that a fully empowered divestiture trustee could further improve NLB's viability.

Furthermore, the **key existing commitments are prolonged**. An important commitment in this regard is the return on equity commitment, which ensures that NLB can only grant new loans if the bank receives a minimum return on equity on those loans. This commitment will help ensure the long term profitability of the bank and limit undue distortions of competition.

NLB will also **not re-enter the businesses it sold** as part of the restructuring plan (such as the leasing business) and will also strictly **comply with an acquisition ban**.

Finally, the new commitment package also includes **additional compensatory measures**, which will improve the viability of NLB and help to avoid undue distortions of competition in the Slovenian banking market:

- NLB will close additional bank branches in its home market and unless a full sale is completed by the end of 2018 also sell its stake in its insurance subsidiary NLB Vita.
- to further remove any viability doubts, NLB will also issue a so-called "Tier 2 bond" (subordinated debt).

The Commission's investigation concluded that the new Slovenian commitment package is sufficient to remove the Commission's doubts concerning the long-term viability of NLB and distortions of competition to the Slovenian banking market. On this basis, the Commission has approved Slovenia's new commitment package for NLB under EU State aid rules.

### **Background**

NLB is the largest banking group in Slovenia with a balance sheet of €13 billion (end 2017 figure). It has received three State recapitalisations, one of €250 million in March 2011, one of €383 million in July 2012 and in December 2013 a third recapitalisation of €1558 million together with a transfer of impaired assets to a State-owned bad bank with an implied aid element of €130 million

The Commission approved in December 2013 under EU State aid rules the €2.32 billion in State aid from these three recapitalisations — equivalent to 20% of the bank's risk weighted assets as of December 2012 —on the basis of the bank's restructuring plan and associated commitments. As a crucial part of this restructuring plan, Slovenia committed to sell 75%-1 share of NLB by end 2017. In May 2017, the Commission accepted a request from Slovenia for a more

gradual sale of NLB. Slovenia still committed to sell (at least) 50% of NLB by end 2017 and the remainder of the shares by the end of 2018.

More information will be available on the Commission's <u>competition</u> website, in the <u>public case register</u> under the case number <u>SA.33229</u>.

# Update on review of valsartan medicines due to detection of NDMA

10/08/2018

# Update on review of valsartan medicines due to detection of NDMA

EMA reviewing valsartan produced by another company Zhejiang Tianyu

As part of the ongoing <u>review of valsartan medicines</u>, EMA has learnt that low levels of N-nitrosodimethylamine (NDMA) have been detected in the valsartan active substance manufactured by a second company, Zhejiang Tianyu.

NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests.

The NDMA levels detected in batches of valsartan from Zhejiang Tianyu are much lower than levels seen in the active substance from Zhejiang Huahai, which triggered a recall of several valsartan medicines in July 2018.

EMA is working closely with international partners to review the impact of the NDMA detected in valsartan from Zhejiang Tianyu and will communicate as soon as additional information becomes available.

There is no immediate risk to patients. Patients should not stop taking any valsartan medicines without consulting their doctor or pharmacist.

A list of medicines containing valsartan from Zhejiang Tianyu will be available from <u>national medicines authorities</u>.

#### More about the medicine

Valsartan is an angiotensin-II-receptor antagonist used to treat hypertension (high blood pressure), recent heart attack and heart failure. It is available on its own or in combination with other active substances.

Medicines containing valsartan as the only active substance have been

authorised in the EU via national authorities. <u>Nine products</u> containing valsartan in combination with other active substances have been authorised centrally.

### More about the procedure

The review of valsartan medicines in relation to the presence of NDMA in the active substance was triggered by the European Commission on 5 July 2018 under Article 31 of Directive 2001/83/EC.

The review is being carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion. The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.

# ESMA updates validation rules under EMIR

The European Securities and Markets Authority (ESMA) has updated today its <u>validation rules</u> regarding the European Markets Infrastructure Regulation (EMIR) with regards to the revised technical standards on reporting under Article 9 of EMIR. The amendments will be applicable from 5 November 2018.

## Errata Double Volume Cap data

The European Securities and Markets Authority (ESMA) is correcting today its <u>Suspensions File</u> in relation to its Double Volume Cap (DVC) data, originally published on 7 August 2018, as required under the Markets in Financial Instruments Regulation (MiFIR).

The original Suspensions File included 13 instruments, which should not have been on the list of ISINs to be suspended from trading, for the reason that they have not been trading for at least twelve months. For ease of reference, the instruments impacted by this correction are listed below.

ISINs of instruments that were removed from the Suspensions File as they should not have been included/ subject to suspension in the first place:

AT0000BAWAG2

CH0042615283 CH0106213793 CH0371153492 CH0406705126 DE0003304002 DE000A161408 DE000A2G9MZ9 DE000JST4000 DK0060907293 GB00BF4HYV08 GB00BYW0PQ60 IT0005279143

There is no impact for the files which include the individual DVC calculations except for the Disclaimer for the removed ISINs. Those files will be corrected with the next publication in September.