EMA encourages tailored development of medicines for older people

01/08/2017

EMA invites comments on reflection paper by 31 January 2018

The European Medicines Agency (EMA) is inviting comments from the public on a reflection paper on how medicine developers can better address the needs of older people who take medicines.

In general, older people are the highest users of medicines. According to Eurostat, they are expected to make up almost a third of all Europeans by 2050, and they take more medicines than the rest of the population. Yet, medicines are rarely developed or packaged to take into account their specific needs. For example, some older people can face challenges such as difficulty opening boxes or bottles, reading instructions, swallowing or breaking tablets and capsules, which can result in medicines not being taken as intended, medication errors and ultimately a reduced quality of life.

The reflection paper describes aspects that medicines developers may consider when designing medicines for older people, such as selecting appropriate routes of administration and dosage forms, dosing frequency, excipients, container closure systems, devices and technologies, and user instructions in the product information.

For example, when there is evidence that older people find it difficult to break a tablet by hand, companies may find ways to improve the breakability of the tablet or consider alternative administration approaches, such as small tablets in a dose dispenser. Similarly, companies may consider redesigning the containers so that older patients can open them easily without any assistance.

Comments are particularly invited on the accuracy of tablet breaking, the administration of medicines through feeding tubes, and on multiple compliance aids and multiple drug dispensing systems (containers that clearly state the name of the day or the moment when a medicine needs to be administrated).

Depending on the outcome of the public consultation, the content of the reflection paper might be further developed into regulatory or scientific guidance.

Alexander Stubb is new Vice-President of the European Investment Bank



Mr Alexander Stubb

Vice-President of the EIB

31/07/2017

European Investment Bank

Alexander Stubb has been appointed Vice-President and Member of the Management Committee of the European Investment Bank (EIB). He takes up his duties today, succeeding Jan Vapaavuori, who had tendered his resignation in June.

Mr Stubb, a Finnish national, was appointed by the EIB's Board of Governors on a proposal from the Finance Minister of the Republic of Finland and with the agreement of the shareholder constituency formed also by Austria, Estonia, Latvia, Lithuania and Sweden.

In the Bank's Management Committee, Mr Stubb will have the oversight of EIB operations in Denmark, Estonia, Finland, Latvia, Lithuania and Sweden and in several countries outside the European Union.

Alexander Stubb commented upon joining the EIB: "I am thrilled to be joining the EIB and look forward to putting my experience at the service of its continuing success. Because the EIB is a European success story: it fosters investment in viable projects, helps make Europe more competitive worldwide and puts money and people to work. It has been called to tackle the historic difficulties that face Europe as a whole, and it has demonstrated that it could deliver and rise to the challenge. I am proud to being given the opportunity to work for the EU bank".

Prior to becoming EIB Vice-President, Mr Stubb served as Prime Minister, Finance Minister, Foreign Minister, Trade and Europe Minister of Finland. His background is in academia and civil service, with a focus on EU affairs. He was a member of the European Parliament from 2004-2008, Finnish government minister from 2008-16, a member of the Finnish Parliament from 2011-2017 and the Chairman of the National Coalition Party from 2014-2016. As of November 2017, he will be the Chairman of the Board of the Crisis Management Initiative (CMI), a non-governmental organisation that works to prevent and resolve conflicts. He holds a PhD from the London School of Economics, has published 18 books and is a self-professed sports-fanatic.

The Management Committee is the EIB's permanent collegiate executive body, consisting of a President and eight Vice-Presidents. The members of the Management Committee are appointed by the Board of Governors — the economy

and finance ministers of the 28 EU Member States.

Under the authority of Werner Hoyer, President of the EIB, the Management Committee collectively oversees the day-to-day running of the EIB as well as preparing and ensuring the implementation of the Board of Directors' decisions, notably regarding borrowing and lending operations.

EIB provides EUR 105m loan to Junta de Castilla y León to support SME growth in the region and to finance investment in transport and rural tourism infrastructure

The European Investment Bank (EIB) and the Junta de Castilla y León have signed two new loans for a total of EUR 105m to support SMEs in the Castilla y León region and finance investment in transport and rural tourism infrastructure. This amount is in addition to the more than EUR 2bn the EU bank has provided to the region since 1989 with the aim of driving economic growth and job creation via projects concerning roads, water supply and sanitation, hospitals, the environment and other areas.

In concrete terms, the EIB has granted a EUR 75m loan to the Castilla y León Institute for Business Competitiveness (ICE, the new name for the former Innovation, Financing and Business Internationalisation Agency, ADE), while another EUR 30m loan has been provided to the Castilla y León Public Sector Infrastructure and Environment Company (Somacyl).

Innovative Growth Plan

The EIB resources directed to the Institute for Business Competitiveness (a body under the responsibility of the Ministry of the Economy and Finance) will be used to finance projects promoted by SMEs and midcaps with participating loans or share capital contributions. These will mostly be channelled via the ADE Capital Sodical SCR company, but could also be granted directly.

This financing comes under the Junta's Innovative Growth Plan for businesses in Castilla y León, and will make it possible to help projects supporting the competitiveness of SMEs and the consolidation of midcaps in the region, thereby promoting economic growth and job creation. The funds provided by the EIB will be allocated to projects needing total investment of up to EUR 12.5m for SMEs and up to EUR 25m for midcaps, with the aim of seeing innovation help them grow.

This initiative is expected to benefit between 50 and 150 companies known for being leaders in research or innovation and that are embarking on a transformation of their production systems using Industry 4.0 technologies, or that are introducing new management models resulting in process efficiency gains. It will also be possible to finance projects surrounding the launch of internationalisation strategies, such as those including training or human resources programmes or dual vocational training.

SMEs and midcaps in Castilla y León that receive these funds will be able to benefit from "soft" loans thanks to the favourable conditions provided by the EIB, both in terms of maturities and interest rates. This financial support will mobilise an estimated EUR 400m in investment and will make it possible to create and maintain around 8 000 direct jobs in the region until 2020.

Rural tourism infrastructure and public transport

The loan signed between the EIB and the Public Sector Infrastructure and Environment Company will provide EUR 30m to finance investments connected to public transport and sustainable rural tourism in Castilla y León.

Regarding transport infrastructure, the EU bank resources will help to modernise and refurbish bus stations, improving accessibility and service quality for the 60 million passengers using them every year.

Somacyl will also use these funds to develop projects in the rural tourism sector, with the objective of increasing the number of visitors and the length of their stays. In concrete terms, the EIB financing will be allocated to building recreational public infrastructure including viewpoints, via ferratas, cable cars, toboggan runs and hiking trails; promoting new tourist accommodation via the refurbishment and repurposing of exceptional buildings; and setting up more camp sites around areas of special natural interest.

The work for this new infrastructure will last until 2020, creating an estimated 900 jobs during the construction phase and 100 more permanent positions in the operational phase.

EU school children to receive milk, fruit and vegetables

Aimed at promoting healthy eating habits among children, the scheme will include the distribution of fruit, vegetables and milk products, as well as dedicated educational programmes to teach pupils about the importance of good nutrition and to explain how food is produced.

This single scheme merges and optimises the existing projects that last year reached over 20 million children. Although participation is optional, all 28

Member States indicated they will take part in the initiative in the 2017/2018 school year.

Phil Hogan, Commissioner for Agriculture and Rural Development, said: "I am very pleased that the new school scheme will be introduced tomorrow. The scheme provides valuable support to millions of European schoolchildren and thousands of farmers in every Member State. Such support has proven particularly important for farmers in recent years and the increased funding will enhance the value of this support. In addition, the new scheme meets my priority of simplification through the integration of the former school milk and vegetable schemes. Finally, I am happy to be involved with an initiative with Commissioners Andriukaitis and Navracsics to promote a healthy lifestyle and I am convinced that this scheme has a valuable part to play."

Fresh fruit, vegetables and drinking milk will be given as a priority to school children. Processed products such as soup, fruit compotes, juice, yoghurts and cheese may also be distributed if this choice is approved by the national health authorities. No added sugar, salt and fat are allowed unless the national health authorities permit limited quantities.

Besides deciding on the exact way to put the scheme in place, like the inclusion of thematic educational measures and other agricultural products, Member States have the option to top up the EU aid with national aid for financing the scheme.

This choice of products shall be based on health and environmental considerations, seasonality, variety and availability with priority to EU products. Member States may encourage local or regional purchasing, organic products, short supply chains, environmental benefits, agricultural quality schemes.

Of the €250 million EU funding agreed for 2017—2018 school year, roughly €150 million will be allocated for fruit and vegetables and €100 million for milk.

The new school scheme forms part of Commissioner **Hogan's** simplification agenda. It allows for greater synergies and efficiencies in the implementation of the new scheme, and complements other measures in the areas of health and education policies.

From 1 August 2017, the two current schemes — the School Fruit and Vegetables Scheme and the School Milk Scheme — will be brought under a single legal framework. The new rules aim at greater efficiency, more focused support and an enhanced educational dimension.

Currently, 24 Member States take part in the old fruit and vegetable scheme and 28 in the old milk scheme. Last year, around 20 million children benefited from the milk scheme and around 11.7 million children from the fruit and vegetables scheme.

Annex: EU aid for school year 2017/2018

Member State	Definitive allocation for school fruit and vegetables in EUR	Definitive allocation for school milk in EUR
Belgium	3 367 930	1 650 729
Bulgaria	2 677 109	1 167 367
Czech Republic	4 082 903	1 842 407
Denmark	2 386 393	1 606 402
Germany	25 826 315	10 947 880
Estonia	565 888	732 225
Ireland	2 007 779	900 398
Greece	3 218 885	1 550 685
Spain	12 932 647	6 302 784
France	17 990 469	17 123 194
Croatia	1 720 946	800 354
Italy	21 704 956	9 261 220
Cyprus	390 044	400 177
Latvia	813 091	745 497
Lithuania	1 134 661	1 091 333
Luxembourg	343 568	193 000
Hungary	3 885 599	1 972 368
Malta	372 747	144 750
Netherlands	7 063 251	2 401 061
Austria	2 946 591	1 278 933
Poland	14 985 916	11 047 202
Portugal	3 283 397	2 220 981
Romania	6 866 848	10 865 578
Slovenia	727 411	363 811
Slovakia	2 185 291	1 020 425
Finland	1 599 047	3 824 689
Sweden	0	9 245 859
United Kingdom	0	4 219 008
Total	145 079 683	104 920 317

For more information

News item on the adoption of the new scheme

Statement by the Spokesperson on the

Election to a Constituent Assembly in Venezuela

The events of the past 24 hours have reinforced the European Union's preoccupation for the fate of democracy in Venezuela.

The European Union deeply regrets the violence and unrest during yesterday's election. It expresses condolences and its sympathy to the families and friends of all those killed. All sides must refrain from violence. The European Union condemns the excessive and disproportionate use of force by security forces. The Government of Venezuela has a responsibility to ensure respect for the rule of law and fundamental rights, such as freedom of expression and the right to peacefully demonstrate.

Venezuela has democratically elected and legitimate institutions whose role is to work together and to find a negotiated solution to the current crisis. A Constituent Assembly, elected under doubtful and often violent circumstances cannot be part of the solution. It has increased division and will further de-legitimise Venezuela's democratically elected institutions.

The President and the government have a special responsibility to restore the spirit of the constitution and to re-establish the trust lost by their attempt to set up divisive parallel institutions.

The fate of democracy in Venezuela is a legitimate concern to all countries in the region, and to Venezuela's partners across the world. In support of ongoing regional mediation efforts, the European Union will continue to seek urgent relief for the people of Venezuela and promote a political solution to the crisis.