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POLITICO Pro Morning Health Care: Doctors on alcohol-Ireland's Beneluxa pitch- Norway shells out for Spinraza 13 February 2018

Please find below the article 'POLITICO Pro Morning Health Care: Doctors on alcohol-Ireland's Beneluxa pitch- Norway shells out for Spinraza' where CPME Secretary General Annabel Seebohm was interviewed by POLITICO on alcohol labeling.

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POLITICO Pro Morning Health Care: Doctors on alcohol — Ireland's Beneluxa pitch — Norway shells out for Spinraza

By **SHIRLEY S. WANG** | 2/13/18, 7:10 AM CET

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ALCOHOL — **DOCTORS WANT POLITICAL COMMITMENT:** Health advocates are rallying for the European Commission, Parliament and the Council to demonstrate political commitment to alcohol labeling rules, even as a March deadline for the alcohol industry to submit a self-regulatory proposal approaches.

Annabel Seebohm, secretary general of the Comité Permanent des Médecins Européens (CPME), or Standing Committee of European Doctors, told Morning Health Care her group wants the Commission to set "clear, harmonized rules" across EU countries regarding a list of ingredients and nutritional content that alcohol producers would have to include on their products. Raising awareness of content and calories can help consumers to make choices, she said, which may reduce levels of drinking and alcohol-related harm.

Take the reins: As the EU awaits industry's March proposal, Seebohm says self-regulation isn't the answer. There is "clear evidence that self-regulation by industry doesn't provide to be effective" in the case of alcohol advertising with the Audiovisual Media Services Directive, she said, leading the group to doubt the industry's ability to self-regulate with labeling.

Health ministers in December called on the Commission to propose alcohol labeling regulation by the end of 2019 if the industry fails to deliver with its proposal.

Off-label proposal: The industry's draft proposal seen by POLITICO last month promotes an off-product labeling alternative, since industry says bottle labeling doesn't allow them to change ingredients or details readily.

According to Seebohm, only including off-product information would be a flawed approach. The industry's argument "doesn't convince me," she said. "Apparently it is manageable for all other actors in the food industry, why not the alcohol industry?" CPME and a group of medical associations across Europe wrote to MEPs and the Commission with their position in January. (Seebohm said they haven't yet received a response.)

Vindication for Buzyn: French Health Minister Agnès Buzyn rankled winemakers and others in a debate last week when she said that wine was no different than other alcohol in that too much can be harmful. She charged that the French hold inconsistent views in which wine is considered culturally good while other alcohol is bad for health, according to French-language medical website Egora.fr. The National Association of Prevention in Alcohology and Addictology (ANPAA) said Monday it welcomed Buzyn's "unambiguous speech."

Wine sector hits back: The issue is under particular scrutiny amid accusations from health groups that there's a conflict of interest in the recent appointments of former wine industry officials by the German and French governments. But wine sector representatives are pushing back against these claims. "This is a nonsense polemic. Both persons have been directly appointed by their leaders and or elected by their citizens because of their skills," Ignacio Sanchez Recarte, secretary-general of Comité Européen des Entreprises Vins, told our colleagues over at Morning Agri.

Good morning and welcome to Morning Health Care! If you missed your flight to Amsterdam from London City Airport Monday (like my father-in-law) because of that unexploded WWII bomb, the London-Amsterdam Eurostar service set to begin in April might be looking mighty useful, passport check delay and all. As for today's news, MHC wouldn't be complete these days without the latest on the Novartis-Greece bribery case, as well as reaction to the Commission's HTA proposal and a lot of pharma news.

Thanks to Carmen Paun, Sarah Wheaton, Kait Bolongaro, Laura Greenhalgh and Nirvi Shah.

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IRELAND — **MOVING TO JOIN BENELUXA:** Irish Minister for Health Simon Harris intends to ask for government approval to talk to the health ministers in Belgium, the Netherlands, Luxembourg and Austria about joining the Beneluxa consortium. The health department confirmed the country's plans to make the approach to Morning Health Care, following a report by Ireland's Business Post.

Harris had expressed interest before in joining the group, formed to negotiate prices for specific drugs with pharmaceutical companies and discuss the value of innovative medicines. "Securing access to new and innovative medicines in a timely and affordable manner is a key objective of government and Ireland is committed to exploring all opportunities to maximize purchasing power through European initiatives," a spokesperson said. Ireland is already onboard with the Valletta Declaration, a similar grouping made up of majority southern European nations.

HTA — GERMAN DRUGMAKERS REACT: Germany — its government, its health technology assessment bodies, its payers — have all panned a proposal for EU-level HTA coordination from the Commission. So the German pharma trade group's approval stands out. The Association of Research-Based Pharmaceutical Companies (vfa) came out Monday in favor of a unified value assessment for new medicines. Diseases don't stop at country borders, so assessment of the risks and benefits of medicines to treat those diseases shouldn't either, the group said. "A differentiation by nationality makes sense only in the negotiated prices, not in the medical evaluation," according to the VFA.

It said national authorities working together to assess the health value of new medicine can work just as well as the EU drugs approval process has done. "In doing so, the national authorities can make specific use of their special skills and experience and the European authorities ensure that they are called up," said the VFA. The Commission is set to present the plan to national health attachés later this week.

FRANCE — **HEALTH CARE PLAN:** Buzyn and French Prime Minister Edouard Philippe today present a plan of "profound transformation" for the national health system to improve care. "Our health system is facing multiple challenges, among which we can mention the development of chronic diseases, insufficient development of prevention or difficulties in accessing care," the government said ahead of today's announcement.

EMA — **MEP FIELD TRIP:** The European Parliament's ENVI Committee will send a fact-finding mission to Amsterdam on February 22, visiting both the temporary location and the future headquarters for the European Medicines Agency so MEPs can get the latest information on the EU drug regulator's double move.

GREECE — **NOVARTIS RESPONDS:** The Swiss drugmaker finally issued a longer statement than "we're cooperating with the investigators" on Monday. Novartis pushed back against what it called a politicized debate as it stands accused of bribing top politicians in Greece for preferential market access. The company said it has been doing its own investigation and "if any wrongdoing is found we will take fast and decisive action and do everything possible to prevent future misconduct."

Syriza backs parliamentary probe: Also on Monday, the ruling party's parliamentary group, Syriza, supported Prime Minister Alexis Tsipras' call for for a parliamentary inquiry into the case. As politicians including EU Migration Commissioner Dimitris Avramopoulos stand accused of taking bribes, the unnamed witnesses that fingered them may be asked to testify before the committee, Greek House Speaker Nikos Voutsis said according to local media. Their identity will be protected, he said.

PHARMA — NORWAY TO SHELL OUT FOR SPINRAZA: After a months-long debate, Norway will buy the rare-disease treatment Spinraza for patients with a fatal muscular disease from U.S. drugmaker Biogen for 7 million Norwegian kroner — over €700,000 — per patient annually, according to Reuters. The government had considered issuing a compulsory license for the drug, in which a national drugmaker rather than Biogen would produce the medicine at a more moderate cost to get the treatment to patients faster.

NICE reverses decision on kidney drug: In the U.K., HTA body NICE recommended tivozanib for adults with advanced kidney cancer who have not had any previous treatment, after previously saying no because the drug was likely to be less effective than existing and less costly current treatments. Drugmaker EUSA Pharma struck a confidential discount pricing agreement, or "patient access scheme," with the U.K. health department, a spokesperson told Morning Health Care, the savings of which were substantial enough to lead NICE to conclude in final draft guidance they offset the potential lower effectiveness compared to existing treatments. NICE says that since not all patients respond to current treatments, alternatives are necessary.

No-go for Batten disease: In draft guidance, NICE said an initial "no" to a highly anticipated gene therapy for a rare condition known as Batten disease, which affects between one and six babies born in the U.K. each year. The long-term benefits were too uncertain to be recommended for routine use of the therapy that's expected to cost £500,000 per year, said NICE.

The Batten Disease Family Association immediately pushed back, saying U.K. patients shouldn't be barred from the treatment because of the lack of long-term data: "Are we suggesting that clinical trials of treatments should run for many decades to enable this data to be collected, or is the fact that children on this treatment continue to thrive and live life to the full after three years not sufficient?"

Big business: Pharmaceuticals were Switzerland's most important export in 2017 accounting for 39 percent of total exports at 83 billion Swiss francs, according to Ärzte Zeitung.

ROMANIA — HEART STOPPING NEGOTIATIONS: We are not sure what Romanian health ministry officials said during salary negotiations with representatives of health care workers on Monday in Bucharest, but one poor individual suffering from heart problems had a heart attack during the meeting. According to a statement from the Romanian health ministry, the man was lucky to be in the same room with the president of the Ambulance Federation and other health workers who resuscitated him until an ambulance could take him to hospital. He is expected to make a full recovery.

Doctors' wages rise: Most Romanian doctors' wages will rise by 70 percent or more come March 1, including those of primary care doctors, residents and nurses, reports Digi24.ro. But some staff, including pharmacists and medical assistants in some units, who already had a salary increase since January will see a dip in wages — as will Health Minister Sorina Pintea herself.

Parents risk fines on vaccines: Pintea said in a radio interview on Monday that parents may be fined if they refuse to be informed about the risks of not vaccinating their children. A vaccination law proposed by her predecessor introducing the obligation for parents to be informed is still before the lower house of the Romanian parliament.

HEP B — **INFECTIONS DECLINE ACROSS EUROPE:** Acute Hepatitis B infection rates dropped across most countries in Europe between 2006 and 2014, according to a recent study from journal Eurosurveillance. Countries that started a vaccination program earlier than 1995 saw a greater reduction in cases than those who began later, and wider vaccine coverage also translated to bigger decreases. Four countries saw an uptick, however: Austria, Iceland, Portugal and Spain.

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Stress: one in ten people at work in Denmark on medication, says report, via The Local.

Cigarette companies don't sponsor the Olympics. Why does Coca-Cola? Health campaigners write in the Guardian.

NHS reports surge in hospital admissions for eating disorders, also from the Guardian.