GIRP PRESS REVIEW
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EARLY BIRD REGISTRATION RATES STILL ONGOING: 8th edition of the GIRP Supply Chain Conference, 16-17 March 2023, Madrid, Spain

GIRP is pleased to announce that early bird registration rates to the **8th edition of GIRP's Supply Chain Conference** are still ongoing. We invite you to join us on **16 and 17 March 2023 in Madrid, Spain** for two full days of engaging sessions and interventions from key actors across the healthcare supply chain.

This 8th edition of the GIRP Supply Chain Conference it will aim at tackling the multifaceted transformation and transition underpinning the core of the pharmaceutical supply chain. While the past years allowed us to draw critical lessons from the Covid-19 pandemic, many challenges still lay ahead, be it the green transition that is now in the spotlight of all the regulators, the digitalisation of the sector that is full of opportunities, or even the overall need to increase the resilience of structures and infrastructures for future crises.

In addition to exploring these different pathways, the Supply Chain Conference will revolve around our traditional session gathering G(M)DP authorities and inspectors to discuss and exchange altogether on the implementation of the Good Distribution Practices. Featuring some of the key regulators on the national and European level, such as heads of national medicines agencies and from the European Medicines Agency, as well as professionals from top-tier companies in the pharmaceutical distribution and industry, the GIRP Supply Chain Conference is a unique opportunity for stakeholders of the pharmaceutical supply chain to meet and discuss on the latest and leading topics of the sector.

View on our full conference programme: https://scc.girp.eu
Register now at early bird rates until 16 January 2023: https://scc.girp.eu/content/register-now-1

12 December 2022 – EUROPE: Long way to go for the EU's health data proposals (Source: APM Health Europe ©)

BRUSSELS, 12 Dec (APM) - The European Commission's ambitious proposal for creating a European 'health data space' has made only limited progress through the legislative machinery, despite more than six months of discussions and more than 20 meetings of the Council working party where member states' experts and officials examine the text. The pharmaceutical industry in Europe is impatient for progress, viewing the proposals as "an unprecedented opportunity to shape the future health data and digital ecosystem", as Nathalie Moll, director general of EFPIA put it. She stressed the "paramount importance" of the measure receiving full support and of its full - and consistent - implementation across the EU.

Moll also expressed concern over uncertainties over the conditions for sharing data, including clinical trial data, and over protection of companies' intellectual property and trade secrets when their data are requested. The proposed regulation, published in May, aims to improve individuals' access to their own electronic health data, to promote EU-wide secondary use for the purposes of research, innovation and public policy, and to encourage the development of digital health services and products. It is still awaiting review in the European Parliament and the Council has requested a formal legal opinion on how its terms relate to national delivery of healthcare.

According to a report from the Czech presidency of the EU health council, the review has focused so far on primary use and has identified concerns so far relating to tight timelines, links to other EU rules (and notably the data protection legislation) and funding for the system's implementation. There are also questions over the governance structure proposed.

Secondary use

Some discussion has taken place on secondary use of data and the links to national data structures. Here, according to the outgoing Czech presidency, outstanding issues include the list of minimum categories for secondary use of data; the tasks of the envisaged health data access bodies (as well as their reporting duties and the fees they might charge); the issuance of data permits; joint controllership of secondary use of data and responsibilities; and data quality labels. The Czech presidency has suggested modifications to the proposal to align it more closely with data protection rules and to overcome possible overlap with the organisation and delivery of health services and medical care.

These proposed adjustments clarify the distinction between data inserted into data bases by individuals and by healthcare professionals, and would strengthen people's rights to obtain information on access to their data. They also include a recommendation to ease specific obligations on data registration and reduce the range of tasks and powers of the envisaged digital health authorities.

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09 December 2022 – EUROPE: EU demands right to break its Covid-19 vaccine contracts with industry (Source: APM Health Europe ©)

BRUSSELS, 9 Dec (APM) - The contracts that the EU has signed with vaccine manufacturers must be changed to prevent surplus and waste, the combined forces of the EU health policy institutions insisted on Friday. The European Commission, the presidency of the health council and all 27 member states, agreed that supplies must be adjusted to shifting demands - and demonstrated a determination to act in concert to persuade reluctant manufacturers to give way. An ostensibly innocuous review of the EU's Covid-19 vaccine strategy at the beginning of Friday's health council in Brussels turned into a ritual denunciation of the contracts and a repudiation of their force.

Flexibility

"Companies must show greater flexibility," summarised health commissioner Stella Kyriakides at the end of the discussion. Circumstances have changed, repeated minister after minister during the meeting, invoking not only progress in countering the pandemic, but also the context of the energy crisis, the war in Ukraine and rising inflation. Their demands include reducing the number of doses to be supplied, extended schedules for deferring deliveries, a stop to contracted production when new variants emerge and the right to export surplus supplies.

"Destruction of vaccines is not something that we can accept," said Kyriakides. Germany and France called for a single EU voice to exert pressure on companies, with a "firm message" to Pfizer, the principal EU supplier. The Netherlands and Belgium both warned that the EU should no longer leave itself dependent on one dominant supplier. Lithuania said it now has a surplus six times its requirements and attacked the obstinacy of suppliers over contractual terms as "mere commercial interest". Denmark said that prices should be lower to reflect the lower degree of investment risk.

Back story

The issue of over-supply is not new. Discussions with the companies have been under way during the year, but they have now come to a head. Surpluses have grown, time-expired supplies have had to be destroyed and

crucially, at this time of the year, obligations are about to kick in on earlier-agreed schedules for additional supplies to be delivered within weeks, as from the beginning of 2023. Kyriakides said some "tangible results" have been achieved through negotiations so far, "but we clearly need to do more in order to align supply and demand". "Our united approach needs to continue in our negotiations with the companies," she said. In respect of threats by AstraZeneca over breach of contract - an issue raised in Poland - Kyriakides urged coordination of the EU position, to "move forward together in litigation".

"Unity is the best way to protect our interests both legally and in terms of public health," she added. From the chair, Czech deputy prime minister and minister of health Vlastimil Vále underlined the need for firm action. "We're still at the level of promises" in talks with the companies and "we need that to be formalised and a contract addendum prepared". He added: "We need the possibility to cancel a part of the supplies and I have asked the Commission to communicate this clearly to producers. "We have all agreed that it is indispensable that vaccine supplies be suspended until the contract is amended," concluded Vále. It would be "unacceptable if we receive more vaccines in January or February" - and "a breach of mutual trust".

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14 December 2022 – GERMANY: BfArM recommends restricting paracetamol fever syrup sales to babies and young children (Source: APM Health Europe ©)

BERLIN, 14 Dec (APM) - Germany's chemical medicines regulator BfArM is recommending restricting the sale of paracetamol and liquid ibuprofen-based paediatric fever syrups to young children and not stockpiling the medicines in pharmacies in light of continued shortages and a spike in demand. Pharmacists should consider offering solid forms of paracetamol and ibuprofen, such as tablets that can be broken in half, for children aged older than four (for paracetamol) and six (for ibuprofen), BfArM said in an updated recommendation on paediatric fever syrups issued on Monday.

For children over the age of nine, paracetamol and ibuprofen-based syrups should only be sold on prescription when these children cannot take these medicines in a solid form. In order to achieve equal distribution of the medicines between different regions, pharmacies and wholesalers should not accumulate more than a week's supply of fever syrup, said the regulator. Last week, several major German payers confirmed they are now reimbursing higher costs of children's fever syrups, including the cases when the syrup is mixed in the pharmacy or imported. AOK, one of the payers, has called for an expanded stockpiling of the fever syrups, as well as a change of the law regulating generic medicine reimbursement in Germany. Manufacturer associations have been blaming Germany's generic medicine regulations for years for making the market unattractive and forcing many generic manufacturers to leave. In July, Ratiopharm, the major supplier in Germany, warned it could not guarantee that the shortage of liquid paracetamol would be addressed by the autumn.

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14 December 2022 – SPAIN: Andalusia to centralise purchases, assessment to speed up access to newer medicines (Source: APM Health Europe ©)

MADRID, 14 Dec (APM) - The health chief of Andalusia region has announced plans for centralised purchasing and assessment of new medicines as part of a move to avoid delayed access. Speaking at the opening of a meeting organised by the Bamberg Foundation in Seville on Monday, Catalina Garcia, Andalusia's health chief, said her government is working on the new regulation to facilitate centralised purchasing and assessment as a way to accelerate access to newer medicines. García said: "When the new decree is implemented, new medicines will no longer be assessed at each hospital. Instead, one assessment will be valid for the whole region in order to make new medicines available faster and in a homogeneous manner." García cautioned that, in Spain, public financing of any medicine is a decision made by the Madrid government, so regions can only do so much about this. She called the health ministry to make moves to avoid delayed access to EU-approved therapies. She said that investing in new medicines should not be considered as mere expense and added that it is the authorities' duty to promote access to innovation.

Upcoming pharmaceutical regulation on the spot
According to EFPIA: Patients W.A.I.T. - Indicators, Spain's authorisation times are among the longest in Europe. Only 54% of EU-approved medicines in recent years are available in the country, whereas 88% of them have been authorised in Germany and 70% are available in Italy and the UK, García added.

These comments add up to numerous voices which have been pointing out for a long time that Spain needs to make authorisation procedures more agile. The government announced new legislation to solve this in November. García said that a wider economic perspective must be added to the assessment of new medicines, pondering healthcare and social variables together with their cost. She added that medical societies and patient groups should be more involved in therapeutic positioning reports (IPTs), which medicine pricing commission CIPM uses to make decisions on reimbursement. She said: "Clinicians with an expertise in the field which is relevant for each new treatment must be included.".

The region has opened "an innovative path" to pay for newer, more expensive medicines, including capping, volume pricing and risk-sharing schemes. However, she thinks that additional funds provided by Madrid will most likely be necessary to guarantee access to innovation. She ended her speech by saying that authorities must facilitate access to therapies which show high efficacy "in spite of their high price" while maintaining sustainability, because this is not spending, but "investing in health".

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09 December 2022 – SPAIN: Low prices leading to medicine shortages in Spain - distribution group (Source: APM Health Europe ©)

MADRID, 9 Dec (APM) - Eduardo Pastor, president of one of Spain's leading distributors COFARES, says he blames "excessively low prices" for medicine shortages in Spain. In an interview with El Economista published on Thursday, he said that shortages have been a problem for a long time and that they need to be properly assessed. "Medicine prices are excessively low in Spain. Manufacturing costs are quite often higher than retail prices and that is one of the reasons for the scarcity of medicines," he said.

Pastor insisted that he prefers using the word "scarcity" because there is not a lack of product, but insufficient supplies due to increases in demand. He suggested that distributors, which have direct information from manufacturers, inform Spanish regulator AEMPS about medicine shortages. He argued that data obtained in community pharmacies are obsolete and do not really account for the specific problem with medicines. He said that the planned new pharmaceutical legislation is a historic opportunity to define what medicines truly are, beyond their cost. He said: "In my opinion, savings in the healthcare system cannot be exclusively based on lower medicine prices. Medicines include other materials, packaging and other elements which are getting more and more expensive. We cannot sustain the dynamics of decreasing medicine prices at higher costs. Manufacturing them is getting more and more difficult." He also said COFARES is working to have distribution included in the new legislation as a key, strategic industry.

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09 December 2022 – UK: Medicine price increases caused by shortages could lead to closure of some pharmacies in England - senior pharmacist (Source: APM Health Europe ©)

LONDON, 9 Dec (APM) - Independent community pharmacies in England could face closures if medicines' shortages continue to lead to higher medicine prices, according to a senior pharmacist. Andrew Lane, chair of trade body the National Pharmacy Association, said there could be a situation in the country where only larger chains are able to mitigate dispensing medicines at a loss due to supply constraints pushing wholesale medicine prices up above National Health Service (NHS) tariffs that govern how much pharmacies charge patients for medicines. "If this shortage of medicines continues, we will actually see some pharmacies exiting because they

will not be able to continue to dispense medicines at a loss," said Lane on Wednesday during a presentation at an online conference organised by the Westminster Health Forum.

"If they cannot procure medicines at anywhere near the price that they're going to get reimbursed on the medicine tariff, then it's not a sustainable business model for anybody," adding that larger pharmacy chains might be able to counter this by purchasing at scale. However, this would create an imbalance and "many independent pharmacies may close", said Lane.

Shortages of generic medicines have become an increasing issue for the UK and other countries in recent years, with Lane saying that dealing with shortages has become "part of the daily life of a pharmacy operation". Major recent cases in the UK include shortages of hormone replacement therapy (HRT) products, while there are now current worries about supplies of antibiotics following multiple cases of strep A infection. Brexit and the Covid-19 pandemic have contributed to supply issues in the country. But the UK's pricing policies also have a major impact, said Mark Samuels, chief executive of BGMA, the UK trade body for off-patent medicines.

He highlighted the UK's voluntary scheme for branded medicines pricing and access (VPAS), which is a pricing agreement between industry and the government that is intended to supporting innovation while controlling medicine spending. In its current form, it is intended to limit the UK's spending on medicines to an annual increase of 2%. To achieve this, there is a rebate on the revenues of branded medicines manufacturers, which also applies to biosimilars and branded generics. This rebate was 5.1% of revenues in 2021 but this jumped to 15% in 2022 and is expected to climb to up to 30% in 2023. This is putting off companies who market branded generics and biosimilars from marketing products in the UK, said Samuels.

"I've had one at least one of our members say to me that they chose not to start manufacturing HRT and not to enter the UK HRT market because of the VPAS tax," said Samuels. In addition to the lack of access, these exits are an additional issue for pharmacies as when companies withdraw a generic product from the market, either for commercial or supply issues, the value increases of the other versions of that medicine and of rival medicines that remain on the market. And pharmacists are increasingly spending time "shopping around" for the lowest priced medicine and even then not always with success, said Lane. "Many of our members are now finding that they are dispensing continually products at a loss. And that's if they can find those products, of course."

Single supplier model

Shortages can also be exacerbated by tender models that rely on single suppliers of medicines, said Jessamy Baird, country lead and head of general medicines, UK and Ireland, Sanofi, noting that every medicine manufacturer can experience "lumps and bumps" in their supply chain. "If you go for a single supplier preference model, you will run a far greater risk of supply pressures. So I'm not certain those lessons have been learned." Lane agreed, describing a single supplier model as a "massive risk" and called on the UK government to look at different models. "We don't want to meet another cliff edge in a year's time, like if we have another pandemic. I think we've got the ability, we've got the data and we can work out what another model could look like where we all benefit."

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12 December 2022 – US: Amgen to buy Horizon for almost $28 billion (Source: APM Health Europe ©)

LONDON, 12 Dec (APM) - Amgen said on Monday it is buying Horizon Therapeutics for approximately $27.8 billion, bringing with it blockbuster thyroid eye medicine Tepezza. Tepezza (teprotumumab) is an insulin-like growth factor-1 receptor inhibitor (IGF-1R) which has been approved in several markets for thyroid eye disease. The medicine brought in sales of $1.47 billion in the nine months to the end of September, growth of 37% from last year. It is the company's top-selling product. The deal values Horizon at approximately $27.8 billion, Amgen said in a statement.

Horizon also markets gout treatment Krystexxa (pegloticase), which it gained from its buyout of Crealta Holdings in 2015. In addition, Dublin-based Horizon markets Uplizna (inebilizumab), which is approved for rare autoimmune disease neuromyelitis optica spectrum disorders (NMOSD). Amgen's chief executive Robert Bradway said the addition of Horizon is a "compelling opportunity", which will enable Amgen to reach more patients with medicines such as Tepezza, Krystexxa and Uplizna. Horizon's other potential new medicines will also complement Amgen's R&D portfolio, added Bradway, who said the acquisition will drive Amgen's revenue growth from 2024. Amgen was left as the sole company interested in agreeing a Horizon takeover deal after both Sanofi and Janssen pulled out from the talks. In August, Amgen announced that it was buying U.S. biotech ChemoCentryx for $3.7 billion to gain control of Tavneos (avacopan), a medicine to treat a rare autoimmune condition that leads to swelling of blood vessels.

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