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12 JULY 2023 – EUROPE: Commission announces additional funding to boost preparedness for health threats.

The European Commission and the European Investment Bank announced on Wednesday (12 July) the creation of the HERA Invest initiative, offering €100 million for innovative solutions to future health threats. HERA Invest, a flagship initiative of the European Health Emergency Preparedness and Response Authority (HERA), will provide an additional €100 million to the InvestEU programme to support research and development (R&D) related to the top priority health threats, financed through the EU4Health programme.

According to the Commission, HERA Invest will promote R&D in Europe to strengthen strategic autonomy, reduce market failures where financial resources do not cover the financing needs, leverage public funding to incentivise private investment, and create new medical countermeasures to protect against health threats. "With HERA Invest, we are investing €100 million in advancing research and development to design new innovative medical countermeasures to step up our preparedness for future health threats," Health Commissioner Stella Kyriakides said in a press release following the announcement.

"HERA Invest will attract additional private and public investment and provide European companies with the certainty needed to invest in ground-breaking innovation to address priority health threats," the EU health chief added.

The HERA Invest funding instrument is targeting small and mid-sized companies (SMEs) in clinical trials that develop medical countermeasures (MCMs), which diagnose, prevent, protect from or treat conditions during a public health emergency. MCMs must be addressing the top health threats which HERA and the member states identify on an annual basis. In July 2022, three specific high-impact health threats were identified: pathogens with high pandemic potential, chemical, biological, radiological and nuclear (CBRN) threats, and antimicrobial resistance (AMR).

Under HERA Invest, the EIB will provide venture loans covering a maximum of 50% of total project costs. Companies must have already raised equity from professional investors, have a sustainable business model and business plan, and have solid corporate governance in place. The EIB will typically invest between €15 and 30 million per project. The EIB is to assess whether an operation is eligible based on defined criteria and the project's commercial and scientific viability. "This support is crucial to keep Europe at the forefront of innovation, and it might well save millions of lives around the planet when a new health emergency hits," EIB Vice-President Thomas Östros said.

The announcement came ahead of a vote on Wednesday (12 July) in the European Parliament plenary on the report, entitled 'COVID-19 pandemic: lessons learned and recommendations for the future'. This is the final COVI subcommittee report on the lessons learned through the pandemic, which calls for a look at what is ahead, by carrying out anticipative research on potential current and future threats, such as chemical, biological, radiological and nuclear risks.

The report underlines the need to improve resilience in times of health crises at both national and European levels by creating incentives to invest and develop production lines in the EU for medicines, vaccines and other medical equipment. HERA, established in September 2021, is a key actor in strengthening Europe's ability to prevent, detect, and rapidly respond to cross-border health emergencies. It is also a key pillar of the European Health Union, which the European Commission first put forward in November 2020, in response to the COVID-19 pandemic and as a means to prepare for future public health emergencies. The establishment of HERA Invest is one of HERA's five flagship initiatives, as outlined in its Work Plan 2023, and it addresses market challenges and failures and boosts the EU's open strategic autonomy.

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12 JULY 2023 – EUROPE: EU Parliament adopts report on lessons to be learned from COVID-19.

EU lawmakers approved a report on lessons to take from COVID-19 on Wednesday (12 July). The text analysed the impact of the pandemic, evaluated EU and national health systems' responses and set a roadmap for future health emergencies. The European Parliament adopted the report "COVID-19 pandemic: Lessons learned and recommendations for the future" by 385 votes in favour, 193 against and 63 abstentions.

While the final report of the COVI special committee carries no legislative weight, it looks to draw lessons from the pandemic and establish a series of recommendations to the member states and the European Commission in order to strengthen European response to health threats.The report recognises that the EU, as well as the rest of the world, was not prepared when the pandemic hit in 2020 and sets as its main objective to establish a strategy for the future.

For that, the text stresses that a high level of human health protection must be ensured in the design, definition and implementation of all EU policies, legislation, funding and activities. It also states that future public health threats will mostly be transnational by nature and stresses the role of unity, shared responsibility and the use of available single-market instruments to better coordinate both pandemic preparedness and management. The text was debated in the plenary on Tuesday, where Commissioner Margaritis Schinas told EU lawmakers that "the clearest lesson from the pandemic is also the simplest, we Europeans are more effective when we act together".

He added that the COVID-19 pandemic demonstrated that the EU institutions have institutional maturity and created a remarkable example during an unprecedented crisis. Ahead of the vote, Christian democrat Spanish MEP Dolors Montserrat, the rapporteur of the file told EURACTIV in an interview that the backing of the Parliament on this report would demonstrate a broad understanding of the need for innovation, better access to medicines and addressing shortages.

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12 JULY 2023 – EUROPE: MEPs give green light to EU Medicines Agency's new fee syste.

European parliamentarians adopted with a large majority a report aiming to simplify the fee structure of the European Medicines Agency (EMA) during a plenary session on Wednesday (12 July). With 595 votes for, 25 against and 25 abstentions the European Parliament gave the green light to the report. "This will modernise a lot the structure of the fees paid to the European Medicines Agency," the rapporteur of the text, Romanian MEP Cristian Silviu Buşoi from Christian Democrats, said right after the vote.

The current fee system, in place since 1995, regulates EMA fees charged to marketing authorisation holders and applicants for obtaining and maintaining EU-wide marketing authorisations for medicinal products for human and veterinary use. When companies make a request related to a marketing authorisation for medicine, they have to pay a fee to EMA for the agency's assessment. This fee also includes the remuneration paid by EMA to national authorities involved in the assessment.

The Commission proposed the update in 2022, following an evaluation of the fee system in 2019, which indicated the need for more flexibility for adopting future developments and more sustainability in the long term. The COVID pandemic has granted new missions to the EMA, and so will the European health dataspace and the new pharmaceutical legislation in the coming months, making the current funding structure no longer efficient. This is something that Buşoi wanted to address: "I wanted to make sure that the EMA will have the necessary funds in order to fulfil its new tasks", he told EURACTIV on Monday (10 July), before the voting session.

The main amendments from the Parliament concern the independence of the agency to ensure public trust in the legislative and regulatory framework for pharmaceuticals in the Union. "Therefore, sufficient funding should be allocated to the Agency so that it can carry out its obligations and transparency commitments", the amendment says. Buşoi told EURACTIV that "most of the budget is coming from private sources, we need to make sure that EMA will remain independent and impartial. That's why there is a need to have a good structure of fees in order to work properly".

The MEPs want transparency not only concerning the fees but also the EMA's work and its decision-making process on funding. For that, another amendment says, Parliament wants "information on the decisions for further fee reductions publicly available on its [EMA's] website, including on the recipients and the reasons for the decision for further fee reductions". The Parliament's proposal also included NGOs and academia as the sectors which could benefit from fee reduction, while the Commission's proposal only mentioned small- and medium-sized enterprises (SMEs). Buşoi hopes the new regulation will be set up by December 2023.

The pharma industry also welcomed the adoption of the report. "The revision of the EMA fees regulation offers an opportunity to make Europe's regulatory network more globally competitive by ensuring that sufficient financial resources go to the European Medicines regulatory network", Nathalie Moll, director general of The European Federation of Pharmaceutical Industries and Association (EFPIA), said in a press release.

The proposal to revise the EMA fee structure was originally published by the Commission on 13 December 2022. The European Council agreed on a more modern and simplified fee structure on 13 June, under the Swedish presidency, before Spain took over on 1 July.

The Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) voted on the file on 27 June. ENVI MEPs agreed with the Council's position on the need for the fees paid to the agency to be proportionate to its work. For that, they also voted for a transparent evaluation of the agency's estimations for workload and costs.

The fee revision follows the extension of the agency's mandate. It was extended in March 2022, but already six months in, EMA's Executive Director Emer Coke warned that "we need more resources to deal with the increase in workload" at an ENVI hearing in Parliament on 25 October 2022. Under the extended mandate, the EMA monitors how public health emergencies affect the supply of critical medicines. It also has to formally coordinate actions at the EU level to guarantee supply.

The EMA's Emergency Task Force (COVID-ETF) got a reinforced role in developing new medicines by supporting their authorisation and conducting safety monitoring, both during the current crisis and in preparation for future ones. The EMA also announced in February the establishment of the Coordination Centre for Data Analysis and Real-World Interrogation Network (DARWIN). Its role is to develop and manage a network of real-world healthcare data sources across the EU and conduct scientific studies requested by medicines regulators and other stakeholders. Additionally, since 1 March, the EMA has been responsible for coordinating EU expert panels that support and advise on the scientific assessment of specific medical devices and in-vitro diagnostics.

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12 JULY 2023 – EUROPE: Stakeholders hungry for increased stake in EU's new health technology assessment.

BRUSSELS, 12 July (APM) - The appetite for involvement in the HTA rules remains unassuaged among patient and payer organisations, health professionals and health technology developers after the first meeting of the stakeholder network created by the European Commission as part of its upcoming system for health technology assessment. The official account just published of the meeting - which took place in June - records numerous demands from stakeholders for more information, more engagement and more scope for input into the creation and operation of the future procedures.

But despite its emollient tone, the official report suggests that many of the ambitions are likely to be disappointed. "Comments and suggestions were noted" and "would be reflected upon" and "specific areas for collaboration will be discussed with the Coordination Group" - the body of national authorities that will run the system, says the report. The stakeholder network is not chaired by a stakeholder but by the European Commission, in the person of Maya Matthews, acting director of one of the new directorates in DG SANTE, 'Digital, EU4Health and Health Systems Modernisation, State of Health, European Semester, Health Technology Assessment'.

Among the points highlighted by the 59 representatives from the 43 stakeholder member organisations that were present was the need for making best use of its expertise - initially on the specificities of the products that will come first in scope under the HTA regulation, oncology and advanced therapies. The network could be a source for the recruitment and selection of external experts for joint clinical assessments, it was suggested, and Learning from current experiences of stakeholders' interaction with the European Medicines Agency should also be incorporated, in view of "the need to understand the alignment between HTA and the regulatory process".

Stakeholders underlined that patients and clinical experts can have an important role in the joint work and the stakeholder network can help in recommending experts and maximising their involvement. They called for further information on the process and timing of interactions they would have on the annual work programme and annual report of the coordination group, as well as on draft procedural and methodological guidance documents.

The importance of real-world data and the need for synergies with other EU frameworks, such as the ongoing pharmaceutical review, the European Health Data Space and medical device rules, was also high on stakeholders' list of concerns. Stakeholders also asked for a specific roadmap for the next steps linking the work of the network to the work of the Coordination Group and its subgroups, and emphasised the questions over readiness for implementation of the regulation in the member states and capacity among HTA agencies, patients and health professionals.

The responses from the Commission suggested a reserved approach to the stakeholder suggestions. Stakeholders are not to be given any special access to discussions of the upcoming implementing acts, and will merely be able to comment on the drafts the Commission will publish for public consultation. The idea of stakeholders as observers to the Coordination Group meetings was met with a reminder that "Article 29 of the regulation defines the role of the stakeholder network to 'support the work of the Coordination Group and its subgroups upon request.'"

Participants called for the continuous sharing of information about upcoming activities, but the Commission mentioned only that "a series of regional information events will be organised during 2023-2024 to raise awareness about HTA among local stakeholder communities and invited members of the Stakeholder Network to promote these events to local constituencies". It also pointed to its regular updates of its - skeletal - implementation rolling plan published on the Europa website.

Another of the points of contention raised at the meeting was the composition of the stakeholder group - selected by the Commission and described as "a rich blend". The low number of payer organisations as members was one of the comments made. The Commission's explanation was to outline the open call process and subsequent application of its selection criteria, and to acknowledge that it did not conduct an additional targeted call "on this occasion". The Commission would "take the suggestions into account as appropriate" when finalising the network's terms of reference, it concluded.

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11 JULY 2023 – EUROPE: EU extends Ozempic review to include more weight-loss, diabetes medicines.

July 11 (Reuters) - The European Medicines Agency (EMA) said on Tuesday it has extended its probe into Novo Nordisk's (NOVOb.CO) diabetes medicines Ozempic and weight-loss treatment Saxenda, following two reports of suicidal thoughts, to include other medicines in the same class. The agency began its review on July 3 after Iceland's health regulator flagged the reports of patients thinking about suicide and one case of thoughts of self harm after use of Novo's medicines.

There have been issues of suicidal thoughts linked to another class of weight-loss medicines, which have hobbled previous attempts by the medicine industry to develop lucrative weight-loss medicines. Sanofi's weight-loss medicine Acomplia, which never won U.S. approval, was withdrawn in Europe in 2008 after being linked to suicidal thoughts. The EMA said on Tuesday it will now investigate the class of medicines known as GLP-1 receptor agonists, which trigger a feeling of fullness after eating. The review is expected to complete in November, according to the agency.

Medicinemaker Eli Lilly's (LLY.N) shares closed down 3.1%. Its diabetes medicine Trulicity also belongs to the same class. Novo's weight-loss medicine Wegovy, which contains active ingredient semaglutide, is also part of the review. Other GLP-1 medicines include Sanofi's (SASY.PA) Suliqua and AstraZeneca's (AZN.L) Bydureon. Both are approved in Europe for treatment of type 2 diabetes. Sanofi said it has not identified any safety concerns related to "suicidal ideation" from use of its GLP-1 receptor agonist. However, the company has started an investigation and will share all relevant information with the European health regulator. Lilly and AstraZeneca did not immediately respond to Reuters' requests for comment. The European health regulator is also investigating GLP-1 medicines for possible risk of thyroid cancer.

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12 JULY 2023 – FRANCE: France picks Germany's Boehringer Ingelheim for bird flu vaccines.

PARIS, July 12 (Reuters) - France has chosen German company Boehringer Ingelheim to supply the 80 million doses of bird flu vaccines needed for its vaccination campaign to start in October, an agriculture ministry spokesperson told Reuters on Wednesday.

The government launched a tender in April to vaccinate ducks against avian influenza, commonly called bird flu, that has ravaged flocks around the world and led to the culling of hundreds of millions of birds. The campaign would make France the first country in the European Union to vaccinate poultry against the deadly virus. Agriculture ministry officials said last month that tests carried out in France on vaccines from French firm Ceva Animal Health and Boehringer Ingelheim showed favourable results.

The ministry did not quantify the value of the order, but said Boehringer's offer was considered better than Ceva's due to the financial criteria, its capacity to supply the doses and storage conditions. Boehringer Ingelheim and Ceva declined to comment. The French poultry industry had asked to have two different vaccines to avoid supply hiccups. They also preferred a vaccine with one of the two doses injected in hatcheries, like Ceva's vaccine, making it easier for farmers, according to a letter from several industry groups to the agriculture ministry, seen by Reuters.

U.S. company Zoetis (ZTS.N) had also applied in the tender but its vaccine did not cover the species of ducks that France wanted to vaccinate initially, the ministry said. "If the decision to vaccinate all year round is taken, a new call for tenders should be launched for an additional order of vaccines with a new call for tender," the spokesperson said in a written answer.

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10 JULY 2023 – FRANCE: French Senate finds quality of medicine shortage management plans 'worrying'.

PARIS, 10 July (APM) - France's Senate has said it has analysed "in detail" the medicine shortage management plans (PGP) submitted by pharma companies to the authorities and found their quality "worrying". Representatives from the Senate's inquiry commission into medicine shortages presented the 36 recommendations from its report to the press last week.

A 2021 decree stated that pharma companies had to submit PGP to France's medicine regulator ANSM on an annual basis for medicines with major therapeutic interest (MITM). The Senate's commission checked the PGP for four active ingredients including on the list of essential medicines published mid-June by the health ministry: an antibiotic, an epilepsy medicine and two corticosteroids for systemic use. This represented 23 presentations (including the brand name medicines).

The commission said in its report it had seen "the best to the worst" with "very variable" information and "a lot" of "insufficient quality" PGP which "must be completely immediately as they cover medicines recently, and sometimes still, out of stock". "The PGP for [Sanofi/Lundbeck's] Sabril [vigabatrin], a vital epilepsy medicine often experiencing shortages, includes no analysis on the risks of stockout," the commission noted. Sanofi has been managing negative press - mainly on Twitter - on Sabril shortages since the beginning of May.

Without giving other names, the report noted PGP "not always entirely written in French", patient impact evaluations which differ between presentations and pharma companies, a "very unequal" manufacturing risk evaluation with only one pharma "analysing in detail the fragilities of the production chain". The commission also noted the number of brand name medicine active ingredient manufacturers affected by the PGP was "two maximum" (except for a generic produced by three different pharma companies), that therapeutic alternatives

were "sometimes listed in precise detail, sometimes in very general terms" and that "monitoring methods for the change in demand [were] rarely presented".

"The same vagueness often applied to the presentation of management measures to be used if there is the risk of stockouts. The same applies for communication campaigns to implement in the case of shortages," it added. Without mentioning the names of the medicines concerned, the report noted that for only one of the four medicines analysed, stockouts, according to the pharma company, developed because of different difficulties: two packaging issues, a production delay and manufacturing delay due to an active ingredient supply problem. For the three others, there was only one issue: "an increase in global demand and finding it difficult to restart factories after the pandemic".

The commission said after carrying out its analysis, it is "urgent to increase ANSM's document checks and thus give it more human and material resources". "Regular" checks must take place on medicines found to be "essential" by the government and if companies have not fulfilled their obligations, fines must be "really dissuasive". The commission also found ANSM's sanctioning powers "are significantly under used". ANSM handed out "only eight fines between 2108 to 2022 for a total of €922,000" and "none was given for violating obligations to daw up a PGP or drawing up safety stocks" until June when EG Labo (Stada group) was fined for not meeting its obligations to draw up safety stocks of amoxicillin. The report was also very critical of the authorities and said there was no one in charge of France's medicine policy.

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12 JULY 2023 – ITALY: Italy responds positively to call for medicine spending reforms ahead of new round of pharma talks.

ROME, 12 July (APM) - The Italian government has responded positively to a call from pharma for reform of medicine spending rules as it prepares for a new round of talks with industry representatives. The annual meeting of the pharma association Farmindustria last week confirmed the good relations between the industry and government with four minister attending (APMHE 819709). It was made clear that Italy will continue to oppose a proposal to reform EU's pharma legislation unless changes are agreed.

Marcello Cattani, president of the organisation, welcomed the support in Europe. But he also hammered home the message that Italy's medicine reimbursement rules need to be overhauled. He warned that the attractiveness of Italy for foreign pharma investment is being put at serious risk because of 'unsustainable' levels of payback to cover perennial overspending of one of the reimbursement budgets. In a system introduced more than 10 years ago, any annual deficit in the 'direct' reimbursement budget, which is used to pay for hospital medicines, has to be half covered by pharma companies in proportion to their sales. The regions are responsible for covering the other half. The pharma payback is paid to the regions where the overspending occurred which means that they can balance their reimbursement budgets.

Cattani noted Italian pharma produced €49 billion of medicines in 2022, with more than 90% of that accounted for by sales to export markets. And yet companies will have to pay €1.5 billion in 2023 to cover overspending of the hospital medicines budget last year. The figure is expected to rise to €1.8 billion in 2024, which is around 15% of the sales of the companies who have to pay it. Cattani wondered how other industries would react if they were faced with similar financial costs imposed by the government. He said: "Now is the time to act fast to be competitive as a country. We deserve a country that changes the rules and does it quickly while respecting the roles and interests of citizens."

The industry is especially concerned by the amount of payback because the other reimbursement budget, for medicines distributed through the pharmacy network, has annual surpluses. The problem is that resources cannot be transferred from one spending channel to another. This may be one of the changes which will be considered by the government.

The use of special funding for added-value medicines was also addressed. Only products recognised as fully innovative are paid for with these resources. Medicines recognised as 'conditionally innovative' are not, but still have to be made immediately available by regional health systems.

Cattani called for the rules to be changed so that potentially innovative therapies can also be paid for through special funding. It was pointed out that there is a surplus in the budget for innovative products, so changing the rules would make for more effective use of resources. The government has indicated that it will consider this change as a way to improve access. Regions would be encouraged to make potential innovative therapies immediately available if they did not have to be paid for through ordinary budgets.

The Farmindustria chief made clear that industry does not want to see expansion of 'equivalence' criteria which would allow for cheaper alternatives, judged to be bio-equivalent or biosimilar, to be used to substitute originator products. He described as 'unacceptable' that these are used in Italy's Law 648 early access scheme. "We need a value-based assessment which takes into account all the avoided costs and the missed social and welfare benefits. Otherwise we will not be able to move forward."

The good relations with the government stem from a meeting at the end of March, organised to discuss aspects of medicines and medical devices research, production and distribution. MSD's CEO in Italy, Nicoletta Luppi, credited the talks with helping her company to decide to invest in a €200 million oncology R&D programme in Italy. It was revealed during the Farmindustria conference that the next meeting has been convened for 20 July when it is likely that new medicine spending rules will be discussed. Health minister Orazio Schillaci reiterated the intention to change the system when he spoke at the Farmindustria meeting. He identified the approach to innovative medicines as one of issues to be dealt with at the upcoming meeting.

Schillaci noted Cattani's comments on the medicines spending deficits, underlining that it is an issue that needs addressing quickly, but also one that requires careful consideration. He pointed to collaboration with industry as an essential part of the process.

The health minister also highlighted reform of AIFA as a key part of the strategy. He cited demographic issues and advances in pharma technology as two issues that should be addressed to keep the system sustainable. "We need to change the rules," he told the meeting. The minister repeated his hope that the reorganisation of AIFA can be completed by the end of the summer or shortly afterwards. He said the reform will result in a more modern agency allowing for new technology and medicines to be available to patients regardless of where they live or how much they earn.

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11 JULY 2023 – UNITED KINGDOM: Government and NHS must work with pharmacy sector to improve shared patient records.

NHS England and the government should work with integrated care systems (ICSs) and the pharmacy sector to improve the quality of shared patient records across the healthcare sector, according to MPs. In a report on digital transformation in the NHS, published on 30 June 2023, the House of Commons Health and Social Care Committee said it backed the Hewitt review of ICSs, which was published in April 2023 and called for the Department of Health and Social Care, NHS England and ICSs to work together to develop a standards framework to be adopted by all ICSs.

In its recommendation, the committee said "this should improve interoperability and data sharing within and between systems". "This should include working closely with sectors that could feed into shared records in the future, including pharmacy, mental health and community health, to ensure that what is put in place meets their needs." The committee's report highlighted the variation in progress towards digital transformation in the NHS, citing evidence from NHS Digital to the inquiry, which it said "told us that some areas of the NHS have been quicker to digitise than others". "They described primary care, where almost all providers have electronic

patient records, as a 'flagship', while highlighting that only 77% of acute hospitals have the same system," it added.

Evidence given to the inquiry from multiple pharmacy chain Boots also highlighted the patchy progress made on shared care records. The report said: "Boots, the pharmacy, told us that wider progress towards implementing interoperable shared care records that cover interactions with the health service across an ICS has been "slow", and that there is underlying "significant variation in data governance and technical system solutions which will slow future progress."

In 2015, then health secretary Jeremy Hunt outlined a timetable — initially set out in the 2014 NHS England 'Five Year Forward View' — which envisaged fully digitised, shared health and care records by 2020. The "paperless by 2020" target was revised in 2016, when a government-commissioned review found that it was unrealistic and recommended 2023 instead. Subsequently, the 'NHS Long Term Plan', published in 2019, said that all providers would be expected to advance to a core level of digitisation, including electronic health records, by 2024.

Commenting on the select committee's report, Daniel Ah-Thion, IT policy manager at Community Pharmacy England, said: "The report correctly emphasises the need to establish records frameworks that eliminate the significant disparities among records systems in terms of technology, training, access and governance models. "We strongly advocate for the implementation of NHS IT records standards that harmonise the underlying standards of the shared care record and other systems. Additionally, we propose the creation of NHS records integration application programming interfaces, enabling clinical IT system suppliers to seamlessly integrate with these records and introduce solutions that reduce the workload of pharmacy teams when it comes to accessing or modifying records as part of an expanded system."

Author: Liz Perkins.

11 JULY 2023 – UNITED KINGDOM: High Court dismisses generic manufacturers' bid to be included in NHS price negotiations

The High Court has dismissed a judicial review brought by the British Generic Manufacturers Association (BGMA) against a government decision to exclude it from being fully involved in negotiations over a new tax scheme for branded medicines sold to the NHS. The UK government and the Association of the British Pharmaceutical Industry (ABPI) are expected to start renegotiating the voluntary pricing and access scheme (VPAS) later in 2023.

Under current VPAS rules, which end on 31 December 2023, manufacturers of branded medicines are required to pay the government 26.5% of their net income from sales of branded medicines to the NHS. In April 2023, the BGMA sought judicial review after requesting full participation in talks on a new deal because of the implications for the producers of branded generics and biosimilars — which make up almost half the medicines in the VPAS — but having instead been offered 'observer status'. A High Court ruling published on 10 July 2023 showed that the BGMA had argued that the ABPI "does not and cannot properly represent the interests of the BGMA members in negotiations with the Secretary of State because its central and predominant role is to promote the interests of in-patent manufacturers to the inevitable detriment of generic manufacturers".

However, the judge in the case ruled that the government's decision to negotiate solely with the ABPI was reasonable and the call for judicial review was dismissed. Mark Samuels, chief executive of the BGMA, said the judgment was "extremely disappointing". "Branded generics and biosimilar represent nearly half the medicines covered in the current VPAS scheme," he said. "These are medicines which, by their nature, already face competition. This reduces their cost to the NHS by typically up to 80% compared to the originator price. This competitive model has been very successful and provides the UK with the lowest cost medicines in Europe." Samuels added it was "not sustainable" for manufacturers to have to pay a further spiralling VPAS rebate on their revenues.

The VPAS levy has quadrupled since 2019, when the clawback on profits for branded medicines was just 9.6%. "Over the past ten years, VPAS has created a system which has treated on- and off-patent medicines in the same way, despite their supply being driven by different business models, cost pressures and market dynamics," added Samuels.

"The implications of a continuing high VPAS rate are significant in terms of cost to the NHS and availability of medicines. We urge the government to take these factors into consideration when setting the rate for 2024 and beyond." Richard Torbett, chief executive of the ABPI, said: "For over 60 years the ABPI has acted as the representative industry body for negotiations on the voluntary scheme for branded medicines — a responsibility we take extremely seriously and one which has been reaffirmed by today's judgment. "While we were disappointed that the BGMA decided to take this action, we recognise their decision was driven by the extreme challenge placed on all parts of the industry from the surge in the branded medicine payment rates.

"The solution to these problems must be a completely new and sustainable approach to medicines provision in the UK, which rapidly brings industry revenue payments in line with comparator countries to unlock investment and growth." A spokesperson for the Department for Health and Social Care said: "We welcome the [High] Court's decision. Our priority in negotiations remains to agree a mutually beneficial new voluntary scheme that supports better patient outcomes, a strong UK life sciences industry, and the sustainability of NHS spend on branded medicines."

Author: Emma Wilkinson.

11 JULY 2023 – UNITED KINGDOM: Regulator approves first RSV vaccine for older adults.

The UK medicines regulator has approved the first ever respiratory syncytial virus (RSV) vaccine for older adults. Arexvy (GSK) has been authorised by the Medicines and Healthcare products Regulatory Agency for the prevention of lower respiratory tract disease caused by RSV in adults aged over 60 years. The authorisation has been granted less than one month after the Joint Committee on Vaccination and Immunisation (JCVI) recommended a routine RSV vaccination programme for babies and adults aged over 75 years in England.

On 22 June 2023, the JCVI said in a statement that there were currently three RSV vaccines in development for older adults — including Arexvy — that are expected to be licensed in 2023 or 2024. The committee proposed the roll out of a one-off vaccination campaign, initially covering several older age groups before moving to routine vaccination for people reaching the age of 75 years. It said it had no preference for the vaccine used.

However, the committee added that the delivery and and implementation of the vaccination will be determined through further consultation between NHS England, the Department of Health and Social Care, public health officials and the devolved administrations. At the time, Sir Andrew Pollard, chair of the JCVI, said it had recognised there was a "significant burden" of RSV illness in the UK population, which has a considerable impact on the NHS during winter. Data suggest that RSV causes around 175,000 GP visits, 14,000 hospitalisations and 8,000 deaths each year in adults aged 60 years and over in the UK.

The MHRA approval was based on data from the international phase III AReSVi-006 trial of 25,000 participants published in the New England Journal of Medicine in February 2023. The authors reported vaccine efficacy of 94.1% against severe RSV-related lower respiratory tract disease, as assessed on clinical signs or by the investigator, and 71.7% against RSV-related acute respiratory infection. The results also suggested effective results regardless of RSV subtype or the presence of underlying conditions. The UK government has yet to formally respond to the JCVI recommendation, but Alastair Buxton, director of NHS services at Community Pharmacy England, commented: "If there is a programme commissioned, community pharmacies would be well positioned to provide it to eligible patients."

Author: Emma Wilkinson.

11 JULY 2023 – INTERNATIONAL: Novo Nordisk says Wegovy launch in Germany won't hit U.S. supplies.

LONDON, July 11 (Reuters) - Novo Nordisk (NOVOb.CO) will launch its weight-loss medicine Wegovy in Germany this month with the injection pen used in Norway and Denmark, instead of the one deployed in the United States to avoid hitting supplies there, the company told Reuters. Wegovy is a weekly self-injection that leads to an average weight loss of 15%, alongside diet and exercise changes. Novo launched the medicine in the U.S. in June 2021, but quickly ran into production problems. It has also been overwhelmed by demand, forcing it in May to restrict the volume of starter doses it provides in the United States to safeguard supplies for existing patients.

Even so, Novo plans to start selling Wegovy in Germany later this month, its third European market after Denmark and Norway. Its use will likely be limited, though, because a decades-old German law bans public insurance schemes from paying for weight-loss medicines. The company is using the so-called FlexTouch device in Germany so as not to affect U.S. supplies, a spokesperson said. The device contains four doses per pen, instead of the one dose in the U.S. pen. Filling of the two different types of syringes is done separately.

The spokesperson declined to give details on production of the pens. The company uses the disposable FlexTouch for other medicines including insulin and Saxenda, its earlier and less effective weight-loss medicine. UBS analyst Michael Leuchten said Novo was able to launch Wegovy in Germany even though demand is still outstripping supplies for two reasons: take-up will be low and, with the different pen, any new demand will not eat into supply for the U.S. market.

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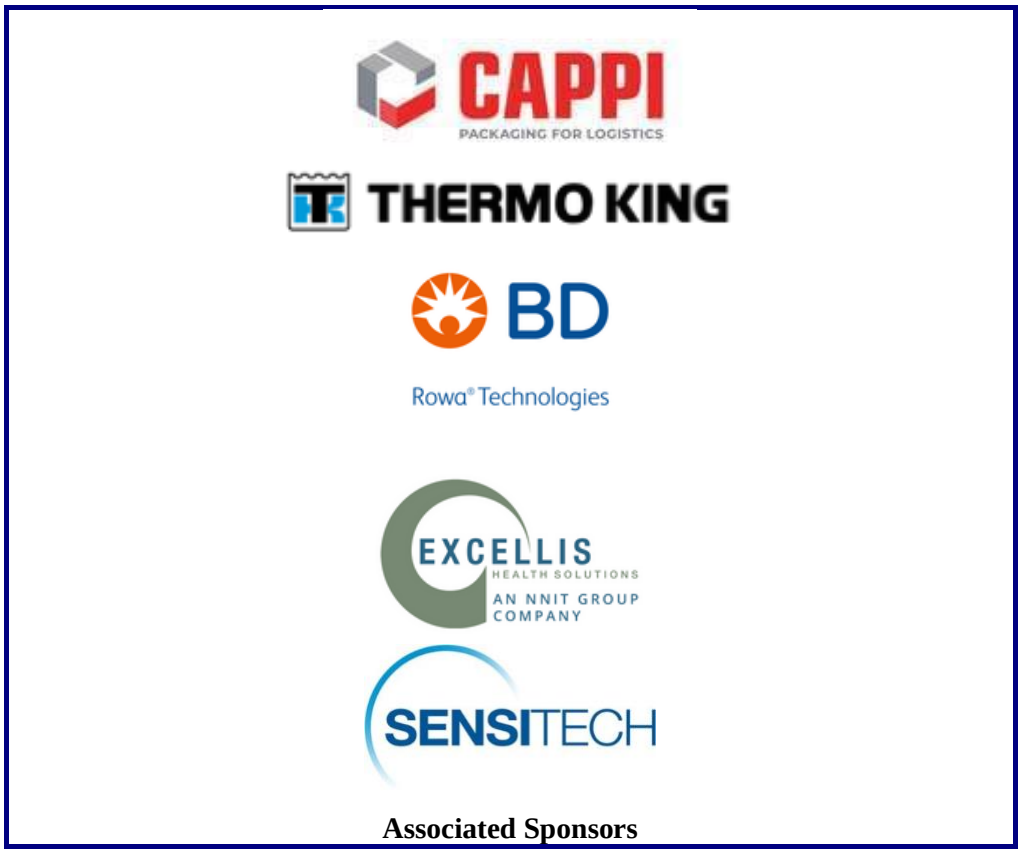

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