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25 March 2024 – EUROPE: Sandoz CEO calls for Europe-wide action to ensure access to antibiotics (Source: APM Health Europe)....2

25 March 2024 – EUROPE: Medicine developers find more fault with EU health technology assessment plans (Source: APM Health Europe)....3

22 March 2024 – BULGARIA: Celebrating 5 years since the entry into force of EU Falsified Medicines Directive (Source: BATEL)....4

22 March 2024 – BULGARIA: Vending machines to 'stand in' for small town Bulgarian pharmacies (Source: EURACTIV)....5

18 March 2024 – FINLAND: Heikki Koski Appointed as CEO of Medaffcon Oy (Source: Tamro) 6

28 March 2024 – GERMANY: German statutory payers call on MPs to stop price confidentiality (Source: APM Health Europe)....6

27 March 2024 – GERMANY: Confidential reimbursement prices burden pharmaceutical wholesalers, PHAGRO demands compensation for additional costs (Source: PHAGRO) 7

27 March 2024 – ITALY: Italy has good medicine access, not delayed by AIFA's consultation with experts (Source: APM Health Europe) 8

26 March 2024 - PORTUGAL: Full-service healthcare distribution: a new specialty (Source Groquifar)....9

28 March 2024 – SPAIN: Spain considering differentiated prices for generics (Source: APM Health Europe)....9

27 March 2024 – SWEDEN: Strong growth for Sweden's pharmaceutical exports (Source: European Pharmaceutical Review (Source: European Pharmaceutical Review) 9

25 March 2024 – SWITZERLAND: Healthcare Information Solutions (HCI) unveils new brand image (Source: Galencia)....10

26 March 2024 – JAPAN: Two global firsts among medicine approvals in Japan (Source: APM Health Europe)....11

26 March 2024 – UNITED STATES: Amazon rolls out same-day prescription delivery with help from AI (Source: Forbes)....12

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- **Ms Rebecca Guntern**, President Europe, Sandoz, Vice-President, Medicines for Europe
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25 March 2024 – EUROPE: Sandoz CEO calls for Europe-wide action to ensure access to antibiotics (Source: APM Health Europe)

KUNDL, AUSTRIA, 25 Mar (APM) - Sandoz is "playing [its] part" in responding to the growing need for antibiotics by investing in production, but more co-ordinated action is needed on a European level to safeguard access to these essential medicines, its chief executive has said. Richard Saynor spoke about the need for more co-ordinated action on prices, taxes and regulation late last week at the opening of a new penicillin production unit in Kundl, Austria. He said the new unit will boost production in "the major and last vertically integrated penicillin production facility outside Asia and the only one in Europe". The plant oversees the entire production processes, including for presentations of amoxicillin and amoxicillin+clavulanic acid, which have experienced significant supply shortages over for the past few years.

"Our investment… can only secure, supply and deliver affordable medicines to patients around the world if they meet a more flexible market framework… [allowing] manufacturers to flexibly adjust prices," Saynor said, referring to increased production costs such as energy and aluminium. "What is also clear is that ensuring [a] reliable supply of essential medicines is a collaborative effort involving many stockholders, including governments, policymakers and health insurance industries," he added.

'CHEAPER THAN A PACK OF M&M'S'
"Essential medicines are not commodities that you can make and sell at rock bottom prices," Saynor said, adding that he is frustrated to see antibiotics sold "cheaper than a pack of M&M's" in certain countries. In France, Sandoz's highest dose of amoxicillin (1 g) has a public, tax-inclusive price of €2.18 for six tablets, up almost 10% since October 2023. Meanwhile, head of Sandoz Austria, Peter Stenico, said on Thursday that the industry "require[s] an economic framework that makes the business viable over the long term" and for that "it needs a European approach in setting the right framework setting fair market conditions", referencing inflation-linked prices.

Saynor, however, recognised that price is "only part of the equation". He called for more progress in public support for industry investments, consideration of production location and environmental impact in calls for

tender and digitalising medicine information notices, which would make it easier to redirect medicine stocks from one country to another in Europe. "There is not one single solution, we have to work across the board," he added.
He pointed out that generics represent about 80% of medicines used in Europe, but only 20% of spending. "The focus frequently is on trying to get from 20% to 19%" of the medicine spend, via price cuts. But "that's not how we're going to get savings", he continued, adding that "the savings are in the 80%" of spending on innovative medicines.

CO-ORDINATION AND SOLIDARITY MISSING
When asked about the lack of co-ordinated European policy on health sovereignty, Saynor said during Covid "the biggest challenge" for Sandoz was not getting the medicines out of India, "but getting medicines across Europe". "It was barriers between different countries across Europe blocking borders to make sure local patients were protected at the expense of other European [patients]," he said. Saynor wants discussions with the European authorities and national governments to make these medicines affordable and available in a sustainable way. To achieve this, "we need to have a predictable level of return over a longer period of time to make those investments, either higher prices or tax benefits in terms of local economies or investment or access to lower priced energy", he said.

There "is not one solution" in Europe he added, given the different healthcare systems in place, "but there has to be an open recognition that this is a European problem and we need to work together to find a solution". Sandoz has 12 plants in Europe, with over 90% of its medicines "filled and finished" in Europe, according to data the company provided last week. Meanwhile, 31% of its medicines sold in France come from a French subcontractor.
The group has invested €200 million in its Austria site since 2021 and plans to invest €500 million in a biosimilar production site in Slovenia, expected in 2026 and in new development centres in Germany and Slovenia.

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25 March 2024 – EUROPE: Medicine developers find more fault with EU health technology assessment plans (Source: APM Health Europe)

BRUSSELS, 25 March (APM) - Another building block was put in place on Monday for the EU's emerging system for joint clinical assessment of medicines - and immediately ran into opposition from a group representing advance medicine developers. The EU Health Technology Assessment Coordination Group (HTACG) published its 'Methodological Guideline for Quantitative Evidence Synthesis: Direct and Indirect Comparisons', describing the most commonly used methods for direct and indirect treatment comparisons, including their strengths and weaknesses.

'DISCOURAGING'
The document's objective is to assist experts assessing medicines, but the Alliance for Regenerative Medicine (ARM) greeted the document as "discouraging news for rare disease patients and the advanced therapy medicinal products sector". ARM says HTACG's insistence on randomised controlled trials "even in cases where RCTs are not feasible" is a failure to comply with the legislation's call for HTA bodies to adopt fit-for-purpose methodologies. The Alliance accuses HTACG of taking insufficient account of earlier representations made by patient groups and academic centres in when EUnetHTA21 issued an earlier version in 2022, displaying an unhelpfully limited approach. The new document continues to maintain that single-arm or non-randomised evidence may be insufficient for estimation of the relative treatment effectiveness in the context of JCA - in contradiction to the legislation.

That judgment should belong to member states, since the legislation limits the JCA to a description - and not an evaluation - of the degree of certainty of the relative effects, says ARM. "Single-arm trials to evaluate rare disease treatments are sometimes necessary for ethical, scientific, and practical reasons," argues the Alliance, adding that they can appropriately demonstrate clinical benefit when informed by real-world data, such as from disease registries. The HTACG approach "will likely result in inconclusive JCA reports for many ATMPs, significantly delaying patient access and jeopardising the implementation of the EU HTA Regulation at the EU

and national levels", concludes a statement from ARM. "The JCA project is at real risk of becoming a failure," ARM warns.

THE GUIDELINE

This HTACG guideline says it presents methods that are used to combine evidence to determine the relative clinical effectiveness of treatments, and "directs assessors towards the pathway that will ideally provide the best estimate of relative effectiveness with the least uncertainty".

When direct evidence from RCTs is not available or indirect treatment comparisons are needed on more than two treatments, "uncertainty for the treatment-effect estimate increases", says the HTACG text.

It is "possible" to provide summaries of evidence syntheses generated in this way, the text acknowledges, but goes on to warn that the certainty of the results provided "remains controversial".

These results are "more likely to suffer from bias and to underestimate the true uncertainty and to depend on untested assumptions".

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22 March 2024 – BULGARIA: Celebrating 5 years since the entry into force of EU Falsified Medicines Directive (Source: BATEL)

The medicine verification system is the first electronic system that unites interested parties in the medicine supply in Bulgaria

The fifth anniversary of the entry into force of the Directive against falsified medicines in the EU and the launch of the Bulgarian medicine verification system was solemnly celebrated on March 19, 2024 in "Sofia Balkan Palace". Representatives of state institutions and organizations, partners in the implementation and development of the Verification System, were awarded certificates of appreciation. The Chairman of the Board of the Bulgarian Medicines Verification Organization (BOVL) Olya Vasileva, Executive Director of the Bulgarian Association of Wholesalers of Medicines (BATEL), emphasized at the opening that successful communication with the institutions and all interested parties is key to the success of the project on the implementation of the Medicine Verification System in Bulgaria, which is proven by the fact that this is the largest public-private project in Europe for the benefit of patients.

In his welcome, Prof. Ilko Getov, Deputy Minister of Health, highly appreciated the work of all participants in the project: "The introduction of the Medicine Verification System in Bulgaria was made possible thanks to the fact that 5 years ago the interested parties, participants in the production and distribution of medicinal products, which are the basis of the project, shook hands. This partnership model is alive and well, he added, and thanked everyone who has been involved since the beginning." "We can be proud of what we have achieved so far," said Iliana Paunova, executive director of BOVL. The medicine verification system in Bulgaria was launched on February 9, 2019, with the aim of providing patients with medicines of authentic origin. It is part of the single European system for the verification of medicines and works stably, respecting high quality requirements in all main and supporting processes. The overall performance and availability indicators of the System are over 99.90%.

Iliana Paunova presented basic facts about the establishment of BOVL, about the successful operation of the Medicine Verification System and about the upcoming steps to improve its functions in Bulgaria and in the EU countries. "In Bulgaria, this was the first electronic system in medicine procurement that worked on a national scale," she noted in her presentation. "The deployment of the scale of this project has become possible in our country thanks to legislative changes, as well as thanks to the cooperation between state institutions and stakeholders in the medicine supply. Another important factor for the successful implementation and functioning of the Verification System is the dedicated work of the BOVL team", noted Iliana Paunova. The guests congratulated the BOVL team and emphasized the outstanding progress for these 5 years in understanding the importance and role of the Medicine Verification System and the need to continue the integration of all information systems in the medicine supply in Bulgaria.

Iliana Paunova presented certificates of appreciation for 5 years of partnership in the implementation of the European Directive on Combating Counterfeit Medicines to representatives of the Health Commission of the

49th National Assembly, the Ministry of Health, the National Health Insurance Fund, the National Council on Prices and Reimbursement of Medicinal Products, The Executive Agency for Medicines, GS1 - Bulgaria, Law Firm "Sabev & Associates" and "Account K" OOD. Certificates of appreciation for 5 years of partnership in the implementation of the European Directive on combating falsified medicines were also received by the representatives of the founding organizations of BOVL, who are also members of the Management Board of the organization: the Association of Research Pharmaceutical Manufacturers (ARPharM), the Bulgarian Generic Pharmaceutical association (BGPharmA), the Bulgarian Association of Wholesalers of Medicines (BATEL), the Bulgarian Association for the Development of Parallel Trade in Medicines (BARPTL) and the Bulgarian Pharmaceutical Union (BFS). BOVL received congratulatory addresses from the Ministry of Health, the National Health Insurance Fund, Information Services, GS1 - Bulgaria, the Bulgarian Generic Pharmaceutical Association, as well as congratulations from the participants in the festive event.

Author: Batel

22 March 2024 – BULGARIA: Vending machines to 'stand in' for small town Bulgarian pharmacies (Source: EURACTIV)

Pharmacy owners would be able to register vending machines for over-the-counter medicines to be placed in towns and villages in Bulgaria where no pharmacies are available, the Ministry of Health told Euractiv.
Nearly 10% of Bulgarian municipalities do not have a single pharmacy on their territory, and many cities with a population of up to 50,000 people do not have a 24-hour pharmacy, further complicating access to medicines. According to the health ministry, the latest amendments to the Medicinal Products in Human Medicine Act will solve part of this problem, as they will allow vending machines outside pharmacies to sell medicines that do not need a doctor's prescription. "The changes in the Medicinal Products in Human Medicine Act are an important step towards improving access to medicines in small towns," the ministry said, adding: "The owners of pharmacies and medicinestores will have the opportunity to register vending machines to be placed in towns and villages where there is no open pharmacy, as well as to work outside the working hours of pharmacies and medicinestores in larger cities."

Vending machines will sell pain relievers, fever reducers, as well as heartburn and indigestion medications, laxatives, anti-diarrheal products, antihistamines, antiseptics and disinfectants, and anti-inflammatory medications. For medicines that require a doctor's prescription or are financed by the state health fund, citizens of small municipalities will still have to travel to the nearest big city to find a pharmacy.

Complicated access to medicines
In February, the National Association of Municipalities in Bulgaria announced that citizens' access to both medical care and medicines has become increasingly difficult in recent years, especially in small and remote settlements, as well as in mountainous areas inhabited mainly by an ageing population.
People's access to medicines and healthcare is also complicated by the lack of public transport. According to the association's data, by the end of 2022, 25 out of a total of 265 municipalities in the country did not have access to medicines. Bulgaria ranks third in the EU regarding the percentage of people aged 65 years and over in the total population, with 23,5%, following Italy (24%) and Portugal (24%), according to Eurostat.

A complex problem
"The problem of access to medicines is complex. Deploying medicine vending machines cannot be the only solution to the problem. Their main purpose is to benefit patients, especially in remote areas or people in cities during off-hours," the health ministry commented. During the debate on vending machines, the National Chamber of Pharmacy expressed doubt that they would address medicine shortages. According to representatives of the pharmacy chamber, mostly older people live in small and remote settlements, and they will not be able to buy medicines from vending machines. The Chamber called on the municipalities to provide free premises where pharmacies can operate, as small towns are full of empty buildings. The Association of Municipalities responded that no pharmacist is interested in going to a remote, hard-to-reach location where 80 people live. Therefore, having vending machines seems like the only solution.

Increasing health culture

Another change in the pharmaceutical legislation proposed by the Ministry of Health is that pharmacies can carry out health promotion activities and not only dispense and prepare medicines. Pharmacies could also roll-out health education programmes for citizens to improve their health culture and disease control. "The inclusion of health promotion activities in pharmacies is extremely important to optimise health resources. These activities may include providing healthy lifestyle counselling, disease prevention education campaigns, screening for various health problems, and more. This will help spread information about a healthy lifestyle more widely and support patients in maintaining their health," the Ministry of Health told Euractiv. Until now, pharmacists in Bulgaria were strictly limited to selling and preparing medicines, while in other EU countries, especially in small populated areas, they have much greater responsibilities, including administrating certain types of vaccines or anti-allergy medicines.

Author: Antonia Kosteva, Krassen Nikolov

18 March 2024 – FINLAND: Heikki Koski Appointed as CEO of Medaffcon Oy (Source: Tamro)

Heikki Koski, currently the Service Business and Development Director at Tamro, has been appointed as the CEO of Medaffcon Oy, effective from April 1, 2024. Medaffcon is a subsidiary of Tamro Oyj. The current CEO of Medaffcon, Jarmo Hahl, will continue to play a pivotal role in shaping the company's future in his new position leading the consulting business. Medaffcon offers research and expert services tailored to the needs of the pharmaceutical industry and healthcare, focusing particularly on evaluating effectiveness and developing and utilizing research methods based on health information. The company aims to extend its expertise and knowledge beyond Finland's borders.

– Jarmo has done commendable work leading Medaffcon since 2010 and has, with his strong expertise, laid the foundation for future growth with his team. We see this as the right moment to expand the business, focusing on both domestic operations and internationalization, says Kai Kaasalainen, CEO of Tamro.
– I have had the pleasure of working with the Medaffcon team to develop the company's operations for over three years, and I am delighted to continue this work as CEO. Medaffcon has an excellent team and expertise, highly satisfied customers, and all the prerequisites to successfully implement a new strategy for international growth, says Heikki Koski.

Medaffcon Oy
Medaffcon Oy, founded in 2009, provides research, expert services and consultancy to meet the needs of the pharmaceutical industry and healthcare sector. Our services combine strong medical and health economics expertise with modern data science. Our key areas of expertise are Real-World Evidence (RWE) research based on real-life data, as well as medical and market access expert and consulting services. The quality and scope of Medaffcon's services are built on high-level content and process expertise, alongside a strong collaboration network within the pharmaceutical industry, healthcare, academia, and research communities. Medaffcon operates in Finland and Sweden, and through collaboration networks in other Nordic countries. The company employs about 30 experts.Since 2017, Medaffcon has been a subsidiary of Tamro Oyj and is part of the PHOENIX group, which is a leading provider of healthcare services in Europe.

Author: Tamro

28 March 2024 – GERMANY: German statutory payers call on MPs to stop price confidentiality (Source: APM Health Europe)

BERLIN, 28 Mar (APM) - German umbrella payer group GKV-Spitzenverband (GKV-SV) has called on members of Parliament (MP) to stop the option of price confidentiality being introduced by a bill. "We appeal to the German Bundestag to stop this plan, which only serves to increase the profits of the pharmaceutical industry," Stefanie Stoff-Ahnis, member of the board of GKV-SV in charge of medicine policy said in a statement on Wednesday.

Health Minister Karl Lauterbach on Wednesday presented the bill on medical research (MFG) that includes an option for pharmaceutical companies to request that the reimbursed price for a new medicine negotiated under

the AMNOG procedure be kept confidential (APMHE 84906). It would avoid some German rebated prices to be taken in international reference pricing (IRP) by other countries.The bill has been sent to the Parliament for discussions that could possibly last until the autumn.

"Secret prices unbalance the tried and tested system of medicine pricing and also create an enormous increase in bureaucracy due to complex information procedures and additional billing procedures. Those with statutory health insurance and employers will pay the bill if the additional contributions have to be raised as a result," Stoff-Ahnis said. "We are not talking about millions, but many billions of euros every year in additional costs for contributors without any added value for healthcare," she added. GKV-SV previously estimated that the measure could cost €20 billion to statutory health insurance (SHI) (APMHE 84810). The umbrella association of six SHI vdek and AOK concurred with GKV-SV's view in separate statements.

Two MPs from the three-party ruling coalition - comprising of social democrat SPD, the Green and liberal democrat FDP - have shown that they have received the message. Paula Piechotta, from the Green party, said she was taking the criticism "very seriously". "We must also consider the interests of our European neighbours: a regulation that improves little in Germany but runs the risk of significantly increasing medicine prices in the rest of Europe is not in Germany's interest because it would run the risk of damaging European cohesion," Piechotta said in an emailed statement on Wednesday.Asked by APM about his opinion on confidential prices after publishing a statement on other measures from the MFG without a word on it, FDP MP Andrew Ullmann only said: "Changes can always be made in the parliamentary process. We will look at this in detail." The SPD group, to which Lauterbach belongs, has not issued any statement.

LIMITED SCOPE

Reactions from pharmaceutical associations on confidential prices have been moderately positive. The research-based pharmas association vfa said the option will be "an addition to the toolbox of German reimbursement rules, suitable for individual cases, but not a key element to reliable reimbursement conditions". President Han Steutel reiterated the call to change the unfavourable pricing conditions for step innovations that were introduced in 2022 (APMHE 84580, APMHE 84524, APMHE 84883). Pharma association BPI similarly said it would be "relevant in individual cases" only and also criticised additional costs for companies. They "will have to permanently offset the higher listed prices" by paying the difference with the selling price to payers, as well as the difference in specific taxes and value-added tax (VAT), says BPI's head of clinical research Jens Peters. "What is more important is a commitment to promoting research and development activities, which is reflected in a healthy price structure," he added. The association of wholesalers Phagro also pointed out they would bear additional costs and asked for compensation. "Higher pharmaceutical prices lead to higher borrowing costs for the purchase and procurement of pharmaceuticals."

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27 March 2024 – GERMANY: Confidential reimbursement prices burden pharmaceutical wholesalers, PHAGRO demands compensation for additional costs (Source: PHAGRO)

The federal government passed the Medical Research Act (MFG) at its cabinet meeting today. The PHAGRO | The Federal Association of Pharmaceutical Wholesalers criticizes the fact that the confidential reimbursement amounts for medicines with new active ingredients provided for would lead to higher costs for the full-service pharmaceutical wholesaler. "In the interest of the patients, for whom the full-service wholesaler ensures a comprehensive and needs-based supply of medicines, we urgently need compensation for the additional costs in the event of the introduction of confidential reimbursement amounts," says Marcus Freitag, Chairman of PHAGRO.

From the perspective of the Federal Ministry of Health, confidential reimbursement prices can provide an incentive for more innovative medicines to be approved in Germany again. To this end, Section 78 paragraph 3a of the Medicines Act is to be changed. Pharmaceutical companies should be able to report a freely determinable selling price (ApU) to the Information Center for Specialty Medicinal Products (IFA). The pricing of wholesalers and pharmacies should be based on this. The reported price should be allowed to remain confidential as long as the document protection applies. The pharmaceutical companies only have to inform those entitled to it and reimburse them for the difference in the ApU actually paid. These plans would place an

additional burden on pharmaceutical wholesalers when purchasing these medicines. This is because higher medicine prices lead to higher borrowing costs for purchasing and procuring medicines.
The additional burden is particularly clear in the area of high-priced pharmaceuticals. The statutory wholesale remuneration is capped from an ApU of 1,200 euros and does not increase further from then on. Applied to all previous medicines with a reimbursement amount and an ApU greater than 1,200 euros, the PHAGRO member companies would have had to spend an additional 3.3 billion euros in 2023 due to the planned new regulations for purchasing.* With a key interest rate of currently 4.5 percent, this would have been the case additional interest payments of at least 10 million euros. There would be further additional costs, for example for insurance.

"The plans for the Medical Research Act show once again how in need of adjustment the Medicine Price Ordinance is. No matter how you feel about the idea of confidential reimbursement amounts – without a legal change, the resulting additional costs will be borne by the pharmaceutical wholesaler," emphasizes PHAGRO chairman Marcus Freitag. "We would be happy to make suggestions on how the compensation system can be sustainably modernized. As part of the pricing chain, the additional burdens on wholesalers must be taken into account in the parliamentary process."

* The reference for the calculation is the price reports in 2023. Until a reimbursement amount for medicines with new active ingredients has been set, pharmaceutical companies have been able to freely determine a price. In 2023, these prices were on average 40 percent above the reimbursement amount. The PHAGRO calculations are based on the assumption that a confidential reimbursement price introduced with the MFG will have a comparable price difference.

Author: PHAGRO

27 March 2024 – ITALY: Italy has good medicine access, not delayed by AIFA's consultation with experts (Source: APM Health Europe)

FLORENCE, 27 Mar (APM) - Italy provides good access to medicines and it is not delayed by medicines agency AIFA's consulting with external experts in the assessment process, a Health Ministry official has told parliamentarians. A written question for the Health Ministry about the availability of the latest treatments, especially innovative therapies to treat cancer, was presented in a social affairs committee meeting last week. It was tabled by Stefano Benigni, a member of the Forza Italia party, which is in the governing coalition.
Information from the Italian Medical Oncology Association (AIOM) was cited as showing patients, in some cases, have to wait more than two years in Italy to access innovative cancer medicines. Regional therapeutic reimbursement lists are partly to blame for this situation because they prolong the process of providing access, it was noted. "Furthermore, according to recent communications from patient associations representing cancer patients, some innovative medicines intended for the early treatment, for example, of pancreatic, breast or lung cancer, have already been available for some time in various countries around the world but are still waiting for evaluation in Italy," it was pointed out.

ITALY EXPANDED USE OF EXTERNAL CONSULTANTS IN 2019
AIFA's expansion of the use of external consultants was highlighted in the premise for the question. This happened in 2019 with increased use of contributions from leading experts in the main therapeutic areas. The aim was to strengthen the scientific and regulatory assessment process. In 2022, external consultation was expanded further with the setting up of specific oncology and oncology/haematology working groups composed of experts to support the activities of the AIFA departments and its Technical-Scientific Commission (CTS). This time, it was aimed at supporting the objectives of the European Cancer Plan 2021 and of the National Oncology Plan for the five-year period 2022-2027. The Health Ministry was asked whether these external bodies have been consulted and how often. It was also asked whether discussions with experts have contributed positively to the achievement of objectives and whether it has improved the availability and access times compared to other European countries for innovative medicines in the oncology and oncology/haematology fields.

EXTERNAL OPINIONS SUPPORT AIFA MEDICINE ASSESSMENT, DO NOT DELAY ACCESS
Health Undersecretary Marcello Gemmato provided a written reply on behalf of the government. He noted that the CTS and the Pricing and Reimbursement Committee (CPR) have been merged into a new Scientific and

Economic Commission (CSE) with the specific aim of streamlining procedures, accelerating the assessment process and providing faster access. Gemmato confirmed that consultation with external bodies was expanded in 2019 and that meetings or discussion with experts take place on a monthly basis. He said oncology and oncology/haematology working groups have also been set up. However, he also warned that AIFA is now looking at whether a new provision should be introduced to better define the use of external advice in light of 'difficulties' that have emerged Nonetheless, Gemmato stressed that opinions of external consultants support AIFA's decisions and do not affect the approval times or access to therapies. He said: "Indeed, according to a recent international study comparing (Italy) with other European countries, these (access) times have been evaluated positively, when considering the high number of medicines fully reimbursed by the National Health Service."

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26 March 2024 - PORTUGAL: Full-service healthcare distribution: a new specialty (Source Groquifar)

A new specialty was recently approved for pharmacists registered with the Order of Pharmacists in the area of pharmaceutical distribution. The Order states that the new specialty is of great relevance considering the growing demands and work carried out in distribution companies, particularly in areas such as technical direction, quality management, among others.

To find out more about the new specialty, see the transitional rules here .

Author: Groquifar

28 March 2024 – SPAIN: Spain considering differentiated prices for generics (Source: APM Health Europe)

MADRID, 28 Mar (APM) - Spain's Health Ministry is considering a change in regulation to allow generic medicines be sold at lower prices than originators, daily newspaper El País reported on Wednesday. Senior Health Ministry official César Hernández told El País that differentiated (lower) prices for generics are being considered as part of a plan to boost generic use. In this scheme, it would be up to patients to pay for the difference if they rather use the branded medicine, it said.

The newspaper said: "This change would be a revolution in Spain's pharmaceutical policies regarding competition because it would allow selling generics and biosimilars at lower prices than originators." The market share of generic medicines has been at a standstill in Spain for decades, El País said. Hernández told the newspaper that Spain is practically the only country where branded and generic medicines have to be sold at the same price. He said: "This [mandatory equal prices for branded and generic medicines] can be a problem for generics and biosimilars because they have to sell at lower prices but they cannot gain market share, which is their incentive." According to Hernández, there is a wide consensus regarding differentiated prices being a good strategy, with most EU countries allowing differentiated prices. However, he cautioned that the decision has not been formally made and that ways to implement the move have yet to be studied. El País quoted Stada head in Spain Peter Goldschimdt as saying: "In Germany, generics account for nine out of each 10 prescriptions, whereas in Spain new generics do not account for 20%."

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27 March 2024 – SWEDEN: Strong growth for Sweden's pharmaceutical exports (Source: European Pharmaceutical Review (Source: European Pharmaceutical Review)

A focus on innovation and high quality is helping Sweden to strengthen its position as a key player in the global life sciences market, SwedenBIO states.

According to SwedenBIO, Sweden's life sciences industry is witnessing a continued increase in export values. Based on statistics from Statistics Sweden, at SEK 152.5 billion, exports of pharmaceuticals reached a total of 7.3 percent of Sweden's total export value. SwedenBIO highlighted that this is an almost 10 percent increase since 2022.

Value of Swedish pharmaceutical exports

Swedish pharmaceuticals exports are currently "significantly larger" than exports of iron and steel. They are therefore of "growing importance to the economy", SwedenBIO explained. With one success factor of Swedish life sciences being the export numbers, "in majority driven by AstraZeneca", Maja Neiman, Scientific Director of SwedenBIO explained to *EPR* that another important influence is "the high numbers and potential of [Sweden's] domestic innovation pipeline". Data from SwedenBIO's 2023 Pipeline report shows that medicine development companies with Swedish headquarters (excl. AstraZeneca), have a combined pipeline of the size of a global Pharma giant, but with 1/20 of the personnel", according to Neiman. Overall, this indicates that the Swedish life sciences industry is strengthening its position as a significant player in the global market, with innovation and high-quality product exports specifically helping to drive global demand, SwedenBIO claimed. As such, Swedish pharmaceutical exports are expected to continue their positive development, SwedenBIO asserted.

Securing the pharmaceutical supply chain

Neiman told *EPR* that to support growth of these exports in Europe, "it is crucial to sustain the entire life sciences ecosystem. We need bold research funding, a healthcare system involved in the creation of new innovations through clinical trials, and we need the full scale of discovery, development and manufacturing capabilities to support the entire value chain within Europe." In addition to pharmaceutical exports, other success metrics such as "patents, licence deals [and] service companies' occupancy rates" need to be considered within the value chain in the life sciences ecosystem, Neiman added. "Given the strong focus on precision medicine, we also need to measure the development of companion diagnostics and other tools and technologies accompanying the medicine development and production."

Sweden's approach

Neiman described how Sweden's life sciences sector has adapted over the past several decades. She noted that the country has "been successful in cherishing the legacy from large pharma companies. When R&D departments of large companies moved out of Sweden… the competence, instruments and housing remained. These facilities are now occupied by small companies who together engage far more researching personnel compared to the period when Sweden housed more larger companies." Importantly, this set up "has enabled a spread of risks that limits consequences when medicine development projects fail", Neiman stated. "We also see that Swedish companies are very connected internationally. Most innovative companies may not have the approach to manufacture and sell the product. Rather, licensing deals with larger pharma may be part of the business plan. One example of that is the Swedish company BioArctic, working on Alzheimer's disease, that early in the development partnered with Eisai to develop lecanemab."

What could the future hold?

Considering key factors that could influence the supply of European pharmaceuticals, Neiman shared that "legislation affecting the innovative power of the EU is a factor that may influence the future supply of innovative medicines. We support all efforts to lower the cost of treatments for patients, but not in a way that interferes with Europe's contribution to new innovations for patients around the globe. "Given the geopolitical turbulence and climate change, we foresee a need to secure global supply chains with alternative routes, to quickly adapt to new circumstances. It will be crucial for Europe to do two things at the same time: both increasing the European capabilities to be able to sustain the entire value chain from start to end, and continue to foster global collaboration. In regards of all sustainability goals, international cooperation is the key."

Author: Catherine Eckford

25 March 2024 – SWITZERLAND: Healthcare Information Solutions (HCI) unveils new brand image (Source: Galencia)

In March, HCI Solutions underwent a rebranding that not only introduces a fresh new look, but also emphasises the company's transition towards developing data-driven healthcare solutions.

The rebranding of HCI Solutions extends well beyond a simple change in visual appearance. It reflects the new strategic direction and embodies a contemporary style for providers of digital eHealth solutions. Through this rebranding, HCI Solutions is positioning itself in line with its vision as a provider of data-driven healthcare solutions beyond its previous offering of index data. This step underscores the company's clear commitment to continuously improving therapy quality and patient safety. The new brand image of HCI Solutions marks a significant milestone on the path to the future of healthcare and underscores the company's commitment to innovation and customer satisfaction.

Website HCI Solutions

Author: Galencia

26 March 2024 – JAPAN: Two global firsts among medicine approvals in Japan (Source: APM Health Europe)

LONDON, 26 Mar (APM) - Several medicine approvals in Japan were announced on Tuesday and Monday, including two global firsts for medicines from Astellas and argenx. Japan became the first country to approve Astellas' Vyloy (zolbetuximab) for patients with CLDN18.2 positive, unresectable, advanced or recurrent gastric cancer. The decision by the Ministry of Health, Labour and Welfare (MHLW) follows a rejection by the U.S. Food and Medicine Administration (FDA) in January due to issues at a manufacturing facility (APMHE 83984). Vyloy is a monoclonal antibody that is designed to target and bind to CLDN18.2, a protein that is present on cancer cells. This binding interaction then induces cancer cell death. The medicine is available under an early-access scheme in Germany (APMHE 84382).

ARGENX'S VYVGART

The MHLW also became the first global regulator to approve argenx's Vyvgart (efgartigimod alfa) for use in adults with primary immune thrombocytopenia (ITP), an autoimmune bleeding disorder characterised by abnormally low levels of platelets. It can lead to increased risk of bruising and bleeding. Vyvgart is already approved in Japan and other markets to treat myasthenia gravis, a rare condition that causes muscles to tire and weaken easily throughout the body.

THREE CHUGAI MEDICINES

There were also approvals for three products marketed by Roche's subsidiary Chugai. These include monoclonal antibody Piasky (crovalimab), which was approved by the MHLW for the treatment of paroxysmal nocturnal haemoglobinuria (PNH), a rare genetic disease that causes the breakdown of red blood cells, resulting in various medical complications, including anaemia and thrombosis. The MHLW's decision is the second approval for Piasky after an approval in China in February covering patients 12 years and older with PNH who have not been previously treated with complement inhibitors (APMHE 84341). The Japan approval does not come with restrictions on age or the use of previous treatments. Piasky is under review for PNH by other regulatory authorities, including in the U.S., Europe and Taiwan. Japan-based Chugai discovered the medicine and is responsible for development in its home country and Taiwan. Roche has development responsibility in the rest of the world. Chugai also announced the approval of Mitchga (nemolizumab) for the treatment of pruritus associated with atopic dermatitis in children between six and 13 years and to treat prurigo nodularis in patients 13 years and older. Both approvals cover use of the medicine in situations when existing treatment is insufficiently effective.

The medicine, which is given by subcutaneous injection, is already approved in Japan for the treatment of pruritus associated with atopic dermatitis in adults and children aged 13 years and older. Mitchga is marketed in Japan by Maruho as part of a deal with Chugai. Switzerland's Galderma has rights in the rest of the world, except for Taiwan. Galderma has filed new medicine applications in Europe and the U.S. (APMHE 83026). The third approval for Chugai is for Vabysmo (faricimab) to treat macular oedema associated with retinal vein occlusion (RVO). The bispecific antibody is already approved in Japan for people living with wet age-related

macular degeneration (AMD) and diabetic macular oedema. It is approved in eye indications in more than 90 countries.

VYXEOS AND FINTEPLA

There were two approvals in Japan for local company Nippon Shinyaku. These include Vyxeos (daunorubicin+cytarabine) for the treatment of high-risk acute myeloid leukaemia (AML). Nippon Shinyaku is partnered on the medicine with Jazz Pharmaceuticals, which holds rights outside Japan. Vyxeos is approved to treat AML in several other markets. The MHLW also approved Nippon Shinyaku's Fintepla (fenfluramine) for the treatment of seizures in patients with Lennox-Gastaut syndrome (LGS), a rare form of epilepsy. The medicine is already approved as a treatment for seizures associated with Dravet syndrome, another form of epilepsy. Nippon Shinyaku is partnered on Fintepla with UCB, which commercialise the medicine in markets outside Japan.

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26 March 2024 – UNITED STATES: Amazon rolls out same-day prescription delivery with help from AI (Source: Forbes)

Amazon Pharmacy is launching same-day prescription delivery in New York and Los Angeles with the help of artificial intelligence and machine learning. It's the latest in a series of moves from the giant online retailer to add more features to its pharmacy operation to help compete with the big pharmacy chains, Walgreens and CVS Health, which already have nationwide same-day prescription delivery. CVS said all of its more than 9,000 stores offer same-day delivery in all 50 states and the District of Columbia, while Walgreens said it has offered same day prescription delivery for almost three years.

In Amazon's case, the company's same-day delivery announced Tuesday will initially be in New York City and the greater Los Angeles area with plans to expand to more than 12 cities by the end of 2024. Amazon will also use a variety of ways, including those powered by "generative artificial intelligence and machine learning," to help its pharmacists fill prescriptions while addressing other patient needs. The goal is to speed up treatment to less than a few hours in many cases. "So much that happens across the country is delayed diagnosis," Amazon Pharmacy's chief medical officer, Dr. Vin Gupta, said in an interview. "We are making that whole process of diagnosis and treatment easy. And very fast."

Author : Bruce Japsen


robopharma
Automation by
Capsa Healthcare
CAPPI
PACKAGING FOR LOGISTICS
THERMO KING
BD
Rowa Technologies