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EU AI Act – Challenges and Opportunities for Pharmaceutical Companies

(Source: An article by Vikas Krishan for Pharma Times)

The EU AI Act is intended to regulate artificial intelligence (AI) technology in the European Union by requiring AI systems to meet strict standards for transparency, accountability and human supervision. It also sets guidelines and requirements for AI use, focusing on promoting the use of trustworthy AI with respect for fundamental rights.

The pharmaceutical industry is strictly regulated due to the impact it has on patient protocols and clinical trial participants, as well as post market surveillance and enforcement.

Compliance is vital. In contrast to this highly regulated approach, there has been criticism that the EU AI Act is too loose in nature and therefore open for interpretation. So, will the Act be a help or a hindrance to the Pharma industry?

Scheduled to take effect in the summer of 2024, the EU AI Act has broad-reaching consequences for pharma companies that are using or plan to use AI as it aims to standardize the rules for its usage, development, market spread and adoption.

The wide scope of the Act has the potential to impact developers and deployers of AI systems based in the EU, those with bases within the EU and those that produce systems that might be used within the EU.

This is important for Pharma companies that increasingly leverage AI to improve the efficiency of drug discovery, clinical trial recruitment and finding new biomarkers.

A major challenge for those creating the Act is in the definition of AI, which has been amended several times already within the Act's drafts. The definition of AI is broad and potentially far-reaching, leading to uncertainty and ambiguity about what AI actually encompasses. To ensure the Act's effectiveness, it is crucial to first address the challenge of defining AI clearly. It is also fundamentally important that the use of AI strikes an appropriate balance between what is acceptable to society and what is not.

The challenge is to find the right balance between these two ends of the spectrum; looking at what drives innovation and

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In Brief...

- **McKesson Corporation** reported financial results for the first quarter of 2025 with revenues of US$79.3 billion (an increase of 6% year-over-year) and net income of US$915 million. Adjusted earnings per diluted share rose 8% from US$7.27 to US$7.88. "We continue to advance our strategic priorities leveraging our broad capabilities across the enterprise. Strong momentum continues across our U.S. pharmaceutical segment, particularly within our broad Oncology offerings…We remain confident in our strategy and ability to deliver on our raised fiscal 2025 guidance and longer-term objectives," said *Brian Tyler*, CEO of McKesson.
- **Walgreens Boots Alliance** announced that it was exploring options for **VillageMD** doctor-staffed clinics, including a sale of all or part of the VillageMD businesses, according to a filing with the **U.S. Securities and Exchange Commission**. The company noted that it had already initiated strategic and operational reviews towards simplifying and focusing its U.S. healthcare portfolio, including an assessment of the company's investment in its majority-owned VillageMD. Walgreens also said it is currently evaluating a variety of options with respect to VillageMD considering ongoing investments by the Walgreens in VillageMD business and expected future cash requirements.
- Cardinal Health reported 4th quarter and fiscal year 2024 financial results, with 4th quarter revenue up 12% year-over-year to US$59.9 billion and fiscal year 2024 revenues of US$226.8 billion, up 11% over 2023. GAAP operating

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Pharma Executives React to Final Price Negotiations with Medicare

(Source: An article by Amy Baxter for PharmaVoice)

While the U.S. Centers for Medicare and Medicaid Services (CMS) is expected to publish the new Medicare prices of the first ten drugs selected for the initial wave of price negotiations on September 1, pharma companies already know how the policy will impact their portfolios.

August 1st marked the end of the official negotiations, but the prices of these drugs will not take effect until 2026. The negotiations were part of the Inflation Reduction Act and pharma companies have been challenging the provision, albeit unsuccessfully so far, through legal actions since the law was passed by the U.S. Congress.

The ten drugs on the list were selected based on Medicare Part D expenditure and range from cardiovascular medications to diabetes and cancer treatments. Included on the list are *Eliquis, Jardiance, Xarelto, Januvia, Farxiga, Entresto, Enbrel, Imbruvica*, *Stelara* and a group of diabetes drugs – *Fiasp, Fiasp*

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EU AI Act *(cont'd.)*...

improvements versus what is exploitative or discriminating. Within clinical trials, AI can be used to predict which groups or demographics will have the best outcomes and success ratios.

The role of AI is fast becoming fundamental to the successful and efficient execution of clinical trials. As part of this, digitalization of data is crucial to successful use of AI. However, it is important for pharma companies to consider where this falls within the confines of the act due to the fact AI's use in clinical trials often deals with demographics, backgrounds and ethnicity.

Ethically, concerns around AI bias have been a key discussion. It is here that any ambiguity within the EU AI Act, if not properly addressed, has the potential to hinder innovation and progress within the pharmaceutical industry. Arguably, the Act is there to create an obligation for organizations to state how AI will be used, and the challenge for Pharma will be the burden of extensive reporting rather than deciding how AI can be used and what are the best uses.

Pharma Executives *(cont'd.)*...

FlexTouch, *Fiasp PenFill, Novolog, Novolog FlexPen and Novolog PenFill*.

Johnson & Johnson potentially has the most exposure in this first wave, although leaders in pharma manufacturing have largely downplayed the impact of the IRA and for the most part did not disclose the new prices during recent earnings calls, although they did discuss their confidence in dealing with the new prices.

Christopher Boerner, CEO of Bristol Myers Squibb (BMS) spoke bullishly on *Eliquis's* long term success on an earnings call, "Now that we have seen the final price, we are increasingly confident in our ability to navigate the impact of [the] IRA on *Eliquis*. *Eliquis* is an important drug for patients. It's going to continue to be an important drug for the company in the short to medium term."

While BMS may be able to weather the storm, Boerner did go on to heavily criticize the IRA's overall impact on pharma, stating that arbitrary price setting by the government on life-saving medicines is not good public policy. BMS also has other products in the pipeline to help fill future revenue gaps.

David Ricks, CEO of Eli Lilly also been vocal regarding his opposition to price negotiations, saying that the law will harm innovation and new drug development, particularly for small molecules.

Merck, the maker of *Januvia*, was the first to sue the U.S. Department of Health and Human Services over the drug pricing provision of the IRA, calling the law "extortion." However, Merck leaders did not discuss the IRA on its most recent earnings call.

Meanwhile, Novo Nordisk and other insulin makers have already been capped at US$35 per month in out-of-pocket costs for beneficiaries in the U.S. The company who manufactures the *Fiasp* and *Novolog* group of diabetes drugs is also the manufacturer of diabetes and weight loss drugs *Ozempic* and *Wegovy*. However, Doug Langa, executive vice president of North America operations said on a recent call that the *Novolog* and *Fiasp* medications are a small part of their business, and that it is too early to know if semaglutide products will ever be included on the negotiation list in the future.

In a global economy, a companies' performance in the U.S. - the world's largest pharma market - can have impacts worldwide.

In Brief (cont.)

earnings were US$1.2 billion and GAAP diluted EPS was US$3.45. Non-GAAP operating earnings increased 16% to US$2.4 billion, driven primarily by segment profit increases in GMPD and Pharmaceutical and Specialty Solutions. Non-GAAP diluted EPS increased 29% to US$7.53 for the year, reflecting the increase in non-GAAP operating earnings across the business, lower interest and other expense, a lower non-GAAP effective tax rate and a lower share count following in-year share repurchases.

U.S. wholesalers/distributors **McKesson Corporation**, **Cencora** and **Cardinal Health** are said to be interested in acquiring privately held **Florida Cancer Specialists & Research Institute**. The cancer clinic operator could be worth up to US$3 billion. The Florida Cancer Specialists employs 250 physicians, 280 nurse practitioners and physician assistants, operates in approximately 100 locations, and embraces the value-based care model where it is reimbursed via a lump sum to treat a patient rather than a per visit or per test. In this way, the provider is incentivized to provide the best, most efficient treatment plan. Cancer care has garnered keen interest from pharmaceutical distributors in recent years in regard to the distribution of specialty drugs.

French pharma manufacturer **Sanofi** confirmed that it will invest €1.3 billion (US$1.4 billion) to build a new insulin manufacturing facility at its campus in Frankfurt Höchst, Germany. The facility, which will total approximately 36,000 square feet, is expected to be completed in 2029 and will employ "several hundred" new workers in addition to its current 4,000 employees.

Eli Lilly is preparing to cement its foothold in the obesity market as competitors look to grab market share. "Our strategy is to comprehensively address this global public health crisis, pursuing opportunities against every rational mechanism, indication and dosage form. We are investing broadly in this disease and now have 11 new molecules currently in the clinic across multiple indications," stated *David Ricks*, CEO of the company. For oral medications treating obesity (which is expected to be the next big thing) Ricks said target engagement and safety will be the key, and Lilly has the most advanced program. Currently Lilly's Mounjaro and Zepbound are leaders in the obesity market.

DKSH Business Unit Healthcare, a strategic healthcare solutions partner to pharmaceutical, OTC, consumer health and medical device companies, has entered a partnership with **Kyowa Kirin Co., Ltd.**, a Japan-based global specialty pharmaceutical company, in line with Kyowa Kirin's announced plans to transform its business in Asia-Pacific. The scope of the partnership covers a promotion and distribution agreement and commercial rights for Kyowa Kirin's established medicines portfolio in South Korea, Taiwan region, Singapore, Thailand, Malaysia and Hong Kong & Macau.living with the virus around the globe.

(Sources: Bloomberg, Company Press Releases, Drug Store News, FiercePharma, Manila Times, Reuters and Yahoo! Finance)