FOCUS

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UK Will Adopt the EU's End-to-End Verification System

(Source: Press Release by the Healthcare Distribution Association (HDA UK) formerly the British Association of Pharmaceutical Wholesalers (BAPW)

The HDA UK has endorsed the 'risk-based' wholesaler verification provision in the *Delegated Regulation of the Falsified Medicines Directive* (FMD) published on 9 February 2016. The issue was a significant concern to HDA UK member companies, as alternatives would have placed unnecessary burdens on the supply chain, including possible delays in being able to supply life-saving medicines speedily to patients. HDA UK recognized the efforts of the European Healthcare Distribution Association (GIRP), which worked closely with them in Brussels to avert the implementation of a more onerous system for UK wholesalers/distributors.

'End-to-end verification' has now been mandated throughout the EU, with the manufacturers of prescription medicines having to place 'safety-features' on all their medicines sold in the EU and those who dispense to patients will verify these 'safety features' before patients receive them.

Following the FMD publication, the UK now has three years to implement the Falsified Medicines Delegated Regulation, with all new measures having to be in place by early 2019. The HDA UK stated that it will utilize the technical expertise of its Responsible Persons' Committee to ensure its members adhere to the highest standards when putting the required technical changes into place. It will also coordinate with the wider supply chain representatives on the HDA UK Members' Liaison Group to ensure the sector is aware of the business changes brought about by the Falsified Medicines Directive.

Martin Sawyer, Executive Director of the HDA UK noted: "It is good news to finally see the publication of the Delegated Regulation that sets the clock ticking in the UK and other EU member states. 'Risk-based' wholesaler verification was crucial in securing a credible and sustainable solution to secure the European medicines supply chain. We look forward to working with our supply chain partners to ensure the Delegated Regulation is implemented to the highest standards so that patients can continue to benefit from a safe medicines distribution sector."

The HDA UK stated that it has been working alongside fellow supply chain stakeholders in the formation of the UK's Medicines Verification Organization (UKMVO), which will manage the UK data repository and verification system. The UK's MVO will be created this year and is aiming to select the IT database provider for the UK by the end of 2016.

The focus of all those working on FMD, notes HDA UK, will now shift to the technical challenges associated with delivering a workable supply chain solution. Due to its importance to distributors and wholesalers, the HDA UK will be discussing the topic with its members at a number of forthcoming events, including its Annual Conference on Thursday 16 June in London and its Business Day on Thursday 17 November in Chester.

In Brief . . .

- **McKesson/Celesio** recently acquired UK-based clinical homecare provider **Bupa Home Healthcare** from its parent company **Bupa** (a global health insurance provider) for an undisclosed sum. The deal is McKesson's fourth European transaction since acquiring Celesio in 2014, following purchases of: Sainsbury (UK-based retail pharmacy), UDG (pharma distribution and nurse-enabled home specialty in Ireland), and Belmedis (pharma distribution and retail pharmacies in Belgium). Bupa Home Healthcare's 1,000 employees and national nursing team provide home-based specialty care and administer 15,000+ prescriptions (including specialty therapeutic areas such as oncology, MS, and RA) to over 35,000 patients in the home setting.
- **AmerisourceBergen** reported a 9.3% increase in revenue to US$36.7 billion for its fiscal 2016 first quarter ended Dec. 31. "Our recent acquisitions, **MWI Veterinary Supply** and **PharMEDium**, as well as strong contributions from our specialty business and our international businesses helped overcome a challenging year over year comparison and a sharper than expected decline in generic inflation," reported *Steven Collis*, AmerisourceBergen president and CEO. The company posted a 7% increase in Pharmaceutical Distribution revenue (to US$35.2 billion), which includes both AmerisourceBergen Drug Corporation and AmerisourceBergen Specialty Group. Separately, AmerisourceBergen and **Publix** announced a long-term agreement around the distribution of branded, generic and

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IFPW FOUNDATION

Implementation Begins as Foundation Partnership with Gavi to Strengthen Supply Chains is Ratified

IFPW, through its charitable arm IFPW Foundation, ratified the previously-announced 3-year US$1.5 million partnership with Gavi, the Vaccine Alliance which is designed to strengthen supply chain management and managers in developing countries through scholarships, mentoring and knowledge sharing.

Implementation of the partnership's projects and programs – representing the first of their kind for the global pharmaceutical wholesale sector – will initially take place through the support of 2 training centers, the existing LOGIVAC center in Benin and the East African Community Regional Center of Excellence (EAC RCE) located on the campus of the University of Rwanda in Kigali. The latter of which will be formally launched on March

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Status of Japan's "Improvement of Ethical Drug Distribution" Program

(Source: Pharma Japan)

The Ministry of Health, Labor and Welfare (MHLW) in Japan is accelerating its move to give shape to a new proposal issued in September by its "Ryukaikon" council for the improvement of ethical drug distribution. One of three working groups under the council, which brings together representatives from drug manufacturers and wholesalers, met on February 9 to discuss ways to tackle distribution challenges between the two segments of the supply chain. The two other working groups one focusing on issues between wholesalers and pharmacies and the other regarding drug barcoding are also expected to meet by the end of the month. In spring, the council will hold a gathering to follow up on steps taken towards the proposal.

The new Ryukaikon proposal, the first since it presented its "emergency proposal" in 2007, furthers the basic principles from the 2007 paper, while setting out ideal distribution practices 10 years ahead based on the rapid generic penetration in the market. A trend that will have a particularly huge impact on wholesalers. Specifically, the new proposal called for continued efforts in promoting the so called "single product, single price" transaction, and suggested the sharing of distribution costs between drug manufacturers and wholesalers.

In a closed door meeting, representatives of the Japan Pharmaceutical Manufacturers Association (JPMA) and the Federation of Japan Pharmaceutical Wholesalers Associations (JPWA) apparently agreed on the need to secure reasonable margins to cover distribution costs for each product as the business environment is changing amid diminishing revenues from off-patent brand name drugs. They agreed to establish a rebate system for generics based on transaction values, rather than a percentage-based system usually adopted for brand name drugs, and also to continue discussing how they should better handle essential medicines. The two sides also agreed to continue their efforts to address the longstanding problem of negative primary margins on sales, or drug wholesalers' losses on sales without factoring in rebates and allowances.

GIRP Introduces Educational Academy (GEA) and Supply Chain Conference

In 2016, GIRP (the European Healthcare Distribution Association) launched its first Educational Academy (GEA), which offers practical, hands-on information and updates on current key topics that impact the medicines supply chain. The GEA is a space for learning, dialogue and exchange between supply chain partners, and offers the latest experiences and updates from the perspective of medicines national inspectorates and agencies as regards supply chain efficiency, quality and safety.

As part of this year's Academy GIRP is organizing a Supply Chain Conference in Brussels on 16-17 March 2016. The Conference "Joining Forces for Transportation Optimization in the Pharmaceutical Supply Chain" will explore the impact of the Good Distribution Practice Guidelines (GDP) on the journey of medicines from Production to Patient (P2P) and the means

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For more information, please contact Christina Tucker at c.tucker@ifpw.com or call (US)703-331-37134

Cyber Defense Systems

(Sources: An article prepared by Utkarsh Palnitkar, Head, Advisory, KPMG in India and published by the EconomicTimes)

KPMG, in India's Cybercrime survey report 2015, indicates that 44% of the respondents believed that the pharma sector was a preferred target for cybercriminals. The sector is such a prime target for cyber attackers, notes the author, because it hosts prized intellectual property (IP) that is of immense value to criminals, enemy governments and competitors.

Around 65% of KPMG's survey respondents indicated that cybercriminals carry out attacks for financial gains; Another 46% believe corporate espionage is the motive behind them. In the context of pharma, the IPs targeted include: drug discovery programs, clinical development programs, drug registration applications, molecular formulae, patient records, production processes, manufacturing records, quality assurance and compliance data.

Companies across sectors have started to gear up their cyber defenses, states the author. Nearly 67% of the survey respondents indicated that they have invested in technology based defense mechanisms. The focus of technology based defenses is however, largely concentrated on defending the IT perimeters against outside threats. This implies that there is limited focus on defending themselves against the insider/business partner threats. The pharma sector in particular, has some of its most sensitive data often scattered across locations, with multiple partners. With such a spread of data and increasing complexity of cyberattacks, it is vital for pharma companies to protect themselves against data leakages, espionage and theft.

To build an effective cyber defense program, organizations should have the following elements in place according to the author: (1) Carry out a detailed cyber risk assessment. A majority, 74% of the respondents from all business sectors in KPMG's cybercrime survey, stated that a detailed cyber risk assessment has not been carried out. (2) Invest in data leak and cyberattack detection tools. The survey indicates that 61% of the respondents from business sectors do not have data leakage prevention applications implemented. (3) Designing a cyberintelligence program that monitors threats, collates actionable cybercrime intelligence, and creates a coordinated cybercrime analytics platform.

While further investments in technology and processes are vital, the human element can either make or break the cyber defense strategy of any organization. The author states that it is imperative for pharma companies to focus on people security and build an ongoing cyber risk awareness program across all levels of the organization.

IFPW Foundation (cont.) . . .

24th in a ceremony that will be attended by top officials from the EAC nations, partners, donors, development agencies, NGOs and other key stakeholders. Once fully operational, these centers will offer the best in academic supply chain curriculum via master's and bachelor's degree programs along with short course offerings covering a variety of relevant supply chain topics. The IFPW-Gavi partnership will provide a mechanism for the industry to complement this invaluable content with the best worldwide thinking and practices from the private sector, thus creating a truly unique and comprehensive experience for both the participants and students and those providing support, with the ultimate objective of improving the availability and reach of life saving vaccines and medicines.

Discussion with IFPW members interested in becoming involved have already begun, opportunities are currently being further developed, and initial activities are underway. As examples: AmerisourceBergen has provided an executive to support a short course being conducted at EAC RCE on leadership and the AmerisourceBergen Foundation will be a sponsor of the upcoming launch event in Kigali; Imperial Health Sciences (IHS) will be sharing content for training materials based upon its extensive experience and deep knowledge of the African markets; manufacturer member GlaxoSmithKline is developing a support package consisting of scholarships, project management and other needed resources; and Eurapharma has been invited to provide strategic guidance to the LOGIVAC center via a soon-to-be established Scientific and Technical Committee.

Additional engagement and support options are always available and interested members and stakeholders are invited to contact IFPW.

Be sure to follow IFPW and IFPW Foundation on Twitter at @ifpw and @ifpwfoundation to keep up with the latest partnership developments and next month's ceremony in Rwanda!

GIRP (cont.) . . .

by which supply chain operators can optimize their approaches to ensuring product safety and quality, regulatory compliance and supply chain efficiency. The aim is to create a platform for dialogue, mutual understanding and collaboration amongst supply chain partners in order to address and advance issues of common concern.

GIRP is very pleased to welcome national GDP inspectors from Spain, Czech Republic, Estonia, Netherlands and Belgium to its first Supply Chain Conference. The inspectors will not only describe the status of GDP implementation in their respective countries, but will also examine recurring challenges and how to create win-win scenarios through lessons learnt and innovative best practice cases from across the supply chain. This conference will serve as a useful forum for learning, exchange and collaboration amongst manufacturers and distributors alike. With an audience from across Europe and the United States, this kick-off conference will set an important milestone in the future of inter-sectoral cooperation.

For more information about the conference, please visit: http://www.girp.eu/supply-chain-conference.

In Brief (cont.) . . .

over-the-counter health and pharmaceutical products which also enables Publix's network of more than 980 pharmacy locations across the southeast US to expand patient access to specialty medications.

- **Cardinal Health** has introduced *MedSync Advantage*, a custom-built medication synchronization program solution built upon the premise that community pharmacists can help improve medication adherence and patient outcomes while increasing efficiency for the pharmacy. "We believe medication synchronization is a core competency for medication therapy management expansion in the pharmacy, and we want to prepare our pharmacies to move toward a value-based pharmacy model for payment in the future," said a company spokesperson, adding, "MedSync Advantage allows us to do that by re-engineering the pharmacy to allow for a more patient-centric approach to care."
- Spanish pharmaceutical distributor **Fedefarma** has joined a project to fund the purchase of new defibrillators which will be installed in community pharmacies throughout the city of Barcelona.
- *Mscripts*, a mobile pharmacy platform, has partnered with **McKesson Patient Relationship Solutions** (MPRS), the company's provider of patient adherence programs through manufacturer sponsorships. The partnership will allow patients to receive coupons from manufacturers via text message or mobile app, connecting mscripts' 6,000-pharmacy network with MPRS's adherence programs and savings offerings that support more than 500 branded products.
- **Rite Aid** stockholders voted to approve the proposed merger with **Walgreens Boots Alliance**, with approximately 97% of the votes cast at a special meeting of stockholders voted in favor of the adoption of the merger agreement (representing approximately 74% of Rite Aid's total outstanding shares of common stock).
- **IFPMA** Director General *Mr. Eduardo Pisani* recently stated that antimicrobial resistance (AMR) is a high priority for the pharmaceutical industry in 2016 and that it is important to enhance research into new antibiotics, but without losing sight of the fact that any novel antibiotic will have to be carefully distributed to patients and be based on a commercially-sustainable model. He also noted that an increased convergence of regulatory standards is the only way to ensure well-controlled accelerated access to medicines and quality of medicines delivered to patients.

(Sources: Barclays, DiarioFarma, Drug Store News and IFPMA)

INTERNATIONAL FEDERATION OF PHARMACEUTICAL WHOLESALERS

for more information please visit
www/ifpw.com/meetings/2016gmm