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The AUTHENTICATION Times

The Official magazine of The Authentication Solution Providers' Association (ASPA)

"Code of Confidence: Navigating the Shadows of Counterfeit Pharmaceuticals – A Deep Dive into Challenges and Remedies"

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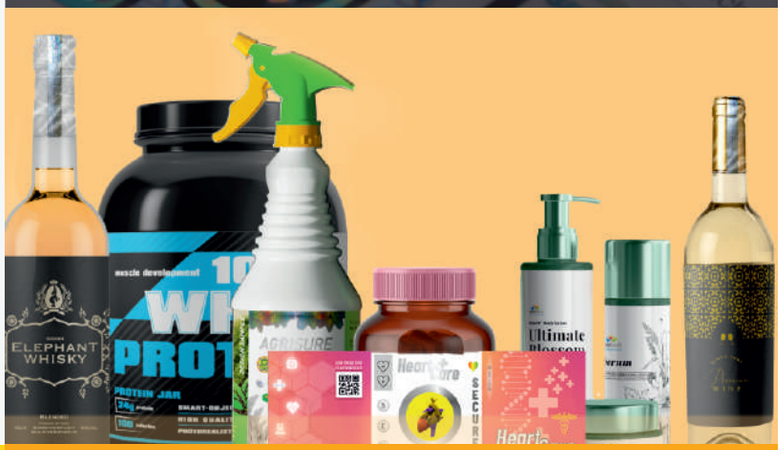

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The AUTHENTICATION Times

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Editor's Corner

Dear Readers

Welcome to the 48th edition of The Authentication Times. In this issue, we delve deep into the persistent challenges of counterfeiting within the pharmaceutical industry, offering a comprehensive overview alongside the Department of Pharmaceuticals, Government of India's insightful year-end review. Witness a new era in pharmaceutical exports unfold as DGFT extends the Track and Trace deadline, presenting the latest industry developments.

Our cover story invites you on a captivating journey into the intricate realm of counterfeit pharmaceuticals. Explore the challenges faced by the industry and discover effective remedies that promise to reshape its landscape. A significant milestone unfolds in this edition as we spotlight ASPA, commemorating 25 years of relentless dedication to advancing authentication and traceability since its inception on January 12, 1998. ASPA, the Authentication Solution Providers' Association, stands at the forefront of industry fortification through groundbreaking collaborations with esteemed organisers. These collaborations aim not only to strengthen the industry but also to provide immense benefits to ASPA members.

Our recently added section, ASPA Members Update, offers a glimpse into our esteemed member companies' latest accomplishments and contributions. Also, welcome our recently joined members: Omet India Pvt Ltd, Krriyan Kontainers Pvt Ltd, Fasiculus India Pvt Ltd, VCQRU Pvt Ltd and Inexto India Pvt Ltd.

Thank you for being part of this enriching journey. Enjoy the read!

I hope you find this issue informative and exciting, and as always, I look forward to receiving your feedback.

Yours Sincerely,

Puneet Maithani
Editor,
The Authentication Times

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About the Authentication Times

The Authentication Times is the official magazine published by Authentication Solution Providers' Association (ASPA). The publication offers in-depth analysis, news, research, article, and expert opinion on the latest developments on Anti-counterfeiting, Brand Protection, Serialization and Traceability in and out of India. The editorial team welcomes news, contributions, and comments.

For further information, subscriptions, contributions and advertisement, please email your submission at vikram@aspaglobal.com or call at +91 7838208944

Pharmaceuticals and Food Anti-Counterfeiting Technologies Market Insights:

The Pharmaceuticals and Food Anti-Counterfeiting Technologies Market, valued at USD 186.57 Billion in 2022, is projected to reach USD 340.25 Billion by 2030, with a 7.8% CAGR from 2023 to 2030. The industry's growth is driven by factors like workability, structural stability, and demand for improvement, with considerations like analysis, purchasing volume, costs, pricing analysis, and regulatory frameworks playing significant roles. This market is crucial for preventing counterfeit drugs and ensuring public health safety.

The COVID-19 pandemic initially impacted the market negatively, but it rebounded post-pandemic, driven by increased industrial manufacturing processes and rising demand for environmentally friendly alternatives.

Key technologies include Authentication, Trace, and Track applications in Food and Pharmaceuticals. The competitive landscape analysis focuses on key players, considering research and development, product innovation, business strategies, and application releases. Geographically, the market spans Asia Pacific, Europe, North America, the Middle East, Africa, and Latin America.

Critical trends include industry-to-industry dominance, micro-market analysis based on growth patterns, regional demand-driven growth, and increasing adoption in the sector. Higher growth rates are expected in specific regions over the forecast period.

**Source:https://marketresearchcommunity.com/pharmaceuticals-and-food-anti-counterfeiting-technologies-market/*

Year-end review of the Department of Pharmaceuticals, Government of India

In 2023, the Department of Pharmaceuticals implemented various programs and initiatives. A major initiative of the Government of India 'Pradhan Mantri Bhartiya Janaushadhi Pariyojana' has achieved its target of opening 10000 retail outlets to provide quality generic medicines at affordable prices to the poor and underprivileged and PLI scheme to strengthen India's manufacturing capacity in the pharmaceutical sector by increasing investment and production.

The Production Linked Incentive (PLI) Scheme for Medical Devices, with a Rs.3420 crore outlay from 2020-21 to 2027-28, aims to boost domestic manufacturing. Managed by IFCI Ltd., it covers four segments and offers a 5% incentive on incremental sales over five years. As of September 2023, 26 applications have been approved, reflecting an investment commitment of Rs.1,330.44 crore and 7,950 employment opportunities.

The Pharmaceuticals PLI Scheme, with a Rs.15,000 crore outlay from 2020-2021 to 2028-29, enhances manufacturing capabilities. SIDBI oversees it, selecting 55 applicants with a committed investment of Rs.17,275 crore. As of September 2023, Rs.25,813 crore has been invested, generating employment for 56,171 individuals.

The Strengthening of Pharmaceutical Industry (SPI) Scheme, with a Rs.500 crore outlay from FY 21-22 to FY 25-26, supports Pharma clusters and MSMEs. SIDBI manages sub-schemes like API-CF, PTUAS, and PMPDS. As of November 30, 2023, API-CF received 20 applications, with 17 found eligible. PTUAS has two approved projects for capital subsidy on loans. PMPDS completed eight studies, with six under finalisation.

These schemes reflect the government's commitment to fostering growth, innovation, and self-reliance in medical devices and pharmaceuticals, building a robust domestic manufacturing ecosystem.

**Source: PIB Delhi*

Anti-Counterfeiting - Initiatives

Govt: Drugmakers must ensure good manufacturing practices

The Indian government has issued comprehensive guidelines mandating that all drug manufacturers adhere to stringent good manufacturing practices (GMP). This move comes in response to mounting complaints regarding the export of substandard medicines, and it underscores the government's commitment to ensuring the production of high-quality pharmaceuticals. The new guidelines, incorporated into the updated Schedule M of the Drugs and Cosmetics Act of 1940, hold manufacturers responsible for the quality of their products. Manufacturers must ensure that their products are fit for their intended use, comply with licensing requirements, and do not pose risks to patients due to safety, quality, or efficacy issues.

One of the key provisions in the updated guidelines is the requirement for pharmaceutical firms to conduct stability testing of drug substances. This testing must align with recommended climate conditions, aiming to bring small and medium enterprises in line with global standards. The revised regulations also stipulate that the release of finished products is contingent upon the satisfactory results of these stability tests. Additionally, manufacturers must inform drug licensing authorities about any recalls and report product defects, deterioration, or faulty production.

Experts from the pharmaceutical industry have welcomed these measures, emphasising their potential to enhance the drug quality management ecosystem. Sudarshan Jain, Secretary General of the Indian Pharmaceutical Alliance, a prominent lobby group, stated that the revised regulations would promote compliance with international quality standards. He noted that the focus on risk management, equipment validation, and self-inspection would contribute significantly to ensuring the manufacturing of safe, effective, and high-quality drugs. To facilitate a smooth transition from the existing rules to the revised ones, the health ministry has provided six to 12 months for large manufacturers (with turnover exceeding ₹250 crore) and smaller firms (with turnover less than ₹250 crore). This transitional period allows companies to adapt their operations and processes to align with the updated guidelines without undue disruptions to manufacturing activities.

Good manufacturing practices, or GMP, are mandatory quality standards encompass control over materials, methods, machines, processes, personnel, and facilities, among other factors. These practices were first incorporated into Schedule M in 1988, and the most recent amendment took place in June 2005. With approximately 10,500 drugmakers, India plays a crucial role in the global pharmaceutical market. Out of these, around 8,500 are categorised as small and medium companies. The country is a significant exporter of medicines to low and middle-income countries, necessitating adherence to safe manufacturing certification requirements.

The Central Drugs Standard Control Organisation (CDSCO) has intensified inspections of manufacturing units and testing labs, uncovering issues like poor documentation, lack of validation, absence of self-assessment, and inadequate testing of raw materials. Approximately 2,000 small and medium companies currently possess the necessary certification.

In 2018, a draft notification aimed to upgrade Schedule M in alignment with international standards. The revised rules introduce vital changes, including a Pharmaceutical Quality System, Quality Risk Management, Product Quality Review, equipment qualification and validation, change of control management, self-inspection, quality audit teams, supplier audit and approval, stability studies, and computerised system validation. These guidelines significantly elevate the quality and safety of pharmaceuticals produced in India, aligning them with global standards. The government's phased implementation approach provides manufacturers the necessary adaptation time, facilitating a smooth transition to these updated and rigorous regulations.

**Source : Hindustan Times*

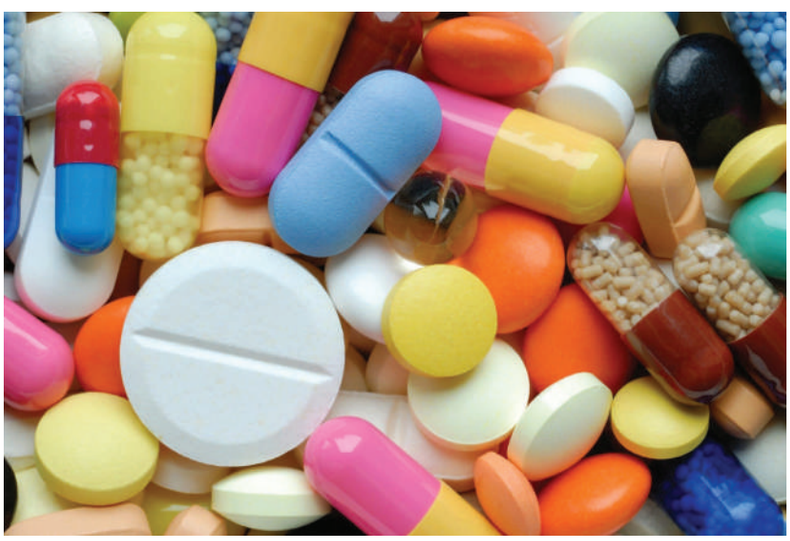
"DGFT Extends Track and Trace Deadline, Unveiling a New Era in Pharma Exports"

The Directorate General of Foreign Trade (DGFT) has extended the implementation deadline for the Track and Trace system, a significant development for the pharmaceutical export sector. This extension, highlighted in Public Notice No. 39/2023, dated February 2, 2024, now sets the February 1, 2025 deadline. Here's a breakdown of the key points:

Focus of Track and Trace System: The system ensures transparency and accountability in drug exports by maintaining parent-child relationships throughout the supply chain at packaging levels.

- **Incorporation of Small-Scale Industries (SSI):** The extension applies universally to both SSI- and non-SSI-manufactured drugs.
- **Strategic Move by Industry:** Industry experts view the extension as strategic, affording manufacturers time to integrate necessary technological infrastructure for compliance.
- **Amendment Overview:** The amendment affects Para 2.76 (vi) and (vii) of Handbook of Procedure - 2023, emphasising meticulous attention to packaging relationships.
- **Government's Commitment:** The decision reflects dedication to supporting industry growth and ensuring India's global pharmaceutical prominence.

As the pharmaceutical sector adapts to this extended timeline, the emphasis on quality control and traceability in drug exports is expected to strengthen India's position as a reliable player in the global pharmaceutical landscape.



"Manoj Kochar, President of the Authentication Solution Providers' Association (ASPA), said, India has strong authentication eco-systems and Indian pharmaceutical brands actively employ various anti-counterfeiting measures. These measures include physical security features such as tamper-evident packaging, holograms, security inks, and destructible labels. The industry also uses digital technologies, including unique serial numbers, barcodes, QR codes, SMS-based authentication, and mobile authentication apps are also being utilised.

This extension is crucial for pharmaceutical manufacturers as it provides them with more time to integrate advanced and new-generation authentication and traceability technologies. As an industry association, ASPA supports the government and industry in these initiatives and aims to foster a technologically robust and compliant pharmaceutical export ecosystem in India. We believe this move will enhance India's global standing in pharmaceutical traceability and authentication solutions."

- Mr. Manoj Kochar, President - ASPA

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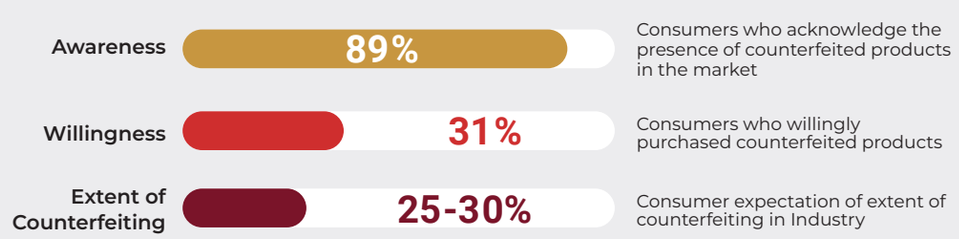
"Code of Confidence: Navigating the Shadows of Counterfeit Pharmaceuticals – A Deep Dive into Challenges and Remedies"

In a recent joint effort by the Authentication Solution Provider's Association (ASPA) and CRISIL, a report sheds light on the profound impact of counterfeiting on India's major sectors. The report, derived from an extensive survey spanning twelve key cities, including Delhi, Mumbai, Kolkata, and Bengaluru, highlights the pervasive nature of counterfeiting, impeding the sustainable growth of crucial industries such as Pharmaceuticals, FMCG, Automotive, Apparel, Consumer Durables/Electronics, and Agro Products.

Pharmaceutical Industry Challenges: India's pharmaceutical industry, renowned globally and ranking 3rd in volume and 14th in value, faces unique challenges. Despite its status as a major producer of generic medicines, the sector grapples with difficulties in implementing organised supply chains on a national scale. Factors such as poor supply networks, inadequate healthcare services, and high medicine costs contribute to the industry's struggles and create opportunities for counterfeiting to flourish.

Consumer Survey Insights:

Consumer survey data shows counterfeiting extent at 25-30% of the market



Industry Overview: CRISIL MI&A data underscores the pharmaceutical industry's vitality, valued at Rs 3,136 billion in FY2021, with projections anticipating growth to Rs 3,607 billion in FY2023-2024. The sector's vibrancy attracts counterfeit activities due to supply-demand gaps, leakages in supply chains, and other vulnerabilities.

Impact of Counterfeiting: The high volumes and value of pharmaceutical products make them susceptible to counterfeiting in this vibrant sector. A supply shortage and the elevated costs of medicines create an environment ripe for counterfeiting in India's pharmaceutical industry. The ASPA and CRISIL consumer survey reveals that 25% of respondents opt for counterfeit medicines due to affordability and the unavailability of authentic products.

Consumers who have willingly purchased at least once counterfeited products	
Pharmaceutical	25%
FMCG/ Packaged Goods	42%
Automotive Parts	36%
Apparel	37%
Consumer Durables/ Electronics	33%
Agro-Chemicals	35%

Note: Pharmaceutical products here refer to all healthcare products such as medicines, medical devices, OTC drugs, OTC consumables such as bandages, cotton, ear buds, etc.

Source: CRISIL – ASPA report on the state of counterfeiting in India

Over the years, India's pharmaceutical industry has grappled with counterfeiting issues. Counterfeit products, always inferior in quality and safety, pose an unpredictable risk to public health. This erodes trust in medicines, healthcare professionals, and the healthcare system. The lack of organised supply chains, unavailability of originals, and high product costs contribute to the prevalence of counterfeit drugs in the pharmaceutical industry.

The survey further underscores the critical nature of counterfeiting in the pharmaceutical sector, where the rise in cases of fake brands and products has become alarming. Unlike other sectors, the consequences of counterfeiting in pharmaceuticals may have life-or-death implications. Respondents cite affordability and unavailability of genuine products as the driving factors behind their inclination towards counterfeit pharmaceuticals, emphasising the urgent need for robust authentication solutions and stringent measures to safeguard public health. As we delve into the shadows of counterfeit pharmaceuticals, it becomes evident that developing a robust 'Code of Confidence' is imperative for the industry's future.

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* Thermal Transfer Ribbons
* Track & Trace Solutions
* Technical Support

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ASPA: Celebrating 25 Years of Advancing Authentication & Traceability (01/12/1998-01/12/2023)

Over the years, ASPA has achieved significant milestones, including the merging of HoMAI's Hologram Roster with the International Hologram Manufacturers' Hologram Image Register (HIR) in 2010, resulting in a global unified registry of security holograms produced worldwide. The formation of the pioneering "Hologram Safety and Security Management Standards (HSSMS)" in 2011 marked a transformative moment, leading to the organisation's evolution from a hologram producers' association to an authentication solution providers' association in 2014.

Thus, HoMAI was re-incarnated as the Authentication Solution Providers' Association (ASPA). Noteworthy events include ASPA's role as a committee member at FICCI-CASCADE, hosting India's first global holography conference in 2013, and organising The Authentication Forum, India's inaugural Leadership Summit on Anti-Counterfeiting and Brand Protection, in collaboration with Messe Frankfurt India (MFI) in 2017. ASPA continues its impactful journey with subsequent Leadership Summits and plans for Traceability and Authentication Forum events. As ASPA marks 25 years of existence, the organisation remains steadfast in its commitment to combating counterfeiting and promoting a secure authentication ecosystem.

"ASPA's Dynamic Role at the PHDCCI- Medical Devices, Pharma & Healthcare Supply Chain Summit"

The PHD Chamber of Commerce and Industry recently organised the "Medical Devices, Pharma & Healthcare Supply Chain'' Summit on February 17, 2024, at PHD House, New Delhi. An event of considerable significance drew industry experts, with the Authentication Solution Provider Association (ASPA) as a Supporting Partner. **Mr. Ankit Gupta, Vice President of ASPA**, contributed to the insightful panel discussions, sharing his perspectives on counterfeiting aspects.

During the discussion, Mr. Ankit Gupta highlighted the pivotal role of ASPA and its member companies in providing comprehensive Authentication and Traceability solutions. Emphasising collaboration as a vital conference theme, he commended the focused dialogue on this crucial aspect. Mr Ankit expressed satisfaction with the collaborative approach, aligning with ASPA's internal unity and collective strength ethos. He referred to the organisation's belief in the philosophy of **"ek aur ek gyarah," emphasising that collaboration should not be a competition (A vs. B) but a synergistic alliance (A + B)**.

Mr. Ankit Gupta shed light on the challenges posed by counterfeiters, noting their comfort with breaking the law to deceive consumers. He stressed the continuous need for innovation and collaboration as countermeasures against the evolving tactics of counterfeiters. The acknowledgement that counterfeiters are aware of their illegal activities implies that the industry must stay one step ahead through constant evolution and collaboration. One of the key takeaways from Mr. Ankit's address was the necessity for an industry-wide commitment to innovation and collaboration. He stressed that the industry's response must be equally dynamic in a world where counterfeiters continuously exploit legal boundaries. By sharing insights and resources, the industry can form a united front against counterfeiting, ensuring fraudulent products do not deceive consumers.

As highlighted by Mr. Ankit Gupta, ASPA's key focus areas align with the organisation's commitment to combating counterfeiting. By providing Authentication and Traceability solutions, ASPA aims to fortify the healthcare supply chain and ensure the authenticity of medical devices and pharmaceuticals. The emphasis on collaboration at the summit reinforces the idea that collective efforts are indispensable in the fight against counterfeiting.

In conclusion, Mr. Ankit Gupta's participation in the summit exemplifies ASPA's proactive approach to industry challenges. By actively engaging in discussions, sharing expertise, and promoting collaboration, ASPA contributes to the continuous evolution of strategies against counterfeiting. The Medical Devices, Pharma & Healthcare Supply Chain Summit served as a platform for industry leaders to unite in their commitment to innovation and collaboration, essential elements in safeguarding the integrity of the healthcare supply chain.

ASPA & IPAMA Present a Technical Seminar on Authentication, Traceability & Secure Sustainable Packaging on 15th March 2024 during IntraPac India 2024

Let's delve into these exciting ventures:

- **PharmaMED HD 2024 (8th Edition):** Joining forces with the Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India, and PHD Chamber of Commerce, ASPA actively contributed to the 8th Edition of PharmaMED HD 2024, a landmark event shaping the future of pharmaceuticals.
- **PackTech Asia 2024:** Unleashing Innovation: In collaboration with the PHD Chamber of Commerce and Industry (PHDCCI) and with the support of the Ministry of Commerce, Govt. of India, ASPA is gearing up for PackTech Asia. This event, slated from March 21 to 23, 2024, at the vibrant Regale Park in Greater Kailash, Jammu, promises to be a melting pot of the latest Packaging Technologies and RBSM (Regulatory, Branding, Sustainability, and Marketing).
- **PackVision Expo 2024:** Pioneering Packaging Technologies: Future Market Events presents PackVision Expo, where ASPA is set to showcase the forefront of packaging innovations. Scheduled from 13 to 15 June, 2024, in the bustling city of Pune, this event is a testament to ASPA's commitment to pushing the boundaries of authentication and traceability solutions.
- **Global Brand Security Summit 2024:** Mark your calendars for the Global Brand Security Summit, organised by Mindcraft Global, in Munich, Germany, from May 22 to 23, 2024. ASPA's active participation underscores its dedication to setting global standards in brand security and combating counterfeiting.
- **ASIA Security Conference and Exhibition:** On July 23 and 24, 2024, ASPA is a proud participant in the ASIA Security Conference and Exhibition, a cutting-edge event hosted by ASIAS SECURITY GROUP SDN. This promises to be a pivotal gathering exploring new horizons in security solutions.
- **Anuga FoodTec India 2024:** ASPA's collaboration extends to the 18th edition of Anuga FoodTec India 2024, set to take place from August 28 to 30, 2024, in the vibrant city of Mumbai. Organised by Koelnmesse Pvt. Ltd., this event will showcase the latest advancements in food technology, aligning with ASPA's commitment to ensuring the integrity and security of the food supply chain.

These collaborations exemplify ASPA's proactive approach to fostering innovation, promoting security, and championing cutting-edge solutions in pharmaceuticals, packaging, brand security, security services, and food technology. ASPA continues to be a driving force, navigating the industry toward a future of enhanced security and technological excellence. Stay tuned for more exciting developments as ASPA continues to shape the landscape of authentication and traceability solutions.

Big News! ASPA Partners with TechSci Research for Pharmaceutical webinar!

Gear up for an insightful webinar in April, unravelling the theme - PharmaGuard: Navigating Counterfeiting Challenges in the Pharmaceutical Supply Chain. Stay tuned for the date and time on the ASPA website.

Join us for a game-changing event, combating counterfeiting challenges in the Pharmaceutical Industry. visit www.aspaglobal.com for updates. Get ready to redefine excellence!

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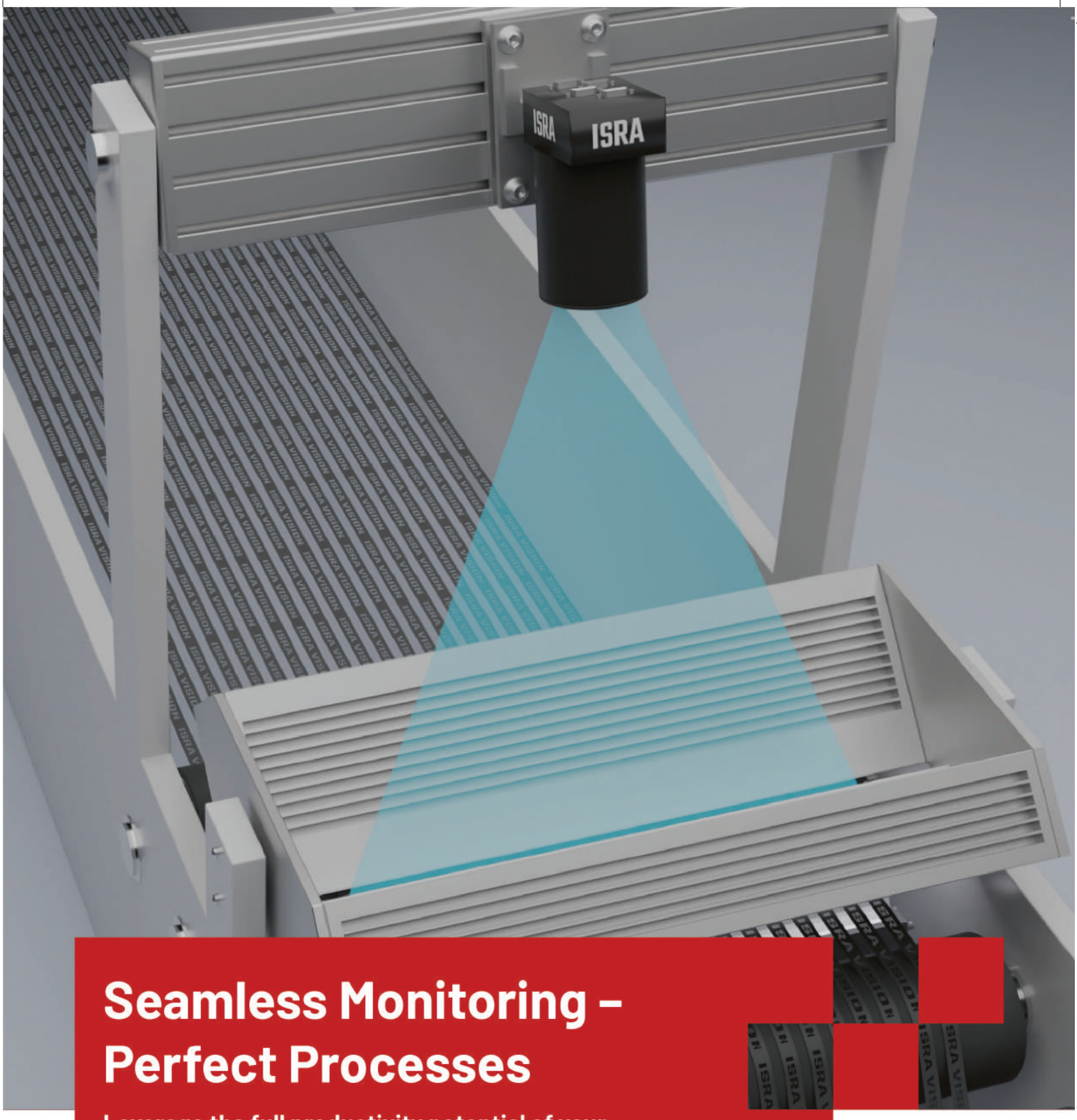
ASPA Members update:

- The company installs an HP Indigo 6k brand protection plus digital press at its facility in Chennai to meet the growing demand in the FMCG sector.
- PharmaSecure proudly received the GS1 India award for Implementation of Standards-based Solutions in 2023, recognising their outstanding work on domestic and export serialisation mandates within the pharmaceutical industry.



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Holographic & UV Packaging Films

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