



- **The EU's 'Pharma Package' approaches adoption: What will change for market access and supply security?**
- **Thailand reforms its *Electronic Transactions Act*: Building the legal framework for digital transactions**
- **A serving of clarity: The Court of Justice of the EU dishes out clarifications on EU rules related to health claims on food**
- **Recently adopted EU legislation**

The EU's 'Pharma Package' approaches adoption: What will change for market access and supply security?

By Florette Peter, Paolo Vergano, and Tobias Dolle

On 28 September 2026, the Council of the EU (hereinafter, Council) adopted the so-called *Pharma Package*, which primarily consists of two legislative proposals: the draft *Directive on the Union code relating to medicinal products for human use, and repealing Directives 2001/83/EC and 2009/35/EC* (hereinafter, draft Directive) and the draft *Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulations (EC) No 1394/2007 and (EU) No 536/2014 and repealing Regulations (EC) No 141/2000, (EC) No 726/2004 and (EC) No 1901/2006* (hereinafter, draft Regulation). In December 2025, the Council and the European Parliament had reached an agreement on the two legal acts, which, *inter alia*, simplify the authorisation process for medicines and establish new rules governing medicines placed on the EU market.

This article examines some of the key changes, notably to data protection and market access conditions, provides an overview of the new provisions on the availability of key medicines, and discusses the related commercial implications for businesses.

The long-awaited reform enters its final legislative stage

On 26 April 2023, the European Commission (hereinafter, Commission) had initiated the first comprehensive overhaul of the EU's regulatory framework for pharmaceuticals in more than two decades, publishing its proposals for the draft Directive and draft Regulation. Following extensive inter-institutional negotiations with the European Parliament and the Council, agreement was reached in December 2025. Seeking to achieve "a careful balance between the needs of patients and the importance of maintaining a strong and innovative pharmaceutical industry in Europe", the *Pharma Package* will replace and consolidate the existing regulatory framework governing medicinal products for human use, which is currently largely set by *Directive 2001/83/EC on the Community code relating to medicinal products for human use*, including their authorisation and supervision, as well as by *Regulation (EC) No 726/2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency*. Specific rules concerning paediatric and orphan medicines (i.e., pharmaceutical products developed specifically to diagnose, prevent, or treat rare, serious, or life-threatening conditions that affect

only a small portion of the population) are integrated into the draft Regulation (see *Trade Perspectives*, Issue No. 13 of 30 June 2025).

The agreement diverges from the Commission's proposals on several significant points. Most notably, the EU co-legislators agreed to increase to eight years the data protection period for new medicines and to revise the conditions for obtaining additional protection. The agreement also foresees the introduction of further safeguards governing incentives for the development of new antimicrobials, extends the '*Bolar exemption*' to cover participation in public procurement tenders, and establishes a mechanism allowing EU Member States to require sufficient supplies of certain medicines to meet national patient needs.

A compromise between innovation and competition

One of the reform's most significant changes concerns the regulatory protection granted to innovative medicines against competition from generics and biosimilars. Under Articles 83 and 84 of the draft Directive, pharmaceutical companies would benefit from eight years of regulatory data protection, during which generic and biosimilar manufacturers may not rely on the original medicines' clinical and preclinical trial data to obtain a marketing authorisation for their own products, followed by one year of market protection, during which manufacturers may obtain a marketing authorisation based on the original medicines' regulatory dossiers, but may not actually place their products on the market. This reduces the combined protection period from the current ten years to nine.

An additional year of market protection may be granted for "*medicinal products addressing an unmet medical need*", where "*at least one of its therapeutic indications relates to a life threatening or severely debilitating disease*" for which no medicine is authorised in the EU, or where the medicine offers a clinically relevant improvement in efficiency or safety, compared to existing treatments. Alternatively, pharmaceutical companies developing medicines containing a new active substance may also obtain an additional year of protection by conducting comparative clinical trials in multiple EU Member States or prioritising the EU when applying for a marketing authorisation, namely by filing in the EU first or within 90 days of the first application elsewhere. Where comparative trials are not feasible or appropriate, both conditions must be met. Companies may secure a further year of protection by obtaining approval for a new therapeutic indication offering significant clinical benefits over existing treatments, bringing the total protection period to a maximum of 11 years.

The reform further aims at encouraging the development of priority antimicrobials, whose commercial returns are often limited by the need to restrict their use to prevent antimicrobial resistance. Under Articles 41 and 42 of the draft Regulation, pharmaceutical companies developing qualifying antimicrobials may receive a transferable data exclusivity voucher granting an additional year of regulatory data protection. The voucher may be used for the antimicrobial itself, for another eligible medicine in the company's portfolio, or be transferred to another pharmaceutical company. However, its use for other medicines is subject to certain restrictions, including a EUR 490 million annual EU sales ceiling during the first four years following marketing authorisation.

The reform also expands the scope of the '*Bolar exemption*', which allows manufacturers of generic and biosimilar medicines to prepare for market entry before the original medicine's patent or supplementary protection certificate expires, referring to an intellectual property right that extends patent protection for a medicinal product by up to five additional years in the EU, without infringing those intellectual property rights. Under Article 85 of the draft Directive, manufacturers will be able to undertake preparatory activities before the expiry of the original medicine's patent or supplementary protection certificate, including obtaining marketing authorisations, completing pricing and reimbursement procedures, and participating in public procurement tenders. As manufacturers are currently limited to conducting studies and trials, the new provisions would allow faster market entry once the applicable protection periods expire and increase competition.

National and supply security objectives

The reform also addresses disparities in access to medicines across EU Member States. Under Article 59 of the draft Directive, EU Member States may require marketing authorisation holders to make protected medicines available in sufficient quantities to meet national patient needs. In this context, EU Member States may request companies to submit national pricing and reimbursement applications, participate in public procurement procedures, or establish a national roll-out plan, which describe “*the quantities and timing of supply of the medicinal product for a defined period of time taking into account the supply needs declared by the Member State and other objective considerations such as manufacturing or distribution capacity*”. Where a company fails to comply within three years of the formal request, regulatory market protection may cease to apply in the EU Member State concerned. However, under Article 169(5) of the draft Directive, where the loss of market protection allows generic and biosimilar medicines to enter the market of one EU Member State, those new medicines may not subsequently be exported to the EU Member States where the original medicine remains protected. In this regard, Recital 70 of the draft Directive expressly recognises that national measures intended to ensure medicine availability must comply with the fundamental freedom of free movement of goods and competition rules guaranteed under Articles 34 and 35 of the TFEU.

At the EU level, the reform will establish a formal legal framework for the [Union list of critical medicines](#), operational since December 2023 and last updated in January 2026. Medicines on this list are prioritised for coordinated measures to identify supply-chain vulnerabilities, prevent shortages, and address dependencies on non-EU suppliers.

Way forward

The forthcoming adoption of the legal instruments under the *Pharma Package* will have significant implications for pharmaceutical companies operating in the EU and those seeking to enter the EU market. The European Parliament is expected to formally approve the draft Regulation and draft Directive at its plenary session during the week of 23 November 2026. Following adoption by the European Parliament, both legislative acts will need to be published in the *Official Journal of the European Union* and will enter into force twenty days after publication, with a transition period of two years before the Regulation becomes applicable and for Member States to transpose the Directive into national law.

For any additional information or legal advice on this matter, please contact Tobias Dolle

Thailand reforms its *Electronic Transactions Act*: Building the legal framework for digital transactions

By Alya Mahira, Pattranit Chantaplaboon, and Paolo R. Vergano

On 29 September 2026, Thailand’s Cabinet approved the *Draft Electronic Transactions Act*, which would repeal and replace the existing *Electronic Transactions Act B.E. 2544*, as amended. The *Draft Electronic Transactions Act* aims at modernising Thailand’s electronic transactions framework, promoting confidence in electronic-based transactions, and aligning domestic rules with international standards.

This article provides an overview of Thailand’s electronic transactions framework and of the *Draft Electronic Transactions Act*, reviews relevant developments in the *Association of Southeast Asian Nations* (hereinafter, ASEAN), and highlights key implications for businesses.

Overview of Thailand’s electronic transactions framework

The *Electronic Transactions Act B.E. 2544*, which has been in force since 2002, is Thailand’s primary legal framework for electronic transactions between private parties, as well as for

certain transactions related to State operations (e.g., government approvals, registrations, orders, and payments). Article 4 of the *Electronic Transactions Act B.E. 2544* defines 'electronic transaction' as "a transaction in which an electronic means is used in whole or in part". The *Electronic Transactions Act B.E. 2544* recognises the legal effect of electronic data, documents, signatures, contracts, and digital identity proofing and authentication, subject to the prescribed requirements outlined in relevant subordinate legislation. The *Electronic Transactions Act B.E. 2544* also prescribes liabilities and penalties for non-compliance by electronic transaction service providers, though it does not expressly define the covered service categories.

Despite having been amended three times, most recently in 2019, the *Electronic Transactions Act B.E. 2544* has not kept pace with developments in electronic transactions, such as electronic transferable records and related services. In addition, the *Electronic Transactions Act B.E. 2544* does not reflect the principles embodied in the relevant *United Nations Commission on International Trade Law* (hereinafter, UNCITRAL) model laws, such as those governing *Electronic Transferable Records (2017)* and the *Use and Cross-border Recognition of Identity Management and Trust Services (2022)*. To address these shortcomings, the *Strategic Transformation Office*, under the Office of Thailand's Prime Minister, prepared the *Draft Electronic Transactions Act*.

Key reforms

The *Draft Electronic Transactions Act* would broaden the scope of the regulatory framework to all electronic transactions, including those between private parties and those involving government entities. Notably, the *Draft Electronic Transactions Act* would promote electronic transactions as the primary, though not mandatory, alternative to paper-based transactions, strengthening Thailand's transition towards a paperless economy. The *Draft Electronic Transactions Act* foresees to consolidate and clarify the existing regulatory framework, expressly recognising electronic seals, electronic stamp duties, and automatically concluded contracts that meet prescribed requirements set out in subordinate legislation.

There are two major reforms under the *Draft Electronic Transactions Act*: Firstly, the *Draft Act* recognises electronic transferable records as having the same legal effect of their paper equivalents, with rules on the control, delivery, endorsement, amendment, and conversion between electronic and paper forms, consistent with *UNCITRAL's Model Law on Electronic Transferable Records*. Secondly, the *Draft Act* clarifies seven categories of electronic transaction services and prescribes the duties and responsibilities of such services' providers. These seven categories of electronic transaction services are: 1) Identity proofing or authentication services; 2) Electronic signature services; 3) Electronic time-and-date-stamping services; 4) Electronic-data receipt, transmission or storage services; 5) Website or domain-name registration or certification services; 6) Electronic transferable-instrument system services; and 7) Other services prescribed by ministerial regulation.

Reflecting the principles provided by *UNCITRAL's Model Law on Use and Cross-border Recognition of Identity Management and Trust Services*, providers are to use reliable methods throughout their services, and to comply with risk-based minimum standards to be prescribed by the *Electronic Transactions Development Agency* under Thailand's Ministry of Digital Economy and Society. The *Draft Electronic Transactions Act* introduces a certification scheme for providers of six specified electronic transaction services and for any additional services prescribed by ministerial regulation, which appears to replace the existing licensing regime for these specified services. However, the specific rules and implementation measures have yet to be provided in subordinate legislation. According to a [statement](#) by the Deputy Spokesperson of the Thai Government, "a total of 26 pieces of subordinate legislation have been prepared, comprising two royal decrees, three ministerial regulations, and 21 notifications".

ASEAN's path towards a digital economy

ASEAN is advancing regional digital economic integration through the forthcoming *ASEAN Digital Economy Framework Agreement* (hereinafter, DEFA), which aims at complementing the existing ASEAN electronic commerce initiatives and aligning ASEAN Member States' digital regulatory frameworks. In September 2023, ASEAN Member States launched negotiations for the ASEAN DEFA, covering, *inter alia*, digital trade, cross-border electronic commerce, payments and electronic invoicing, and digital identities and authentication. Reportedly, the ASEAN DEFA would require ASEAN Member States to maintain or endeavour to align their legal frameworks governing electronic transactions with the *UNCITRAL Model Law on Electronic Transferable Records*. According to the Secretary-General of ASEAN, Kao Kim Hourn, this includes “a wider use and recognition of electronic bills of lading, warehouse receipts, and other transferable records through interoperable standards”. The ASEAN DEFA is also expected to promote the cross-border use of digital identities, particularly through the development of an ASEAN Unique Business Identification Number (UBIN), and require ASEAN Member States to endeavour to ensure the cross-border interoperability of their respective electronic invoicing frameworks. The ASEAN DEFA was substantially concluded in May 2026 and is to be signed on the sidelines of the 49th ASEAN Summit, which will be held from 16 to 18 November 2026, in Manila, the Philippines (see *Trade Perspectives*, Issue No. 18 of 5 October 2026).

Thailand's *Draft Electronic Transactions Act* supports the prospective alignment with the ASEAN DEFA's objective of paper-less transactions. Notably, the *Draft Electronic Transactions Act* would align Thailand's framework for electronic transferable records with the internal standard reportedly reflected in the ASEAN DEFA, thereby ensuring a more consistent regional approach. Forthcoming pieces of subordinate legislation are expected to clarify relevant rules and procedures, including, *inter alia*, reliable methods for identity proofing and authentication. However, it remains unclear whether these instruments would address the cross-border recognition and interoperability reportedly referenced in the ASEAN DEFA. In turn, the ASEAN DEFA will soon provide the regional framework to guide the implementation of the *Draft Electronic Transactions Act*, including by promoting compatible standards, cross-border recognition, and interoperability across ASEAN, thereby strengthening trust in regional electronic transactions.

Implication for businesses

The forthcoming new *Electronic Transactions Act* is poised to enhance legal certainty for electronic transactions in Thailand, reducing paperwork, processing time, and cross-border trade costs. Following the legislative process, the *Electronic Transactions Act* will take effect 180 days after its publication in the Royal Thai Government Gazette.

For any additional information or legal advice on this matter, please contact Paolo R. Vergano

A serving of clarity: The Court of Justice of the EU dishes out clarifications on EU rules related to health claims on food

By Alya Mahira, Imelda Jo Anastasya, and Paolo R. Vergano

On 17 September 2026, the Court of Justice of the EU (hereinafter, CJEU) delivered its rulings in cases C-657/24 and C-721/24, both concerning the interpretation of *Regulation (EC) No 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods* (hereinafter, Nutrition and Health Claims Regulation, NHCR). In particular, the rulings clarify certain issues related to the distinction between the terms “labelling” and “advertising”, the type of statements that qualify as “health claims”, and the manner in which mandatory statements accompanying “health claims” and “reduction of disease risk claims” must be provided.

This article provides a brief overview of the NHCR, discusses the CJEU's rulings, and analyses their implications for food businesses making health claims.

The Nutrition and Health Claims Regulation

The NHCR, which applies since 1 July 2007, governs the use of nutrition and health claims in the labelling, presentation, and advertising of foodstuffs marketed in the EU. The NHCR establishes the rules that food business operators must comply with when making claims about the nutritional or health benefits of their products (see *Trade Perspectives*, [Issue No. 2 of 29 January 2024](#)). The rules aim at ensuring that health claims are “clear, accurate, and based on scientific evidence”.

According to Article 10(2)(a) of the NCHR, health claims must include “*in the labelling, or if no such labelling exists, in the presentation and advertising, a statement indicating the importance of a varied and balanced diet and a healthy lifestyle*”. Article 2(5) of the NHCR defines “health claims” as “any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health”, whereas Article 2(1)(d) defines “labelling” as “any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a foodstuff and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such foodstuff”. However, the NHCR does not provide for a definition of the term “advertising”.

A specific category of health claims under the NCHR concerns the “reduction of disease risk”, which Article 2(6) defines as “any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease”. Under Article 14(2) of the NHCR, such claims must be accompanied by a statement indicating that “the disease to which the claim is referring has multiple risk factors and that altering one of these risk factors may or may not have a beneficial effect”. These requirements are relevant to the CJEU’s judgments in cases C-657/21 and C-721/24, which address issues concerning the interpretation of Articles 2(1) and 10(2)(a), as well Articles 2(6) and 14(2) of the NHCR, respectively.

Case C-657/24: When the label speaks for the advertisement

In 2020, *Kyberg Pharma*, a German pharmaceutical and healthcare company, published an advertisement in print media, promoting a food supplement with the claims “*Lose weight the healthy way*” and “*Glucomannan helps you lose weight as part of a low-calorie diet*”. A German association dealing with unfair commercial practices (i.e., *Schutzverband gegen Unwesen in der Wirtschaft*) brought an action before the Munich Regional Court on the grounds that the advertisement made health claims without including a statement indicating “the importance of a varied and balanced diet and a healthy lifestyle”. The Munich Court ruled in favour of the association, finding that “labelling” also encompassed print media advertising, and ordered *Kyberg Pharma* to cease promoting the food supplement.

Kyberg Pharma appealed the decision to Germany’s Federal Court of Justice, arguing that “labelling” and “advertising” were distinct concepts and that, since the required statement was included on the product label, it did not need to be repeated in the advertisement. The Federal Court of Justice observed that the concept of “labelling” includes “any words and particulars relating to a food and placed not only on the packaging but also on any document included with or referring to such food”.

However, the Court was uncertain whether this definition also encompassed advertisements published in print media. Accordingly, it referred the matter to the CJEU for a preliminary ruling on whether print media advertisements constituted “labelling” and if not, whether the mandatory statement on “the importance of a varied and balanced diet and a healthy lifestyle” may be omitted from the advertisement where the statement is printed on the product label.

The CJEU held that print media advertising promoting a food supplement does not fall within the concept of “labelling” under Article 2(1) of the NCHR, as it serves a different purpose. The Court notes that “labelling” concerns the delivery of food to the final consumer, whereas

“advertising”, whether printed or audiovisual, concerns the promotion of the supply of food by the food business operator. This interpretation clarifies the scope of “labelling” under the NHCR and that, where the mandatory statement is included on the product label, Article 10(2)(a) of the NHCR does not require its repetition in print advertisements promoting the product.

Case-721/24: When dosage becomes a health claim

From October to December 2022, *Vista-Life*, a Belgian pharmaceutical company, published four advertisements for its food supplement *Vista-D3*. The advertisements included statements that daily consumption is preferable to taking a larger dose all at once and that sublingual administration (*i.e.*, placing the supplement under the tongue) was the “*preferred route of administration which offers a number of advantages over peroral administration: more rapid absorption helps in avoiding the first-pass effect in the liver and enzymatic degradation in the gastrointestinal tract*”.

On 9 December 2022, Belgian pharmaceutical companies *Laboratoires S.M.B.* and *Brussels Reps Pharma* brought an action for an injunction before the Brussels Business Court on the grounds that both statements constituted health claims, and that such claims failed to include a statement indicating that “*the disease to which the claim is referring has multiple risk factors and that altering one of these risk factors may or may not have a beneficial effect*”, as required by Article 14(2) of the NHCR. The Court ruled in favour of *Laboratoires S.M.B.* and *Brussels Reps Pharma* and ordered *Vista-Life* to cease promoting the food supplement.

Following an appeal by *Vista-Life*, the Brussels Business Court referred the matter to the CJEU for a preliminary ruling on whether statements concerning the frequency of intake and/or the method of administration of a food supplement constituted “*health claims*” and whether the mandatory statement accompanying reduction of disease risk claims must use the exact wording prescribed by Article 14(2) of the NHCR.

The CJEU ruled that *Vista-D3*’s statements relating to the frequency of intake or method of administration of a food supplement did indeed constitute health claims, more specifically “*reduction of disease risk claims*”, within the meaning of the NHCR, as they suggest that the relevant practice contributes to a beneficial effect on health and prevents or reduces an adverse effect on health that might result from a different frequency of intake or method of administration. Accordingly, such claims must be accompanied by the mandatory statement prescribed by Article 14(2) of the NHCR.

However, the CJEU clarified that *Vista-Life* is not required to reproduce the statement *verbatim*, provided that the wording used accurately, clearly, and understandably conveys the meaning required by that provision. The Court based its interpretation on the recitals of the NHCR, which require the Regulation to be read in conjunction with Article 7 of [Regulation \(EU\) No 1169/2011](#), mandating food information to be “*accurate, clear and easy to understand for the consumer*”, without prescribing a specific wording.

Implications for food businesses

The CJEU’s judgments in Cases C-657/24 and C-721/24 provide further clarity on the interpretation of the NHCR. On the one hand, the judgments confirm that mandatory statements need not be duplicated in advertising, when they already appear on a product’s labelling, and that the statement required under Article 14(2) of the NHCR need not reproduce the prescribed wording *verbatim*. On the other hand, the CJEU highlights the need for businesses to carefully assess their marketing claims and ensure compliance with the applicable requirements by confirming that statements concerning the frequency of intake or method of administration may constitute health claims, including reduction of disease risk claims.

Businesses should verify whether product descriptions contain phrases such as reference to dosage, which may constitute health claims, and ensure that the wording of the mandatory

statements, accompanying such reduction of disease risk claims, conveys the meaning prescribed by the NHCR.

For any additional information or legal advice on this matter, please contact Paolo R. Vergano

Recently adopted EU legislation

Trade Law

- *Regulation (EU) 2026/2269 of the European Parliament and of the Council of 7 October 2026 on temporary trade-liberalisation measures applicable to certain products originating in the Republic of Armenia*

Trade Remedies

- *Commission Implementing Regulation (EU) 2026/2245 of 8 October 2026 making imports of certain polyvinyl alcohols originating in the People's Republic of China subject to registration with a view to allowing the levy of anti-dumping duties on the imports subject to registration*

Customs Law

- *Commission Implementing Regulation (EU) 2026/2265 of 6 October 2026 concerning the classification of certain goods in the Combined Nomenclature*

Food Law

- *Commission Implementing Regulation (EU) 2026/2238 of 2 October 2026 amending Annexes XIII and XV to Implementing Regulation (EU) 2021/404 as regards the entries for Namibia in the lists of third countries or territories, or zones thereof authorised for the entry into the Union of consignments of fresh meat and meat products of certain ungulates*
- *Commission Implementing Regulation (EU) 2026/2228 of 14 October 2026 amending Implementing Regulation (EU) 2021/405 as regards the lists of third countries or regions thereof authorised for the entry into the Union of consignments of certain animals and goods intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council*

Alya Mahira, Florette Peter, Imelda Jo Anastasya, Joanna Christy, Paolo R. Vergano, Pattranit Chantaplagoon, and Tobias Dolle contributed to this issue.

Follow us on Bluesky [@fratinivergano.bsky.social](#)

To subscribe to *Trade Perspectives*®, please click [here](#). To unsubscribe, please click [here](#).

FRATINIVERGANO specialises in European and international law, notably WTO and EU trade law, EU agricultural and food law, EU competition and internal market law, EU regulation and public affairs. For more information, please contact us at:

FRATINIVERGANO – EUROPEAN LAWYERS

Boulevard Brand Whitlock 144, 1200 Brussels, Belgium. Telephone: +32 2 648 21 61, Fax: +32 2 646 02 70. www.fratinivergano.eu

Trade Perspectives® is issued with the purpose of informing on new developments in international trade and stimulating reflections on the legal and commercial issues involved. *Trade Perspectives*® does not constitute legal advice and is not, therefore, intended to be relied on or create any client/lawyer relationship.

To stop receiving *Trade Perspectives*® or for new recipients to be added to our mailing list, please contact us at TradePerspectives@fratinivergano.eu

Our privacy policy and data protection notice is available at <http://www.fratinivergano.eu/en/data-protection/>

