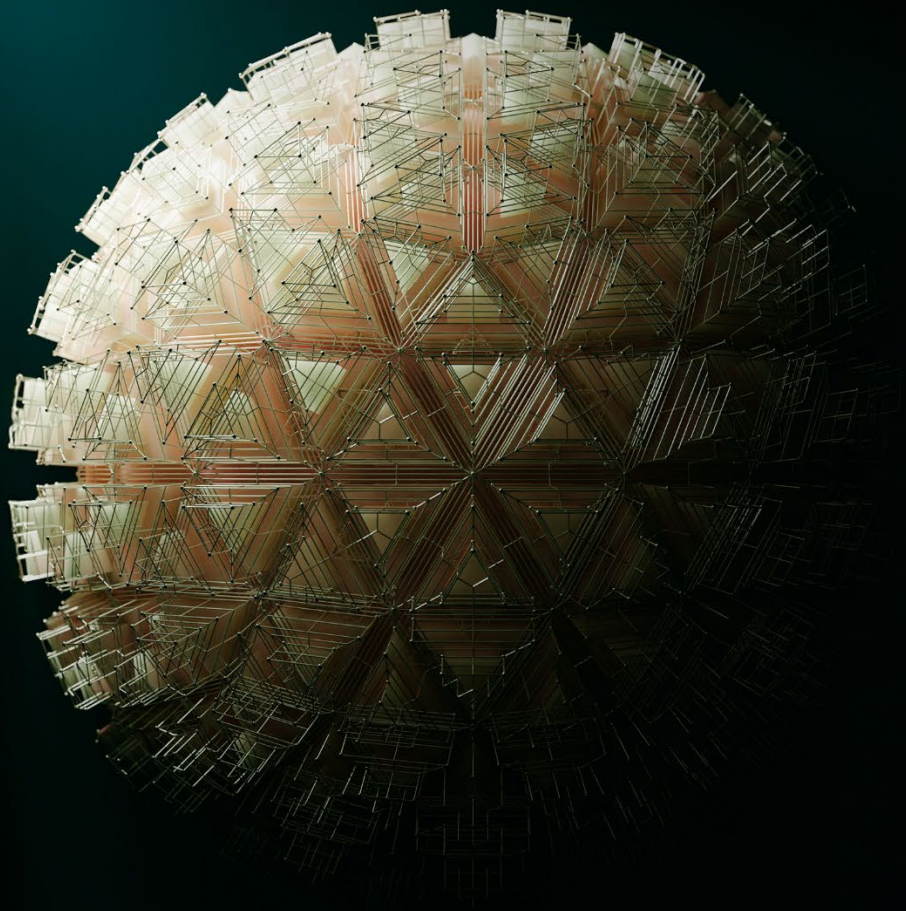
LIFE SCIENCES AT VINGE

Life Sciences Report 2025



VINGE

vinge.se

Life Sciences At Vinge

Europe's life sciences sector is being reshaped by ambitious investment and policy momentum, exemplified by the European Commission's strategy to make Europe the world's most attractive hub for life sciences by 2030. At the same time, the regulatory climate has tightened, with evolving legal frameworks for pharmaceuticals and medical devices, as well as for the use of data and AI systems.

Drawing on extensive experience, deep sector insight and Vinge's full-service business law offering, Vinge's Life Sciences Practice Group helps clients navigate rapid change with whatever expertise needed. We translate complex, shifting rules into clear, practical strategies – turning regulatory pressure into competitive advantage.

Vinge's Life Sciences offer spans not only core life sciences areas – such as pharmaceuticals, biotechnology, and medical devices – but also adjacent sectors. These include cosmetics, veterinary and animal health, food, beverages, and alcohol, as well as related industries like chemicals, nutrition, healthcare services, and digital health. This broad scope enables the firm to support clients across the full spectrum of regulated products and innovations.

This edition of the annually published Vinge Life Sciences Report distils some of the legislative reforms and regulatory developments that have shaped the sector over the past year and other selected topics of interest.

LIFE SCIENCES AT VINGE

Our End-to-End Offering

Concept & strategy

We advise on capital structure and financing arrangements. We draft and negotiate founder, partner, and investor agreements and shape early IP and data strategies. We chart regulatory pathways for pharmaceuticals and medical devices and establish collaboration frameworks with academia, incubators, CROs, etc.

R&D and IP Build

We structure core R&D agreements and safeguard patents, trade secrets, and other intellectual property from day one, including licensing of rights to provide a secure basis for R&D cooperation. We ensure compliant data use and robust AI governance.

Clinical trials

We draft and negotiate clinical trial agreements. We provide commercial and regulatory advice to ensure compliance with applicable legislation.

Authorisation & Commercialisation

We provide guidance on CE-marking and draft and negotiate commercial agreements, for example licensing, distribution, manufacturing, supply, and material transfer agreements. We support ongoing regulatory matters, including marketing, market access, pricing, reimbursement, labelling, and product information.

Post-Market and Exit

We support post-market surveillance and act as counsel in disputes, for example patent disputes and administrative proceedings relating to market access and pricing. We advise on the execution of strategic transactions and exits.

Contacts

Christoffer Nordin
Counsel
christoffer.nordin@vinge.se

Åsa Hellstadius
IP Expert, Doctor of Laws LL.D.
asa.hellstadius@vinge.se

VINGE

Contents

The EU's new legislative frameworks on data and AI

With the adoption of Regulation (EU) 2025/327 on the European Health Data Space ("**EHDS**"), Regulation (EU) 2023/2854 on harmonised rules for fair access to and use of data ("**Data Act**"), and Regulation (EU) 2024/1869 on harmonised rules for artificial intelligence ("**AI Act**"), the EU has introduced a comprehensive framework governing data and AI. Stakeholders in the life sciences sector within scope of these regulations must now ensure conformity with their respective requirements. This article provides an overview of these frameworks, and the cross-cutting obligations introduced.

EHDS

The EHDS entered into force on 26 March 2025 and will become fully applicable on 26 March 2027. The regulation improves access to health data for care delivery (primary use) and enables secure, trustworthy reuse of health data for research and innovation (secondary use). Given the scale of implementation work within the Member States, many obligations will apply after a phased rollout, with several taking effect four years after the regulation's entry into force.

A central pillar of the EHDS is the compliant electronic health record system ("**EHR**"), namely software intended for healthcare providers (and patients) to store, view, and exchange personal electronic health data. To place EHR systems on the EU market, manufacturers must ensure two core elements: an **interoperability component** (to enable the sharing of electronic health data with other software and devices) and a **logging component** (to ensure traceability of who has accessed the data). EHR systems must also meet requirements on technical documentation, information to users, and CE marking.

Wellness applications fall within scope where the manufacturer claims compatibility with EHR systems, whereas, in such cases, labelling obligations apply. For approved secondary uses, organisations may request access to electronic health data via a Health Data Access Body ("**HDAB**"). Upon request, data holders must provide the data subject to EHDS safeguards for intellectual property and trade secrets and may recover certain costs associated with making data available.

Data Act

Applicable since 12 September 2025, the Data Act aims to strengthen the EU's data economy and promote a competitive data market. It grants users of connected products and related services the right to access and share data generated by their use.

A connected product is a product that obtains, generates, or collects data concerning its performance, use, or environment, and that can communicate those data. Medical devices may therefore fall within scope if they meet this definition. The Data Act also covers related services, meaning a digital service that is necessary for the use of the product, improves it, or adds features. For example, an app connected to an insulin pump that enables users to track blood glucose levels would typically be a related service.

The Data Act establishes a framework under which users must be able to access certain data generated by connected products and related services. It also includes provisions requiring data to be shared with third parties upon the user's request.

AI Act

The EU's first comprehensive legal framework on AI will become fully applicable on 2 August 2026, with rules phased in beforehand. The AI Act follows a risk based approach where obligations vary according to the level of risk posed by an AI system, determined by its intended purpose as set by the provider.

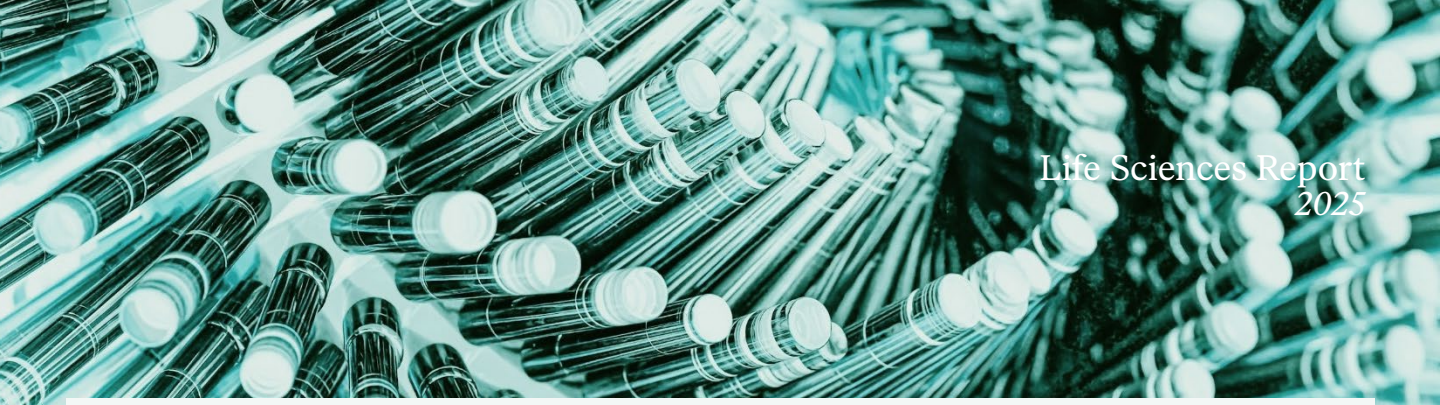
Healthcare AI systems that are subject to Regulation (EU) 2017/745 on medical devices ("**MDR**") or Regulation (EU) 2017/746 on in vitro diagnostic medical devices ("**IVDR**"), and that require third party conformity assessment under those regimes, are classified as high risk AI systems under the AI Act. Providers of high risk systems must, among other things, establish a risk management system, implement a quality management system, and ensure robust protection of personal data. When dealing with AI systems in healthcare, potential risks should be considered early in development to ensure that systems are designed to mitigate them effectively.

Simultaneous application

The EHDS, the Data Act, and the AI Act have certain overlap in scope, but are, however, intended to be applied simultaneously. In relation to personal data, Regulation (EU) 2016/679 ("**GDPR**") also applies alongside these regulations. Multiple regulations may therefore at the same time apply to a given service, system, product or device, resulting in a layered set of demands and requirements for business to navigate.

Considerations

- **Identify your products and services.** Establish which products and services you manufacture, provide, or use. Assess each against the EHDS, Data Act, and AI Act to establish whether and how they apply.
- **Identify your role.** Identify your role under each regulation (for example, manufacturer, provider, user, or data holder). Roles are often linked to the specific product or service.
- **Identify relevant provisions.** Map the specific provisions that apply to your organisation and products or services. Evaluate whether adjustments are needed to meet obligations and whether terms and conditions for use require updates.



Strengthening the EU life sciences framework – recent initiatives

Over the past year, the European Commission has proposed several major legislatives aimed at strengthening the EU's life sciences framework. The Critical Medicines Act, the European Biotech Act, the European Innovation Act and the proposal on New Genomic Techniques each address different but complementary aspects of the EU's competitiveness, resilience, and technological sovereignty. Together, the initiatives aim to strengthen the EU's ability to innovate and produce within its borders while ensuring a reliable supply of essential medicines and technologies.

Critical Medicines Act

Introduced in March 2025, the proposed Critical Medicines Act ("**CMA**") responds to growing medicine shortages, rising geopolitical risks, and market failures that have exposed vulnerabilities in the EU's pharmaceutical supply chains. The act aims to ensure that patients across the Union can rely on a stable supply of essential medicines by promoting diversified, EU-based manufacturing and greater supply chain transparency.

A central feature of the proposal is the *Union List of Critical Medicines*, which identifies products of vital public health importance and tracks their supply chain dependencies. According to the proposal, manufacturers of these medicines will be required to share data on production and sourcing to help anticipate and mitigate shortages. Further, to strengthen production capacity, the CMA introduces *Strategic Projects*, which are industrial investments that may receive EU funding, fast-track permitting, and state aid support.

The Act also provides for collaborative procurement mechanisms and the establishment of a *Critical Medicines Coordination Group* to facilitate implementation and strengthen cooperation among Member States.

The legislative proposal is currently under discussion in the European Parliament and Council, with implementation expected to begin in 2026.

Biotech Act

While the CMA focuses on supply resilience, the forthcoming European Biotech Act, with a legislative proposal expected in 2026, turns attention to Europe's innovation capacity and industrial competitiveness. The Commission views biotechnology and biomanufacturing as key enablers of the green and digital transitions yet acknowledges that complex and fragmented EU rules currently hinder investment and delay the path from research to market.

The Biotech Act is expected to make EU regulatory framework for biotechnology clearer and more consistent. The Act seeks to simplify and harmonise the regulatory framework for biotechnology across all these fields and aims to support companies at every stage of development – from start-ups and scale-ups to established manufacturers.

The Biotech Act will form part of the broader *Strategy for European Life Sciences*, aiming to translate Europe's strong research base into market-ready innovation and global competitiveness. The Act is expected to clear the way especially for gene therapies, RNA-based therapies, vaccines and diagnostics.

Innovation Act

In July 2025, the Commission launched a call for evidence and public consultation to all stakeholders to contribute to what is referred to as the European Innovation Act. Motivated by the observation that there is a discrepancy between the amount and quality of research and innovation within the EU and the extent to which these translate into available products, the initiative aims to reduce this discrepancy by aligning innovation policies, reduce hinders for innovation, and cut unnecessary bureaucracy. Although still an embryo, the proposal illustrates the EU's commitment and efforts to promote and safeguard innovation. It is aimed at lowering barriers for*, inter alia*, start-ups and university spin-offs.

New Genomic Techniques

New genomic techniques ("**NGT**") refer to breeding methods that involve the targeted modification of the genetic material in plants, animals, or microorganisms. NGT is a more modern and precise method in comparison to its predecessors. NGT is special since, to date, there are no crop derived exclusively from NGTs that have received authorisation for food or feed use within the EU. Nevertheless, NGTs are a hot topic within the EU as it may ultimately have a great impact on the future supply of food and feed.

In March 2025, the Council agreed on its position for negotiations with the European Parliament on new NGT rules, establishing common political ground in a politically highly sensitive area. While there are many political disagreements to combat, this marks an important milestone to move forward with the NGT regulation and allow the new techniques to eventually reach the market. The position agreed provides for a more transparent procedure with e.g. all NGT plants being required to be listed in a public database and additional rules before an NGT can be placed on the market.

The EU pharmaceutical reform package

The EU pharmaceutical reform package ("**Pharma Package**") represents the first major revision of EU pharmaceutical legislation in more than two decades. Since the last major revision, the sector has become increasingly globalised, yet patient access to medicines still varies across the EU. The reform aims to better meet patient needs, improve security of supply and shortage management, and bolster Europe's competitiveness and capacity for innovation. The European Commission published its proposals in April 2023 and, on 4 June 2025, the Council agreed its negotiating position. On 11 December 2025, the Council and the European Parliament reached an agreement on the Pharma Package; an important step to a final legislative product. The provisional agreement needs to be endorsed by both the Council and the European Parliament, before its formal adoption.

Key elements

The Pharma Package introduces significant changes, including adjustments to data and market exclusivity, incentives to tackle antimicrobial resistance, and measures addressing shortages. Proposals also include a broadened Bolar exemption (see further below) and improved exclusivity initiatives for orphan medicinal products (medicines for rare diseases).

Regulatory Data Protection and Market Exclusivity

Regulatory data protection and market exclusivity periods are being adjusted. According to the proposed measures, innovative drugs will retain eight years of regulatory data protection with one additional year of market protection following a marketing authorization. Additional periods of market protection could be granted to pharmaceutical companies when certain conditions are met. If an unmet medical need is addressed by the product, an additional 12 months of exclusivity would be awarded. An additional 12-month extension would also apply if the product includes a new active substance and satisfies a set of requirements, including conducting comparative clinical trials. It will also be possible to extend the market exclusivity with 12 additional months if an authorisation is obtained for a new therapeutic indication.

In practice, this means a new drug will benefit from nine years of total protection (8+1) as standard, instead of the current ten years with a possibility to extend the market exclusivity period with the various extentions. However, the proposed measures envisage a cap of 11 years on the combined regulatory protection period. This cap also applies to regulatory protection for orphan medicinal products addressing a disease with no current available treatment.

Further, the Pharma Package introduces transferable exclusivity vouchers for the development of antimicrobials. The voucher gives the right to 12 additional months of data protection for one authorised product.

Compulsory licenses

The Pharma Package proposes an EU level framework for compulsory licences to improve crisis management, allowing manufacture of critical medicines in emergencies without the patent holder's consent. Compulsory licensing is currently regulated on a national level, and the establishment of such rules on EU-level allows for more efficient administration and streamlined handling by appointing the Commission as the approving authority.

Nevertheless, compulsory licensing is a hot and controversial topic balancing societal needs of rapid access of medicines in a crisis situation against the exclusive right granted to a patent holder which has invested time and recourses to bring an invention to the market. Consequently, the proposal addresses such issues by including limitations as to scope and duration of the licenses and requires fair and adequate compensation to the rightsholders.

Unitary supplemental protection certificate

Another key aspect in the Pharma Package is the introduction of the unitary Supplemental Protection Certificate ("**SPC**"), a centralization of the current national regulations of SPC. The SPC regime is a *sui generis* right compensating holders of pharmaceutical or plant patents by allowing additional five years of exclusivity after the expiry of the patent term. SPC's are based on an EU regulation but are granted and takes effect in each member state separately which makes the system ineffective in relation to the new unitary patent court system ("**UPC**").

By allowing for unitary SPCs, the SPC system will align with the unitary patent system and more effectively streamline the European system for compensating holders of pharmaceutical patents for the revenue loss related to the time period required for regulatory approval processes for medicinal and plant protection products. However, key challenges still need to be addressed, in particular which authority to handle the system.

Extended transitional periods under the MDR and IVDR

EU regulators continue to balance two priorities within the medical device sector - maintaining patient access to safe devices and strengthening regulatory oversight. Accordingly, key transition timelines under the Medical Devices Regulation (EU) 2017/745 ("**MDR**") and the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 ("**IVDR**") have been extended, coupled with tighter conditions for benefiting from those extensions. The aim is to avert shortages, give manufacturers and notified bodies time to complete conformity assessments, and support the phased rollout of "**EUDAMED**", the EU's central database for device information. This article summarises the transitional periods and how businesses should adapt to remain compliant.

MDR transitional periods

Legacy devices (i.e. certain devices which were certified under the previous directives) may remain on the market for a limited time provided they remain safe, unchanged, and the manufacturer has demonstrably progressed the transition to the MDR.

Key dates

- **High-risk devices** (Class III and certain Class IIb implantable devices) may remain on the market until 31 December 2027.
- **Moderate-risk devices** (Class IIa, non-implantable IIb devices, and Class I sterile/measuring) may remain on the market until 31 December 2028.
- **Class III custom-made implantable devices** must have an MDR-compliant quality management system ("**QMS**") certificate by 26 May 2026.

To qualify, manufacturers must typically within the previously applicable deadlines have applied to, and entered into a written agreement with, a notified body. They must also have maintained full compliance with the previous directives without significant changes to design or intended purpose.

IVDR transitional periods

The IVDR extensions follow the same logic as the MDR, allowing manufacturers to keep devices available while transitioning to the stricter IVDR system.

Key dates

- **High-risk IVDs** (Class D) may remain on the market until 31 December 2027.
- **Moderate-risk tests** (Class C) may remain on the market until 31 December 2028.
- **Lower-risk IVDs,** including Class B devices and Class A sterile devices, may remain on the market until 31 December 2029.

To make use of these transition periods, manufacturers must within the previously applicable deadlines have implemented an IVDR-compliant QMS and concluded an agreement with a notified body. An application must also have been submitted to a notified body by the class-specific deadline (2025–2027). Class A non-sterile and new IVDs have been required to comply with the IVDR since 26 May 2022.

Gradual rollout of EUDAMED

EUDAMED is being rolled out module by module. Its six modules cover actor registration, UDI/device registration, notified bodies and certificates, vigilance, market surveillance, and clinical/performance studies. Several modules are available for voluntary use. Mandatory use will be phased in, with certain modules expected to become compulsory in early 2026.

Next steps for businesses

To prepare effectively for the evolving MDR/IVDR regime, businesses should prioritise the below actions.

- Confirm eligibility for transitional provisions for each device and document how all conditions are met.
- Engage early with notified bodies to secure capacity and meet application and agreement deadlines.
- Maintain or enhance QMS to meet Article 10 requirements under the MDR/IVDR
- Sustain robust post-market surveillance and vigilance to ensure that legacy devices remain safe and compliant.
- Start using available EUDAMED modules on a voluntary basis to build readiness ahead of mandatory use.
- Manage supply chains and inventory to avoid placing non-compliant legacy devices on the market after the relevant cut-off dates.

The extended MDR and IVDR timelines provide welcome breathing room but do not lessen the substantive obligations. Businesses should use the transitional periods as a structured implementation window to minimise supply disruption and compliance risk.

The Cybersecurity Act: What to know before it takes effect

The Swedish government has adopted a new Cybersecurity Act (the "**Act**") which will enter into force on 15 January 2026. The Act will implement the NIS2 Directive, which aims to ensure a high common level of cybersecurity across the EU. Even though the Act has not yet entered into force, it is important to start preparing now for the new requirements and obligations that are expected to take effect.

What is the purpose of the Cybersecurity Act?

The Act transposes the NIS2 Directive into national law, with the objective of achieving a high common level of cybersecurity across the EU. NIS2 and the Act broaden the regulatory scope by extending cybersecurity obligations to additional sectors and categories of entities. As a result, a significantly higher number of organisations will now fall within the scope of the Act compared with the previous regulatory framework.

Does your entity fall within the scope of the Cybersecurity Act?

Before the Act enters into force, you should assess whether your entity falls within the scope of the Act. The Act applies to entities operating in 18 designated sectors, including health, the manufacture, production and distribution of chemicals, as well as production, processing and distribution of food, among others. Within the health sector, the scope of regulated entities has been expanded from solely healthcare providers (including hospitals and private clinics) to also include EU reference laboratories and entities that carries out research and development activities of medicinal products, manufactures basic pharmaceutical products and preparations, and medical devices considered to be critical during a public health emergency. Further, the manufacture of *e.g.* medical devices and in vitro diagnostic medical devices will fall within the scope of the Act.

An entity operating within any of the designated sectors falls within the scope of the Act if it meets or exceeds the size threshold for a medium-sized enterprise. Entities in these sectors may also fall within the scope of the Act even if it does not meet the size threshold, for example, where the entity is the sole provider in Sweden of a service essential to the maintenance of critical societal or economic activities. In addition, government agencies, regions and municipalities are also, under certain circumstances, covered by the Act.

Where an entity falls within the scope of the Act, the obligations under the Act will generally apply to the entity as a whole, and not only to the specific activities that trigger its inclusion.

VINGE

What does the Cybersecurity Act mean for your entity?

Entities falling within the scope of the Act should prepare, *inter alia*, for the following obligations:

- **Register your entity**. Entities must register with the authority designated by the government immediately after the Act enters into force. The competent authority may differ depending on the sector in which the entity operates.

- **Take cybersecurity risk-management measures**. Entities will be required to adopt and maintain appropriate and proportionate technical, operational and organisational measures to manage cybersecurity risks. These measures must cover areas such as risk analysis, network and information system security, incident handling, business continuity, and supply chain security.

- **Management training**. Members of the management must receive training in cybersecurity risk-management practices. The training should ensure that management has sufficient knowledge and skills to identify cybersecurity risks, assess appropriate risk-management measures, and understand their impact on the services provided by the entity.

- **Establish procedures for handling of incidents**. Entities will be required to establish procedures for handling significant incidents. Once becoming aware of a significant incident, entities must within 24 hours submit an early warning to the authority designated by the government (likely the Swedish Civil Contingencies Agency, MSB). Furthermore, entities must within 72 hours submit an incident notification to the authority.

Administrative fines

It is important to note that entities which are in breach of the Act risk significant administrative fines. The size of the fines depend on how the entity is classified but may amount to the higher of 2% of the entity's total worldwide annual turnover in the preceding financial year or EUR 10,000,000.

What happens next?

The Act will enter into force on 15 January 2026. Although the Act has not yet entered into force, it is important for organisations to take a proactive approach and begin preparations already at this stage.

The government has also tasked the Swedish Civil Contingencies Agency (MSB) and the Swedish Post and Telecom Authority (PTS) with preparing regulations in several areas, including reporting obligations, cybersecurity risk-management measures, and the definition of significant incidents. This assignment shall be reported by 15 January 2026 at the latest.

Marketing of prescription medicines

Pharmaceutical companies that wish to communicate about their products and activities must navigate a comprehensive framework governing the marketing of prescription medicines. This framework comprises laws, regulations, ordinances and industry ethical codes, all of which are intended to protect the general public, patients and healthcare professionals. Two core prohibitions sit at the center of this regime: a ban on marketing medicines or indications that are not approved in Sweden (commonly referred to as pre-launch marketing), and a ban on marketing prescription medicines to the general public.

Beyond reputational harm, unauthorized marketing or marketing of unapproved indications may result in injunctions and administrative fines imposed by the Swedish Medical Products Agency (*Läkemedelsverket*), the Consumer Agency (*Konsumentverket*) as well as public reprimands and potential penalties from Lif's Information Review Board (IGN) and the Board for the Assessment of Pharmaceutical Information (NBL).

These prohibitions give rise to practical questions for companies operating in the sector.

Some of the questions we frequently receive concern:

1) how to communicate research, innovation, health benefits and social responsibility without prompting unwanted action by authorities or industry bodies.

2) where the line is drawn between product marketing (marketing of a specific medicine) and institutional marketing (company level communications), and

3) how to describe research and activities without crossing into unauthorized marketing of an unapproved medicinal product.

Typical grey-area situations

Despite the extensive regulations, it is not always clear what constitutes unauthorised marketing of medicines. In many situations, there may be a grey area between what is permitted and what is prohibited depending on the content, purpose, target audience and context of the information. Some of the most common grey area situations, where we have also seen a significant increase in enquiries, concern institutional marketing and the pre-launch marketing of medicines.

Institutional marketing

Institutional marketing comprises company level communications that are not linked to a specific medicinal product, for example, information regarding a pharmaceutical company's general activities aimed to present a positive image. This may include interviews or campaign articles in specialist magazines that focus on the pharmaceutical company's business development and profitability.

While institutional marketing is permitted, it must not mention or allude to prescription medicines in a manner that could be regarded as product marketing to the general public. Whether a particular communication constitutes product marketing or institutional marketing is assessed case by case, based on an overall evaluation of the circumstances. A common risk arises when companies share updates on a therapeutic area or clinical trials relating to a forthcoming medicine. In such instances, the design and placement of the content, the specificity and prominence of product related information, and the intended audience all require careful calibration to avoid the communication being deemed product marketing.

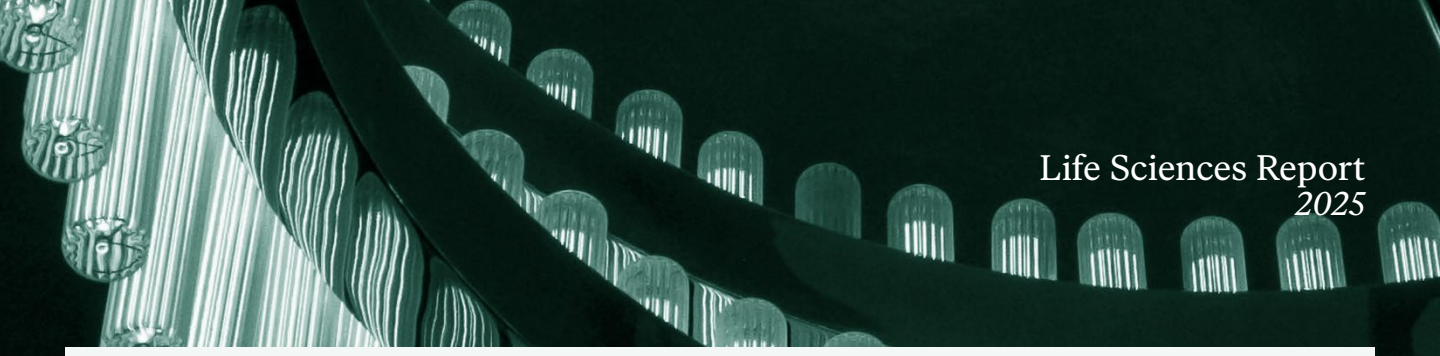
Pre-launch marketing of medicines

Pre-launch marketing is information about medicines that have not yet been approved for sale, or about indications other than those approved. Such marketing is prohibited under the Medicines Act, the Medical Product Agency's provisions and the pharmaceutical industry's ethical regulations since it risks creating false or exaggerated expectations about a medicinal product or its effects.

There are, however, contexts in which discussion of an unapproved medicine or indication may be appropriate and lawful, such as presenting at a scientific congress or publishing clinical study results. In these settings, the information must be directed to appropriate recipients, such as researchers or investors, and not to the general public. The assessment of the target audience turns on factors including where the information appears and how it is formulated.

In some situations, a communication may raise both pre-launch and product marketing concerns, which is why a comprehensive, holistic assessment should be undertaken for each planned marketing measure.

VINGE



A new Bolar exemption – what to expect from a broader exemption?

Background

The so-called Bolar provision has its roots in American case law, where a judgment-based exception was created in 1984 to allow generic manufacturers to use patented products during the patent term for purposes of applying for marketing authorisations in order to be able to offer the generic medicine immediately upon patent expiry. The Bolar provision in EU law was introduced in 2004 through an amendment of Directive 2001/83/EC and reads as follows (noting that the referenced paragraphs 1–4 pertain to generic manufacturers' obtaining of marketing authorizations):

"*Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products*."

Perhaps not so surprisingly, introducing the exemption in a directive has meant that national implementations have varied in nature. Consequently, a need for EU-wide harmonization of the Bolar exemption has been identified. This has been part of the Commission's political movement with the aim of modernizing the EU pharmaceutical legislation, with a view to combat excessively strong patent rights. As was the case before its original introduction, the Commission has also stressed the Bolar exemption's importance in the context of permitting swifter market entry of generic competition.

A wider exemption

In view of the above considerations, a revised Bolar exemption is part of the proposed EU Pharma Package, a legislative proposal consisting primarily of a new regulation and a new directive, with the latter containing the suggested revised Bolar provision. The Commission's proposal expands the scope of the current exemption (i.e. acts exempted from the scope of protection otherwise conferred upon a patent or SPC rights holder) to those which are conducted for the purpose of generating data for the application for a marketing authorization and/or pricing and reimbursement approval for a generic, biosimilar, hybrid or bio-hybrid medicinal product (including pricing and reimbursement approval).

From a Swedish law perspective, it may be noted that the proposal is silent in terms of whether or not the exempt actions must be outright necessary for such purposes – only necessary actions in this regard are exempt from the current wording of the EU law Bolar exemption and the Bolar exemption as implemented in Swedish law. It may also be noted that the Commission's proposal explicitly states that "[t]his exception shall not cover the placing on the market of the medicinal products resulting from such activities." Lastly, it follows from the Commission proposal that the exempt actions may also be conducted by third parties, meaning that third-party suppliers may benefit from the exemption. In practice, this means

that generic manufacturers may outsource e.g. the production of medicinal products, if it is for the ultimate purpose of obtaining marketing authorization, which has been a hot topic when discussing the scope of the Bolar exemption.

The Commission's proposal was thereafter revised by the European Parliament, which removed the Commission's limitation of medicinal products (e.g. biosimilars and hybrids) which would be covered by the Bolar exemption (meaning that also other medicinal products, such as innovative products, also could benefit from the exemption). The European Parliament further introduced wording to the end that the exempt actions must be "necessary" for the outlined purposes (e.g. obtaining marketing authorization). In this regard, the revised proposal aligns better with current Swedish legislation.

Lastly, and most recently, the Commission's proposal has also become subject to the Council's review. The Council's revised proposal strays significantly further from the Commission's original proposal. Whereas the Council agrees that only necessary actions are exempt and also ensures that third-parties may carry out the exempt actions (i.e. that generic manufacturers may outsource e.g. production of necessary product samples), the Council expands the scope of the suggested Bolar exemption to cover also the submission of procurement tenders as long as marketing or sales do not begin until the relevant exclusive rights have expired. In other words, the Council's suggestion would entail that a generic manufacturer may compete for a procured contract with an original manufacturer whose patent or SPC remains in force, as long as products are not to be supplied to the customer before the referenced patent or SPC has expired. It is debatable if this can be reconciled with the wording of the same proposal pursuant to which the exemption "shall not cover the placing on the market of the medicinal products resulting from such activities". On the one hand, the limited supply produced for the purpose of obtaining a marketing authorization will not be placed on the market in a strict sense, but on the other hand it may be argued that the very same limited supply is what a generic manufacturer brings to the table at the time of submission of a procurement tender.

Concluding remarks

With the agreement reached on 11 December 2025 between the Commission, the European Parliament and the Council, it seems as if the Council's position on the scope of the Bolar exemption is upheld. Thus, the combination of having third-parties benefit from the exemption and allowing for generics to submit procurement tenders would entail a significantly more generics-friendly Bolar exemption going forward. It remains unsure what the outcome of such trilogue will be and there will surely be lively political discussions preceding any final decision. What is certain is that the outcome will be of great importance to all the parties involved, but in very different ways depending on if you are on the patent side or on the generic side.

Authors

Christoffer Nordin
Counsel

Åsa Hellstadius
IP Expert, Doctor of Laws LL.D

Siri Blomberg
Associate

Axel Lennartsson
Senior Associate

Malin Dejke
Associate

Ian Jonson
Senior Associate

Therese Baltzarsson
Associate

Avidh Tajik
Associate

Katja Häglund
Associate

Nicklas Thorgerzon
Technology & Data Protection Expert

VINGE