The Paris office of Hogan Lovells is pleased to provide this English language edition of our monthly e-newsletter, which offers a legal and regulatory update covering France and Europe for October 2025.

Please note that French legal concepts are translated into English for information only and not as legal advice. The concepts expressed in English may not exactly reflect or correspond to similar concepts existing under the laws of the jurisdictions of the readers.

If you would like to consult this newsletter from past months, please click here.

For additional information, please speak to your usual contact.

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- **Insurance**

France – Update by the ACPR of eight instructions intended for insurance and reinsurance undertakings subject to its supervision

The *Autorité de Contrôle Prudentiel et de Résolution* ("**ACPR**") published on 22 October 2025 eight instructions intended for insurance undertakings subject to its supervision. These instructions replace existing ones or formalise procedures that, until now, had not been the subject of any dedicated instruction.

- Instruction n° 2025-I-15 relating to the documents to be provided in the context of carrying out insurance activities under the freedom of establishment or the freedom of services in another State of the European Economic Area. This instruction replaces Instruction n° 2017-I-20 of 23 November 2017.
- Instruction n° 2025-I-16 relating to the form for the appointment or change of the general representative of a branch.
- Instruction n° 2025-I-17 relating to the contract portfolio transfer approval file.
- Instruction n° 2025-I-18 relating to the file for the declaration or approval of a merger or demerger without transfer of a portfolio of insurance contract by insurance undertakings.
- Instruction n° 2025-I-19 concerning the content of applications for administrative authorisation or extension of authorisation for insurance or reinsurance undertakings.

  This instruction replaces Instruction n° 2015-I-15 of 30 June 2015, as amended by Instructions n° 2019-I-10 of 18 April 2019 and n° 2024-I-11 of 21 October 2024.

- Instruction n° 2025-I-20 concerning the content of the prior declaration file for the affiliation, withdrawal, or exclusion of a *mutual insurance group company* ("**SGAM**"), a *mutualist group union* ("**UMG**"), or a *social-protection insurance group company* ("**SGAPS**"). This instruction replaces Instruction No. 2015-I-17 of 30 June 2015, as amended by Instruction n° 2018-I-15 of 11 July 2018, Instruction n° 2019-I-11 of 18 April 2019, and Instruction n° 2024-I-11 of 21 October 2024.
- Instruction n° 2025-I-21 on the information to be provided to the *Autorité de Contrôle Prudentiel et de Résolution* in the context of the acquisition or extension of a holding in an insurance or reinsurance undertaking, an insurance holding company, or a supplementary occupational pension fund. This instruction replaces Instruction n° 2015-I-34 of 17 December 2015, as amended by Instruction n° 2018-I-08 of 11 July 2018, Instruction n° 2019-I-12 of 18 April 2019, and Instruction n° 2024-I-11 of 21 October 2024.
- Instruction n° 2025-I-22 on the content of the file for the conclusion of, or amendment to, a substitution agreement. This instruction replaces Instruction n° 2016-I-06 of 11 March 2016, as amended by Instruction n° 2018-I-10 of 11 July 2018, Instruction n° 2019-I-13 of 18 April 2019, and Instruction n° 2024-I-11 of 21 October 2024.

These instructions will enter into force on 1st January 2026.

Source : Instruction n° 2025 I-15, Instruction n° 2025-I-16, Instruction n° 2025-I-17, Instruction n° 2025-I-18, Instruction n° 2025-I-19, Instruction n° 2025-I-20, Instruction 2025-I-21 and Instruction 2025-I-22

France – Publication of several documents by the ACPR and the AMF as part of the Fintech Forum

The *Autorité de Contrôle Prudentiel et de Résolution* ("**ACPR**") and the *Autorité des Marchés Financiers* ("**AMF**") jointly published on 9 October 2025 several documents as part of the Fintech Forum, notably concerning among other the application of Regulation 2022/2554 on digital operational resilience for the financial sector ("**DORA Regulation**") and the fight against money laundering and terrorist financing ("**AML/CFT**"):

- A document presenting an overview of the DORA Regulation nine months after its entry into application in France. The presentation is structured around four points, (**i**) a reminder of the regulatory framework of the DORA Regulation, (**ii**) initial findings since its entry into force, in particular regarding the implementation of the new obligations that apply for each entity, the AMF's support, the submission of the register of information, and the number of reported incidents, (**iii**) feedback on cyber-risk supervision, and (**iv**) the next steps, including ongoing support in 2025 and strengthened supervision from 2026 onward.
- A document on AML/CFT, presenting the points of attention raised by the supervisors as well as the main issues for entities subjects to AML/CFT requirements. The presentation is structured around five points, (**i**) an overview of the deployment of Artificial Intelligence ("**AI**") in the field of AML/CFT, (**ii**) a presentation of the tool called "LUCIA" an AI-based financial monitoring platform used by the ACPR, (**iii**) a report on preventing "mule accounts" used for laundering fraud proceeds and other scams, (**iv**) the European Banking Authority's guidelines on restrictive measures, and (**v**) an update on the supervision of the crypto-asset sector.

Source : Document on AML/CFT, and Document presenting an overview of the DORA Regulation

European Union – Publication by EIOPA of a series of consultations concerning Solvency II

The European Insurance and Occupational Pensions Authority ("**EIOPA**") published on 9 October 2025 a series of consultations within the framework of Directive 2009/138 of 25 November 2009 ("**Solvency II Directive**"), as amended by Directive 2025/2.

These consultations concern proposed amendments relating to the following documents:

- The Implementing Regulation 2015/2451 of 2 December 2015 laying down implementing technical standards with regard to the templates and structure of the disclosure of specific information by supervisory authorities (EIOPA-BoS-25/374), and Implementing Regulation 2015/500 of 24 March 2015 laying down implementing technical standards with regard to the procedures to be followed for the supervisory approval of the application of a matching adjustment (EIOPA-BoS-25/376).
- Guidelines on valuation of technical provisions (EIOPA-BoS-25/382), as well as Guidelines on ring-fenced funds (EIOPA-BoS-25/384).
- The Delegated Regulation (EU) 2015/35 completing Solvency II Directive, on the simplified calculation of the risk margin (EIOPA-BoS-25/378).
- Guidelines on the assessment of supervisory powers to remedy liquidity vulnerabilities (EIOPA-BoS-25/380).

EIOPA aims to simplify and streamline the regulatory framework applicable to European insurance and reinsurance undertakings. In particular, the consultation proposals concerning the revised guidelines provide for a reduction of at least 25% in the number of guidelines.

EIOPA invites stakeholders to submit their comments on each of the consultation documents before 5 January 2026.

Source : Publication by EIOPA of a series of consultations concerning Solvency II

European Union – Publication by EIOPA of guidelines on promoting diversity within the boards of insurers and reinsurers and on methods for determining market shares for reporting purposes

The European Insurance and Occupational Pensions Authority ("**EIOPA**") published on 14 October 2025 new guidelines on (i) diversity considerations that insurance and reinsurance undertakings must take into account when selecting the members of their administrative, management and supervisory bodies ("**AMSBs**"), and on (ii) the methods for determining market shares for reporting purposes.

The Guidelines on promoting diversity (EIOPA-BoS-25/392) aim to promote diversity in the composition of governing bodies within insurers and reinsurers, based on their education, professional background, age, gender and geographical origin, both when recruiting new members and on an ongoing basis.

This report forms part of the revision of Directive 2009/138 of 25 November 2009 ("**Solvency II Directive**"), which requires insurance and reinsurance undertakings to put in place policies promoting diversity within their administrative, management and supervisory bodies, notably by setting quantitative objectives relating to gender balance.

The Guidelines concerning the methods for determining market shares for supervisory reporting under the Solvency II Directive (EIOPA-BoS-25/395) amend the existing guidelines with a view to simplifying and streamlining them by providing additional clarifications on the process and on the respective roles of supervisory authorities and insurance and reinsurance undertakings in determining market shares. They also include an explanatory text detailing the adjustments made and the clarifications introduced.

These guidelines will enter into force on 30 January 2027.

Source : Publication by EIOPA of guidelines on promoting diversity within the boards of insurers and reinsurers and on methods for determining market shares for reporting purposes

Authored by Ghina Farah and Maxime Kaya.

- **Intellectual Property**

France - **Extension of the inter-professional agreement on contractual practices between authors-screenwriters and producers of fiction feature films**

The Decree of 16 October 2025 extends the interprofessional agreement of 15 October 2025 on contractual practices between authors, screenwriters and producers of feature films. It makes the provisions of this agreement binding on all French producers and screenwriters, which governs in particular the conditions of remuneration, exploitation rights and contractual obligations of the parties. The aim is to strengthen the protection of authors and to ensure greater transparency in the contractual relations of the film sector. The decree, published in the Official Journal, has regulatory value and is part of the Intellectual Property Code (Articles L.132 25 1 and L.132 25 2). It is also a tool for regulating the audiovisual market, guaranteeing a balance between producers and creators. In practice, any contract that does not comply with this agreement can be challenged, and trade unions or professional bodies can request its application. This extension reflects the State's desire to standardise good practices, encourage national creation and protect authors from commercial pressure.

European Union - **Launch of a pilot programme between the EPO and the Australian Patent Office under the Patent Cooperation Treaty on 1 March 2026**

Following the annual bilateral meeting last July, the EPO and the Australian Patent Office strengthened their cooperation, announcing three months after their meeting their intention to launch a pilot programme under the Patent Cooperation Treaty on 1 March 2026. This pilot program will allow Australian applicants to designate the EPO as the International Searching and Preliminary Examining Authority (ISA/IPEA) for PCT applications. This will give Australian applicants a strategic advantage through rapid search reports and detailed written opinions that help accelerate the path to European patent protection.

International - Madrid System: Modification of the Individual Fee for Brunei Darussalam, Cambodia, Chile, Oman, Trinidad and Tobago and the United Arab Emirates

In accordance with WIPO's notices, the amounts of the individual fee to be paid under the Protocol Relating to the Madrid Agreement are modified downwards when the following countries are designated in an international application, in the context of a designation subsequent to an international registration and in respect of the renewal of an international registration in which they have been designated: Brunei Darussalam (WIPO Opinion No. 20/2025); Cambodia (WIPO Opinion No. 21/2025); Chile (WIPO Opinion 22/2025); Oman (WIPO Opinion No. 23/2025); Trinidad and Tobago (WIPO Opinion No. 24/2025) and the United Arab Emirates (WIPO Opinion No. 25/2025). The new amounts will come into force on November 2, 2025.

Authored by Iris Accary and Apolline Thiolon

- **Life Sciences**

France – Carbon score for hospital procurement (Ministry note):

Information note no. DGOS/CABINET/DGCS/PNRR/2025/153 of 29 October 2025 on the arrangements for implementing the public methodology for the carbon footprint of medicinal products was recently published for the attention of the Directors-General of the Regional Health Agencies (ARS).

This ministerial note forms part of the Ecological Planning of the Health System (PESS). The Ministry of Health and the Ministry of the Economy, in conjunction with a consulting firm, have worked on the construction of a public methodology for assessing the carbon footprint of medicinal products, referred to as the “medicinal product carbon score”.

The structures concerned:

- the measures apply to healthcare and medico-social establishments with an in-house pharmacy (PUI), and to joint purchasing structures, for the implementation of the public methodology for assessing the carbon footprint of medicinal products;
- the objective is to encourage establishments to integrate the result of the medicinal product carbon score as an award criterion**,** since the inclusion of an environmental criterion will become compulsory in public contracts as from August 2026**,** in accordance with the Law of 22 August 2021 on combating climate change and strengthening resilience to its effects.

Assessment of bids by contracting authorities:

- the text expressly targets contracting authorities, as defined in Article L. 1211-1 of the French Public Procurement Code, and refers to Article L. 2152-7 for the implementation of the decisive criterion;
- the environmental criterion for assessing bids may, also, be accompanied by other criteria linked to the subject matter of the contract, whether environmental or social, depending on the purchasing strategies developed by purchasers. This criterion must be associated with a clause inserted in the special technical specifications (CCTP);

- it is also indicated that the presentation of results based on another methodology could be qualified as an irregular tender if the reference to the carbon score methodology appears in the consultation documents.

Operational implementation of the methodology:

- Annex 1 lists the 18 priority molecules with their international non-proprietary name (INN), designated as medicinal products, with a view to placing them on a decarbonisation trajectory. This list will be regularly updated on this page and will support the use of the medicinal product carbon score in bid procedures, which is on a voluntary basis;
- if the purchaser wishes to use this score for medicinal products that are not on the list, the note recommends a period of 3 to 6 months between the announcement of the inclusion of this criterion in their contracts and the receipt of tenders, so that the bidders can carry out these calculations.

Control of data:

- The institutional circuit for validating the results of the medicinal product carbon score is planned for the first half of 2026 and will allow the bidder to have the score validated by an accredited third-party verifier, with the cost of this validation being borne by the bidder.
- Pending the implementation of this institutional circuit, these scores are certified by third-party verifiers, namely:
    - the contracting authority itself;
    - economic operators selected by the contracting authorities.

European Union – Implementing Regulation of the HTA Regulation (health technology assessment, procedural rules applicable to interaction during joint clinical assessments of medical devices and in vitro diagnostic medical devices)

Commission Implementing Regulation (EU) 2025/2086 of 17 October 2025 is adopted in accordance with Regulation (EU) 2021/2282 on health technology assessment (HTA).

- Regulation (EU) 2021/2282 organises, among other things, the selection of medical devices and in vitro diagnostic devices that are to be subject to joint clinical assessments at European Union level. It provides, for example, for the Commission to adopt, at least every two years, an implementing act selecting the devices concerned.
- Regulation (EU) 2025/2086 falls within this framework and constitutes the sixth and final implementing regulation. Its purpose is to lay down detailed procedural rules for interaction between the different actors involved (coordination group, notified bodies, expert groups, health technology developers, patients, etc.), for the exchange of information relating to the preparation and updating of joint clinical assessments and for the models to be used in the context of these assessments.

The main new elements introduced by Regulation 2025/2086:

- cooperation between the coordination group of the Member States on health technology assessment and the Commission with the notified bodies and expert groups;

- interaction between the coordination group and device developers, patients and experts (clinical and other) during joint clinical assessments;
- rules on the selection and consultation of stakeholder organisations and individual experts in the context of joint clinical assessments;
- the formats and templates of the dossiers containing the information, data, analyses and evidence to be provided by device developers for joint clinical assessments;
- the formats and templates of the joint clinical assessment reports and summary reports.

Since the entry into application of Regulation (EU) 2021/2282 in January 2025, nine joint clinical assessments are ongoing in the field of advanced therapy and oncology medicinal products.

The regulation emphasizes on defining an assessment scope that takes account of the needs of the Member States, on setting deadlines for finalising draft reports, on the systematic use of the HTA platform for all exchanges, and on the management of confidential information and personal data.

Authored by Joséphine Pour and Gabriele Grandin de l'Eprevier

- **Litigation**

France – Draft Decree "RIVAGE": launch of the consultation on the reform of civil appeals

The Ministry of Justice has opened a consultation on the draft decree "RIVAGE" ("Rationalisation des instances en voie d'appel pour en garantir l'efficience"), marking a new phase in the ongoing procedural reform. The draft is built around three key measures: (i) raising the threshold for appellate review to €10,000, thereby limiting access to a second level of jurisdiction; (ii) extending the mandatory attempt at alternative dispute resolution to all disputes valued at €10,000 or below (expected to apply from 1 September 2026); and (iii) introducing a filtering mechanism allowing courts of appeal to summarily dismiss manifestly inadmissible appeals (including time-barred appeals, lack of standing or absence of any grievance).

The stated objective is to reduce the volume of appeals and enable courts of appeal to focus on higher-value matters, in a context where the average time to a hearing currently reaches 14 months. A series of working meetings with the Bar will take place in November and December to refine the text before it is submitted to the Conseil d'État.

Authored by Nicolas Rohfritsch and Mizgin Laura Delikaya

- **Public Law**

France – Public procurement: transposition of the energy efficiency directive

Ordinance n°2025-979 of 14 October 2025, transposing articles 7, 26 and 27 of directive (EU) 2023/1791 of the European Parliament and of the Council of 13 September 2023 on energy efficiency, published in the Official Journal of the French Republic on 15 October 2025, strengthens energy efficiency and energy-sobriety in public procurement contracts and concession contracts.

The directive establishes a common framework for members States to promote energy efficiency within the European Union by reinforcing the requirements for energy efficiency and sobriety in public procurement and concession contracts.

The ordinance of 14 October 2025 transposes the objectives of the directive and amends the French public procurement code to require purchasers and contracting authorities to take energy efficiency and energy conservation into account when defining their needs. In addition, purchasers and contracting authorities must purchase only energy-efficient products, services and works, subject to exceptions relating, for example, to public safety reasons or technical inadequacy. These provisions apply to public procurement contracts and concession contracts for which procurement procedure is launched, or a contract notice has been sent for publication on or after the date the ordinance comes into force, for needs whose estimated value is equal or exceeds the EU thresholds.

France – Public procurement: publication of a standardised financial annex

On 21 October 2025, the Economic Observatory for Public Procurement published a standardised financial annex for public procurement contracts. This document aims to harmonise exchanges between purchasers and economic operators.

The financial annex, provided in the form of an Excel spreadsheet, contains six tabs covering notably the unit price schedule, price variation and discounts. This tool is intended to enhance the reliability and efficiency of public procurement by promoting transparency and consistency in exchanges.

European Union – Public procurement: new EU procurement thresholds

Commission delegated regulations (EU) n° 2025/21/50, 2025/2151 and 2025/2152 of 22 October 2025, published in the Official Journal of the European Union on 23 October 2025, slightly lower the thresholds for the application of the formal EU procedures governing the award of public procurement contracts and concession contracts.

The new thresholds are set at EUR 5,404,000 (excluding VAT) for works and concession contracts (down from EUR 5,538,000), EUR 140,000 (excluding VAT) for government supply and service contracts (down from EUR 143,000), EUR 216,000 (excluding VAT) for supply and service contracts awarded by other contracting authorities (down from EUR 221,000) and EUR 432,000 (excluding VAT) for supply and service contracts awarded by contracting entities (down from EUR 443,000).

These new thresholds will apply from 1 January 2026 for two years.

European Union – Public procurement: public consultation on the revision of the public procurement contracts and concessions directives.

On 3 November 2025, the European Commission launched a public consultation to revise directives 2014/23/EU and 2014/24/EU on concession contracts and public procurement contracts. A proposal for revision is expected in the second half of 2026. The consultation is open to all and is particularly aimed at contracting authorities, public purchasers, companies, and professional associations. Contributions can be submitted until 26 January 2026.

This initiative follows the evaluation report on these directives published by the European Commission in October, which showed that the directives had only partially achieved their objectives. The report pointed a lack of clarity and increased complexity of the rules, as well as a significant rise in the overall value of public procurement contracts

Authored by Bruno Cantier, Astrid Layrisse and Ronel Cayanan