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IP & Life Science News

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The European Commission proposes another extension of the transitional periods for implementation of the in vitro diagnostic medical devices regulation (IVDR)

Another proposal for extension of the transitional period for implementation of Regulation (EU) 2017/746 on in vitro diagnostic medical devices ("IVDR") has been introduced by the European Commission. The initiative is a result of the realisation that several manufacturers of in vitro diagnostic medical devices are not able to comply with the more rigorous requirements and obligations under the new IVDR within the transitional deadlines in force. Under the new proposal, all deadlines would be extended by 2 ½ years.

As of now, manufacturers of in vitro diagnostic medical devices in class D (which are considered high-risk devices) must observe the requirements and obligations under the IVDR by 26 May 2025, whereas manufacturers of in vitro diagnostic medical devices in class A – C must do so by 26 May 2026 or 26 May 2027 (or by 26 May 2028 for certain devices manufactured and used in health institutions). However, if the new proposal is adopted, the deadline for class D medical devices is extended another 2 ½ years, after which the requirements must be observed no later than 31 December 2027. For the devices in class A – C, the deadline is extended with 2 ½ years as well, entailing that the requirements and obligations for class C devices must be observed no later than 31 December 2028, and for class B and certain class A devices (placed on the market in sterile condition) no later than 31 December 2029.

The devices may be placed on the market or put into service until the dates set out above if certain conditions are met, including, inter alia, that those devices still comply with Directive 98/79/EC on in vitro diagnostic medical devices and that, no later than 26 May 2025, the manufacturer must put a quality management system in place.

The Commission's proposal for a Regulation amending Regulation (EU) 2017/746 was made on 23 January 2024 and is now before the Council of Ministers and the European Parliament.

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In vitro diagnostic medical devices

In vitro diagnostic medical device refers to any medical device, which is a reagent, reagent product, calibrator, control material, specimen set, instrument, apparatus, device, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro (translated from Latin: "in glass") for the examination of specimens taken from the human body, including blood and tissue donations.

In vitro diagnostic medical devices are categorised into risk classes A - D. Class A and B are associated with the lowest risk and contain devices such as pregnancy tests and sterile blood collection tubes, while class D is associated with the highest risk, and contains devices such as HIV and hepatitis tests.

About the new in vitro diagnostic medical devices regulation (IVDR)

On 26 May 2022, the IVDR entered into force - a year after Regulation (EU) 2017/745 on medical devices ("MDR"). The Regulations replaced the previous Directives in the area with the aim of increasing patient safety by strengthening the requirements for clinical documentation, monitoring and safety. The IVDR introduces, inter alia, a risk-based classification system, after which devices are classified in four classes: A, B, C or D depending on the intended purpose of the device and the risks associated with using it. By introducing this new classification system, all devices must be re-classified, particularly due to the fact that correct classification of a product is essential to determine which conformity assessment procedure the manufacturer must initiate in order to have the product CE marked.

The CE marking demonstrates and documents that the device complies with the IVDR, which is required for the device to be placed on the market in the European Union. For in vitro diagnostic medical devices in risk classes B, C and D, a notified body must be engaged to certify the device. However, only 12 notified bodies have been appointed by the Commission and the Member States, which has led to a severe shortage of recertification capacity. As a direct consequence hereof, the process of obtaining CE marking currently takes an average of between 13 to 18 months.

The Commission proposes the following extensions of the transitional periods

For high-risk devices in class D

- **Current deadline:** 26 May 2025
- **Proposed extended deadline:** 31 December 2027

For medium-risk devices in class C

- **Current deadline:** May 2026
- **Proposed extended deadline:** 31 December 2028

For lower-risk devices in class B and class A (only those marketed in sterile condition)

- **Current deadline:** May 2027
- **Proposed extended deadline:** 31 December 2029

Manufacturers of risk class D devices must further engage an EU reference laboratory to verify the performance of the devices. These reference laboratories have only just recently been appointed (December 2023) and are not expected to be operational until the summer of 2024.

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The aim of the Commission's proposal

The shortage of recertification and verification capacity with both the notified bodies and the reference laboratories entails extreme difficulty for especially manufacturers of in vitro diagnostic medical devices in class D in terms of meeting the current transitional deadlines in the IVDR. Products, that are unable to be CE marked and/or tested in due time, are at risk of being taken off the market and thus be unavailable to both the healthcare system and patients.

An extension of the transitional periods in the IVDR ensures security of supply of medical devices in the healthcare system. The extension also serves the interests of the manufactures that otherwise risk having their access to the market for vital medical devices restricted until the devices meet all the requirements and obligations under the IVDR.

The reason for proposing to extend the transitional deadlines for devices in classes A, B and C as well is that, even though it is primarily medical devices in class D that raise a concern, lack of extension with regard to classes A, B and C devices might entail a risk that products within these classes would be deprioritized by the notified bodies.

Devices not covered by transitional provisions in the IVDR:

- In vitro diagnostic medical devices that hold a certificate issued by a notified body under Directive 98/79/EC, and which do not require involvement from a notified body under the IVDR (class A, non-sterile devices under the IVDR).
- All new in vitro diagnostic medical devices certified and marketed after 26 May 2022.

Accura comments

The proposal to extend the transitional period of the IVDR underlines the purpose of the IVDR, as the potential risk of losing access to vital medical devices in society is not compliant with the main purpose of the Regulation: *increasing patient safety*.

Giving manufacturers, notified bodies and reference laboratories more time to complete the necessary conformity assessment procedures without lowering the requirements in the IVDR should therefore be seen as a positive short-term solution to mitigate the risk of shortages.

If you are interested in more information on this topic, we published a newsletter about the decision to extend the transitional periods for recertification of medical devices under the new MDR in March 2023, which you can retrieve here.

A revised Product Liability Directive for the digital age

A revised EU Product Liability Directive is on its way.

On 14 December 2023, a provisional political agreement was concluded between the European Parliament and European Council on the Commission's proposal for a revised Product Liability Directive. The revised Directive will replace the current Product Liability Directive from 1985 (Directive 85/374/EEC).

The currently applicable Directive concerning liability for defective products was adopted nearly 40 years ago and was born out of a political decision to harmonise the legal protection of consumers in respect of product defects, which previously differed between Member States. The Directive has been implemented through national legislation - in Denmark, by way of the Danish Product Liability Act.

According to the European Commission, a need for a revision of the legal framework to meet the complexity of products in the digital age has become apparent, and the European Commission proposed a revised Directive in 2022 (COM(2022) 495). The revised Directive has, thus, been on its way for some time.

The revised Product Liability Directive will provide for a right to compensation based on strict liability for "material losses" caused by a defective product in the form of death or personal injury, harm to or destruction of property, or loss or corruption of data. The scope of the Directive is, however, extended, and the revised Directive will have a number of measures that impose requirements on the way actions for damages have to be dealt with.

Once the revised Directive enters into force, the EU Member States will have a 12-month transposition period to comply with the Directive. In Denmark, an adjustment of the Danish Product Liability Act will be necessary to meet the new requirements.

Economic Operators will be liable for defective products

According to the proposed Directive, the manufacturer of a defective product will continue be liable for claims for compensation. However, the revised Directive extends the scope of parties concerned to further cover "economic operators", meaning that besides the manufacturer of a product or component, the (i) provider of a related service, (ii) the authorised representative, (iii) the importer or (iv) the "fulfilment service provider" or distributor of the product can be held liable e.g., if the manufacturer is based outside the EU. This measure is introduced to ensure that there is always an EU-based business that can be held liable for a defective product.

Burden of proof

Although it will still be the main rule that the claimant must prove (i) defectiveness, (ii) the damage, and (iii) the causal link between the two, the revised Directive will make it easier for a claimant to lift the burden of proof. The revision will, under certain conditions, shift the burden of proving the existence of an injury and a defect to the defendant. Moreover, the burden of proof is lightened in favour of the claimant, as the causal link between a defect and the damage will be presumed in cases where the damage is of a kind typically consistent with the established defect. The causal link or the defectiveness will also be presumed in some cases where technical or scientific complexity causes excessive difficulty in proving liability.

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Disclosure of information

The revised Directive will also oblige the manufacturer to disclose, to a necessary and proportionate degree, information in court when the injured party (claimant) has presented facts and evidence sufficient to support that the claim for compensation is "plausible". The obligation to disclose necessary information is to be applied in a way that takes the protection of trade secrets and confidentiality into account.

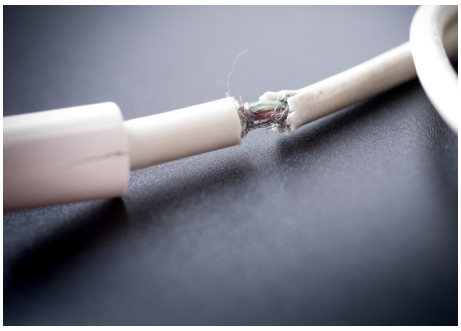
An additional implication of the revised Directive is that the limitation period of 10 years looks set to be extended to 25 years in cases where the claimant has not initiated proceedings within the regular limitation period due to the latency of a personal injury.

All in all, the changes above may increase the incentive for consumers to initiate product liability litigation. This can affect businesses through an increase in the number of claims filed against them and in turn increase their overall legal costs.

Additional changes with respect to digital products

In addition to the revised Product Liability Directive, another EU Directive concerning liability for damage caused by artificial intelligence (AI) (the AI Liability Directive) has been proposed (COM/2022/496). This Directive will apply to non-contractual civil law claims for damages caused by a "high-risk" AI system, where such claims are brought under fault-based liability regimes, i.e., regimes that provide for a statutory responsibility to compensate for damage caused intentionally or by a negligent act or omission - as opposed to the Product Liability Directive, which as stated above will provide for strict liability.

In the proposed new revised Product Liability Directive, the definition of "products" will further be revised to include products of a digital nature. Furthermore, products for which a manufacturer can be held liable for defects will include digital manufacturing files and software, including AI (when it comes



to AI-systems, the difference between the proposed Product Liability Directive and the AI Liability Directive is, *among other things*, that the Product Liability Directive applies to claims made by private individuals against the manufacturer of a defective product, whereas the AI Liability Directive proposes liability for claims made by any natural or legal person against any person, for damages caused by an AI system.)

Another definition which has been expanded is the revised Product Liability Directive's definition of "damage". With the revision, damages will include medically recognised harm to psychological health and loss or corruption of data that is not used exclusively for professional purposes.

Accura comments

Overall, the revised Product Liability Directive will be adapted to better suit the issues of the digital age, including in relation to AI and other software. However, the implications of a shift towards a legal framework that makes it easier for consumers, who claim to have suffered damages, to make claims and bring proceedings without necessarily having the burden of proof will be of concern to businesses. Accura will be following how the Danish legislator chooses to transpose the provisions of the revised Product Liability Directive into Danish law.

If you have any questions regarding the revised Product Liability Directive, do not hesitate to contact us at Accura's team of IP & Life Science specialists.

Highlights from the Danish Medicines Council's annual report for 2023

On 1 February 2024, the Danish Medicines Council released its annual report for 2023 (retrievable in Danish here) containing highlights of the Council's work in the preceding year.

The Danish Medicines Council

The Danish Medicines Council is an independent council assessing whether new medicinal products (and indication extensions) are recommendable as standard treatments at the Danish hospitals.

In the preface of the annual report, the Council addresses the criticism it has received with respect to its decisions on whether to recommend medicinal products or not by reminding all interested parties that not all new medicinal products are better than the ones already available. Medicinal products are recommended by the Council if their effect is sufficiently documented and their price reasonable.

Joint assessments of new medicinal products

EU Regulation 2021/2282 on health technology assessments (HTA) will apply from January 2025. Under the supervision of the Danish Ministry of the Interior and Health, the Medicines Council is, along with certain other Danish authorities, part of the preparatory process for implementing the EU Regulation in Denmark.

Among other things, the EU Regulation concerns clinical assessments of medicinal products, which will become a shared task among the EU Member States. The EU Member States may all appoint representatives to a so-called Member State Coordination Group on HTA, which will carry out the joint clinical assessments going forward. It is stipulated in the preamble of the EU Regulation that joint HTA is aimed at reducing the administrative burden currently on pharmaceutical companies due to parallel assessments in multiple EU Member States.

To begin with, the joint HTA will, however, only concern medicinal products for the treatment of cancer and advanced therapy medicinal products. The aim is that additional categories of medicinal products will be included in the scope of joint assessments under the EU Regulation.

Despite the endeavours to increase cooperation on clinical assessments across the EU, some matters of HTA will still be handled nationally, including analysis of health economics, pricing, and decisions regarding the introduction of new products.

In addition to the joint effort on an EU level, the Medicines Council also entered the Nordic HTA-collaboration FINOSE in 2023, which is a collaboration between Finland, Norway, Sweden and now also Denmark with the purpose of carrying out joint HTA in these Nordic markets. Accordingly, pharmaceutical companies can under certain conditions decide whether the clinical assessment of their medicinal product shall be carried out by FINOSE or the respective national HTA agency of the participating countries.

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New guidance for applicants for applications based on alternative contract models

In December 2023, the Medicines Council published a new guidance for applications to the Council based on alternative contract models. Alternative contract models, as opposed to standard contract models, tie pricing to specific economic or effect-related outcomes. The idea is that alternative contract models may increase developers' incentive to provide the best possible offering in relation to both quality and costs of a medicinal product. Please refer to Accura's news article from December 2023 on this new guidance and the process for assessment of an alternative contract model, which is retrievable here.

Reduced processing times compared to 2022

The Medicines Council is obliged to process applications regarding new medicinal products within a time limit of 16 weeks from the submission of a complete application. The Council does, however, have the option to invoke a clock-stop rule when more information is required. Furthermore, an extended clock-stop rule can be invoked in cases where unpredictable technical issues render this necessary. The effect of this rule is that the time spent solving these issues does not count towards the final processing time.

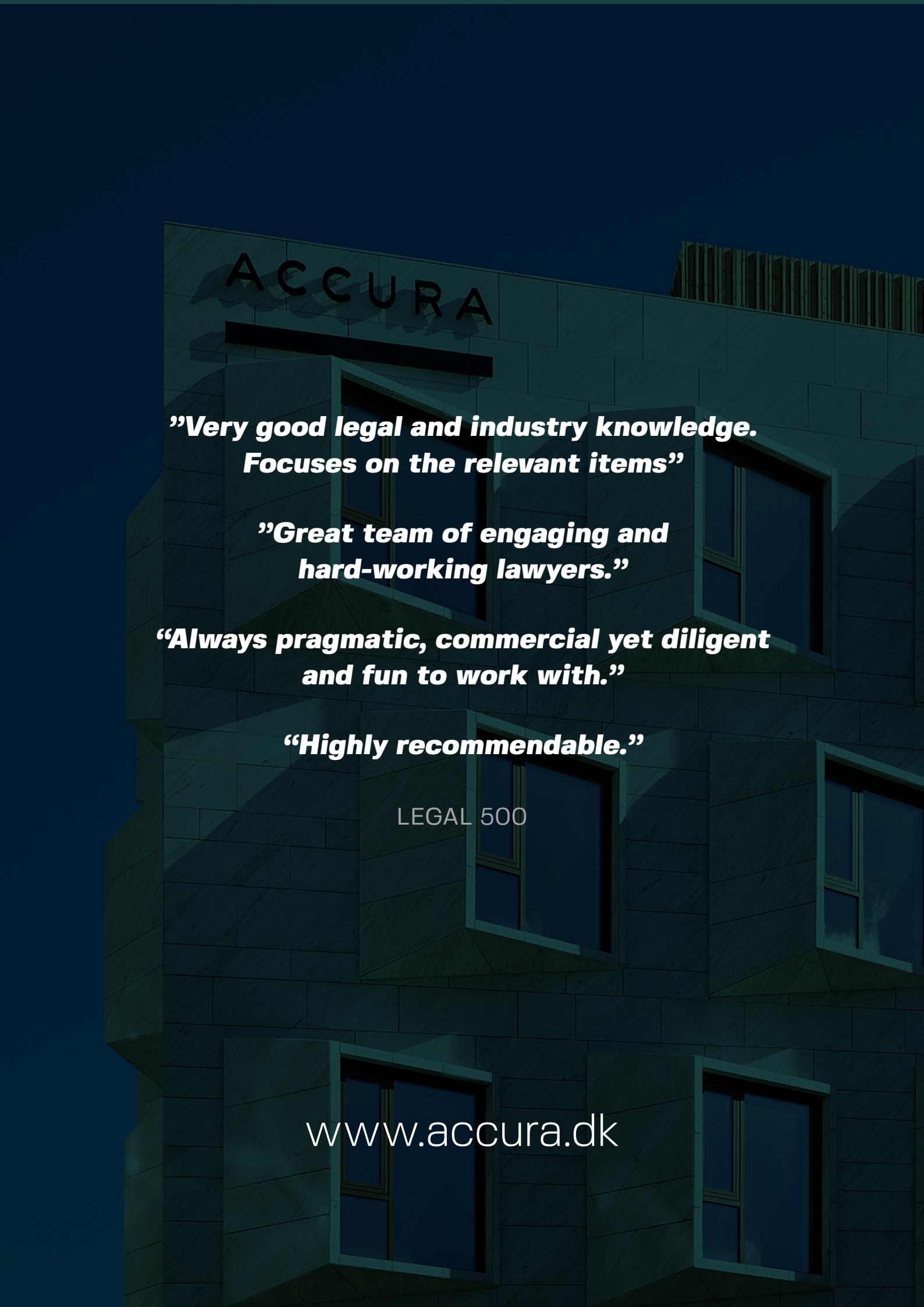
The number of applications completed within the time limit has increased from 24% in 2022 to 56% in 2023. Furthermore, the Council has reduced the number of cases where the Council has made use of the regular clock-stop function from 12 in 2022 to 6 in 2023, and of the extended clock-stop function from 5 in 2022 to 1 in 2023.

The reduced processing time is the result of a recommendation from Danish Regions to the Council to make improvements with respect to both processing times and the effectiveness of processes within the Council.

Accura comments

The annual report for 2023 indicates a tendency towards a more efficient process for assessments of new medicinal products benefitting both pharmaceutical companies in terms of simplicity and speed in the application process and patients by ensuring availability of new medicinal products.

Please reach out to Accura's team of life science specialists for further information regarding the function of or application process at the Danish Medicines Council.



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