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IP & Life Science News

ACCURA

Environmental claims in pharmaceutical advertising

Green marketing and greenwashing have been at the top of the legislative radar for quite some time and are now also emerging explicitly into the field of pharmaceuticals. In this regard, the Danish Ethical Committee for the Pharmaceutical Industry (ENLI) has recently clarified when the use of environmental claims in advertising for medicinal products is compliant with the Code of Practice on Promotion etc., of Medicinal Products aimed at Healthcare Professionals (the Promotion Code).

The clarification is made in the wake of a new decision from ENLI's Appeals Board where the Board found that a draft comparative advertisement for a medicinal product primarily focusing on climate issues would breach the Promotion Code if published.

The Promotion Code's objectivity requirement and the Appeals Board's decision

As a main rule in pharmaceutical advertising, advertisements for medicinal products must be sufficiently complete and objective and must not mislead or exaggerate the properties of the promoted product (the Promotion Code Article 4(2)). An advertisement must therefore always contain, as its primary purpose, professional and relevant information about the product. The main purpose of this requirement is to avoid that the promoted medicinal product, also in comparison to other relevant products, is promoted on parameters irrelevant for healthcare professionals' assessment of the therapeutic effect of the product(s).

In the specific Appeal Board's case, the Board refused a pharmaceutical company's proposal for an advertisement including environmental claims in a comparative context between one of the company's products and a product of a competitor. The Appeals Board stated that the comparative advertisement did not meet the requirements of objectivity in the

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Promotion Code Article 4(2).

The primary focus of the promotional comparison was environmental considerations and the recyclability of the applicators of the two respective products. While the inclusion of this type of information did not in itself constitute a breach of the Promotion Code, the Board found that medicinal products must not be marketed with environmental considerations and recyclability as the principal message of the advertisement.

In its decision, the Appeals Board more specifically stated that in order to meet the requirements of objectivity, information on environmental aspects may only be included as a supplementary element to the primary health-related and otherwise 'professional' information about the products' efficacy and safety profile, possibly accompanied by a comparison of e.g. price. If the emphasis is put on this type of information, thus constituting the differentiating element(s), (documentable) environmental aspects are not prohibited as such in pharmaceutical advertising.

Accordingly, the primary differentiator in advertising must be based on information on the medical efficacy and safety profile of the given product(s), whereby environmental claims must neither be more prominent than the information on efficacy and safety nor otherwise constitute the main element of pharmaceutical advertisements.

Accura comments

The recent clarification on the use of environmental claims and considerations in pharmaceuticals advertising issued by ENLI emphasises that green marketing is a very relevant aspect also in the area of pharmaceuticals. Pharmaceutical companies with activities in Denmark should make themselves familiar with ENLI's opinion on green marketing in pharmaceutical advertising and make sure to tread cautiously if considering to incorporate environmental claims in promotions for its medicinal products – not least by making sure that any environmental aspects are not central to the advertisement.

Watch this space: A new AI artist is in town

A new type of AI model is able to create any image you can imagine from a written prompt. The output image will be based on a vast number of existing images (the training data), but the image itself will be instantly generated and never seen before. You may type something like "A Vincent van Gogh style painting of people reading an interesting article", and the AI models will give you an – often – impressive approximation of that in image form. As you can imagine, such AI models have a long range of application possibilities and could particularly become a useful alternative to companies' use of stock photos.

However, the new AI models ignite a discussion on rights to copyrighted works when AI is involved and what this means for traditional artists.

The image is licensed with a CreativeML Open RAIL-M license and prompted from an open-source beta version of the Stability.ai platform

The new development might best be described as the inverse of a previous development in AI research, namely automated image captioning, whereby algorithms are able to prompt an image caption in natural language based on objects it has already labelled in a given image. The new development turns this upside down to convert natural language text into images that are instantly generated as opposed to simply retrieved from the internet in the style of a Google image search.

The new AI models give rise to the central question: Who owns the rights to the images that are a result of this process (the 'output images' or 'generations')?

Some argue that the artistic work is embodied in the formulation of the natural language prompt itself. This argument seems to view the new AI model as merely another tool in the artists' toolbox, comparable to the transition from paintings to photography where at least some jurisdictions recognise that the artistic work may be found in the creative composition.

Others argue that - because the output images are entirely AI-made (albeit "inspired" by other artistic works) with the user contributing only an idea via text prompts - the results are owned by the developer of the AI model. Or perhaps the output images are not copyrightable at all, but rather part of the public domain.

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For now, it is clear that the output images of these new AI developments are in a tricky copyright position. This is presumably why the terms of use of Dall-E (one of the largest platforms developed and owned by OpenAI) attempt to set aside the copyright issues by claiming ownership of the output images by contract. Whether you can even impose such an obligation in relation to output images remains to be seen and may vary depending on jurisdiction. The issues around copyright law and the interests that are at stake does not become simpler when you consider the ability of these AI models to copy an artist's style without copying a specific work due to ability of the models to extract patterns from massive amounts of data.

Accura comments

The absence of a clear legal consensus on these issues threatens to create unpredictable and arbitrary legal situations and does not provide a satisfying degree of legal certainty for any of the involved parties. An attempt to reach a legal consensus which both traditional artists, users and platforms consider fair is important.

A way of (partially) resolving some of the issues could be to introduce mandatory labelling of the prompt that has generated the output image and a specification of the generating AI model. Another solution could be to introduce an opt in/opt out method with respect to the images that are part of the training data, though this limitation of training data might severely hamper the development of the models.

An indication of what is to come may be found in the recently announced partnership between Shutterstock, one of the largest online libraries of stock photos, and OpenAI in which Shutterstock is to integrate OpenAI's DALL-E 2 and launch a fund for contributor artists. According to the press release, Shutterstock will push forward with an "ethical" action plan which includes the launch of a fund to "compensate artists for their contributions"

The new AI models are part of a fascinating development albeit one that is not without its legal and ethical issues. Hopefully a good and fair solution to the issues can be found. We will continue to monitor the area.

Misleading marketing conduct likely to be made imprisonable – ”It must not pay off to break the law”

As a response to a number of companies having systematically practiced misleading marketing, the Danish Ministry of Industry, Business and Financial Affairs has opted to take action by proposing to amend the Danish Marketing Practices Act resulting in violations of the Act's prohibition against misleading marketing becoming punishable by imprisonment.

It is illegal for traders to use false information in their trading practices, or in other ways mislead consumers by leaving out essential information about product characteristics, costs, delivery, etc., or by presenting information in an ambiguous, incomprehensible or unsuitable manner, cf. sections 5 and 6 of the Danish Marketing Practices Act.

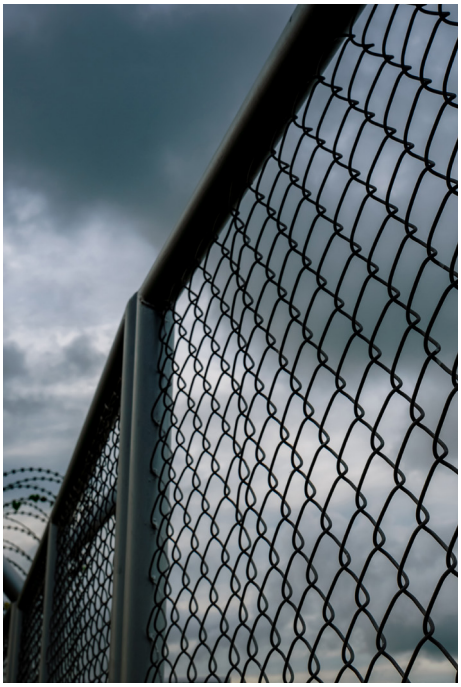
According to the existing rules, violations of the prohibition against misleading marketing in the Danish Marketing Practices Act are punishable by way of fines, unless an increased penalty is due under section 279 of the Danish Criminal Code as a result of the trader committing fraud.

Earlier this year, a new penalty model was introduced in the Danish Marketing Practices Act, according to which the level of fines is calculated on the basis of the gravity of the violation and the trader's turnover. You can read more about the new penalty model in our previous newsletter here.

Imprisonment

With the new legislative proposal, the Ministry suggests adding to the Danish Marketing Practices Act that violating the Act's sections 5 and 6 under aggravating circumstances may be punished by up to 4 months imprisonment if the violation or omission was committed with intent or gross negligence. The courts must assess each case on its merits, and the level of sentencing may be deviated from in an upward or downward direction if mitigating or aggravating circumstances apply.

A key feature of the proposed amendments is to increase the preventive effect of the option of sanctions against traders, and the Ministry has made it clear in the legislative proposal that ”it must not pay off to break the law”.



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Aggravating circumstances

The legislative proposal also specifies which aggravating circumstances may result in imprisonment up to 4 months. According to the proposal, the following will be considered an aggravating circumstance:

1. **Subsequent offence**
   The trader has committed a similar violation or omission within the past 5 years. The violations of the trader do not have to be identical as long as they are similar.

2. **Systematic violations with a financial aim**
   The violation or omission of the rules is systematically committed by the trader with financial gain in mind.

3. **Use of aggravating trading practices**
   The trader has been using aggravating trading practices in connection with the violation or omission of the rules. Usage of harassment, illegal coercion, violence or undue influence, which significantly limits the consumer's freedom of choice, are considered aggravating trading practices that may increase the level of penalty.

The Ministry expects that the proposed rules will enter into force on 1 July 2023. However, the recent general election in the Danish Parliament will likely delay the processing of or otherwise affect the proposal or result in cancellation.

Accura comments

In recent years, the Danish Consumer Ombudsman has had intensive focus on traders' violations or omissions of the rules on misleading marketing under the Danish Marketing Practices Act. In particular, the Consumer Ombudsman has reported various telecommunications and electricity companies to the police and issued fines for systematical violations of the rules on misleading marketing which have been committed with a financial gain in mind. Notwithstanding the primary preventive purpose of the legislative proposal, we expect that the option of imprisonment will be put to use under such aggravated circumstances.

Accura will continue to monitor the development and processing of the legislative proposal. If you have any questions, please feel free to contact us.

New Product Liability Directive may be on its way

On 28 September 2022, the EU Commission published a proposal for a new Product Liability Directive, which is intended to replace the current EU Product Liability Directive (85/374/ECC) of 25 July 1985. The purpose is to modernize and, thus, adapt the product liability rules to new and emerging digital technological developments, such as AI and 3D printing.

The proposal is subject to a public hearing process expiring on 2 December 2022.

Below we outline some of the main changes and impacts of the proposed regulation on businesses, should the proposed directive be accepted in full.

Products: Software and AI

In the proposed directive, it is suggested to broaden the scope of "products" covered by the directive, to include emerging and new technologies. More specifically, "products" shall not only cover tangible products, but also intangible products or products, which are integrated into other products. Consequently, software, AI systems, digital manufacturing files etc. will be governed by the proposed directive, and defects will be subject to strict liability for the manufacturer. Software will be included, notwithstanding whether it is stored on a device or accessed via cloud technologies. This includes for example digital health applications, cleaning robots, or similar.

In addition, digital services which are integrated in or interconnected with a product will also be subject to the strict liability, provided that the absence of the service would prevent the product from performing one of its functions. This includes for example GPS-systems, which are dependent on traffic data, or home security systems, which will not function properly without a subsequent monitoring service.

As a result, software companies and service providers falling within the above scope may experience an increase in the level of (potential) liability. Companies will need to consult their insurance policies to ensure adequate coverage from potential claims from consumers.

Damages: Loss or corruption of data

Currently, consumers are entitled to compensation under the Product Liability Directive, if a product causing damage in the form of death or personal injury,

or harm or destruction of property. The proposal introduces a right to compensation for the loss or corruption of data, and thereby cyber vulnerability will also be subject to strict liability. A large part of ordinary consumer appliances include data, either storage, processing or other utilization, such as login details, products being connected via the internet, etc.

In addition, it is proposed that consumers can be compensated for any medically recognized psychological damages caused. This expansion of the types of damages covered will lead to companies having to assess their liability under the directive, as manufacturers and distributors being heavily reliant on data may be subject to liability under the proposed directive. Again, businesses should perform an assessment to ensure adequate insurance coverage.

Entities subject to liability

The proposal aims at protecting consumers equally, notwithstanding whether the manufacturer being located inside or outside the EU. Consequentially, a level playing field for EU and non-EU manufacturers will be created.

It will accordingly be possible for online platforms and marketplaces to become liable under the proposed directive, provided that they act as sellers.

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Online platforms and marketplaces can however not become liable, should they be able to inform the consumer of an appointed EU representative of the manufacturer.

In addition, the EU Commission recognizes in the proposal that in a circular economy, products are meant to have a longer durability and increasingly be subject to repairs, refurbishment and remanufacturing processes. Defects caused by such upgraded, updated or modified products will also be protected under the proposed directive. This introduces a new liability for parties performing such services and reselling the products, if such party has modified the product substantially and outside the control of the original manufacturer. Thereby an additional category of businesses must take into account the potential liability under the new (proposed) Product Liability Directive.

Burden of proof

Despite many worrisome discussions amongst practitioners and businesses during the past years, the proposal for the new directive does not introduce a reversed burden of proof. It will still be up to the consumer to prove the defectiveness of the product, the damage suffered and the causal link between the two.

The proposal does, however, introduce a reduction of the consumer's burden of proof under specific circumstances, where the defectiveness of a product is to be presumed by the courts. This includes for example situations where it is established that a product does not comply with mandatory safety requirements.

In addition, national courts may presume product default and causality between damage and defect, if the technical or scientific complexity of a claim is considered significant. It will be up to the manufacturer to rebut this presumption.

Information access

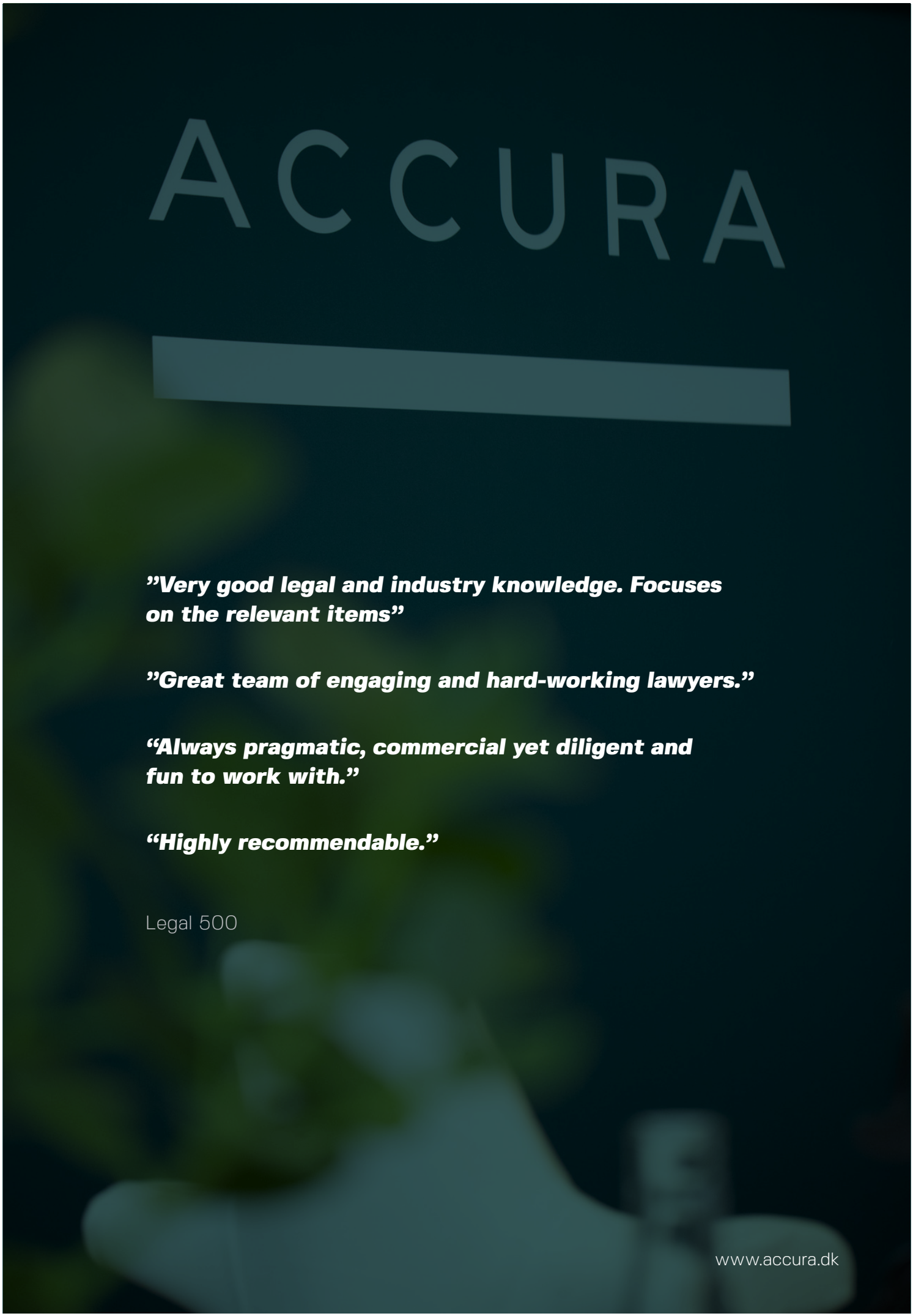
Under the proposed directive, the EU Commission aims to grant consumers better access to information regarding defective products to ease the consumers' burden of proof. It is proposed that national courts can order manufacturers to disclose any necessary and proportionate information regarding a product subject to litigation. This is expected to have effect specifically in the fields of pharmaceuticals, smart products and AI technologies.

As such information may very well include confidential information and trade secrets, the courts are obligated to consider legitimate interest from both parties of the proceedings, including third parties concerned, in relation to such disclosure. The courts must take adequate measures to the extent possible, to protect confidential information and trade secrets.

Accura comments

The new Product Liability Directive is still just a proposal. However, we recommend that businesses consider in due time any effects of the proposal. An array of new businesses will potentially have to consider, how much their risk of liability is increased due to the new regulation, and how such risk will be managed. Further, such businesses should consider their current insurance policies and consider whether they will provide sufficient coverage in case the new proposal will become accepted in its current version.

We will follow the developments within the area of product liability closely and provide an update as soon as it is clear, which rules will become adopted by the European Union.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