

12 January 2024

Kate Dalby
Financial Reporting Council (FRC)
8th Floor
125 London Wall
London
EC2Y 5AS

Re: Proposed changes to ISA (UK) 250 Consideration of Laws and Regulations in an Audit of Financial Statements

Dear Kate Dalby,

AstraZeneca supports the FRC's mission to serve public interest by modernising auditing standards to align with today's complex business environment and thereby provide greater assurance to users of financial statements (including investors).

AstraZeneca is not providing responses to the detailed consultation questions in this submission. As a preparer, we rarely respond to consultations on auditing standards, however, given the likely significant impact of the proposed amendments to ISA (UK) 250 on UK businesses, we believe it is important that we register our concerns.

Our specific concerns to the proposal are listed below:

1. Expanding the requirement to encompass all legal (direct and indirect) non-compliance is a significant step up which will require the business to evidence and demonstrate a complete list of exposures (against which the auditor will need to provide reasonable assurance). Public companies are subject to a vast number of laws and regulations, and larger companies operating in different geographies especially those in highly regulated industries, such as pharmaceuticals, are subject to thousands of laws and regulations at any point in time (for example, via The Medicines and Healthcare Products Regulatory Agency in the U.K, The Food and Drug Administration and Public Company Accounting Oversight Board in the US).

In our view, the proposal would make the financial statement audit take on characteristics of an operational or legal compliance audit, which is a significant extension to the key purpose of a financial statement audit (which is to provide reasonable assurance that such statements are materially correct and fairly present the financial position, results of operations and cash flows of the company).

2. The proposal does not take into account a company's existing compliance and audit functions, the compliance processes in place, and the shared responsibility of the board of directors, the audit committee, the chief compliance officer, and the general counsel who work collaboratively to foster a system that effectively manages the legal and regulatory exposure and supports the delivery of both high-quality financial statements and audits, ensuring protection of public interest.

We believe the proposals will create significant additional audit effort across businesses as well as the audit practice and may adversely impact overall audit quality. Audit firms will likely expect increased compliance documentation from preparers to support their review and sign-off. In our view, the 15 hours identified by the FRC's impact assessment is grossly underestimated.

3. Auditors are not Lawyers and the proposed amendments would expand the auditor's role beyond its core competencies, and thus require auditors to seek both local and global external legal expertise to gain the confidence required to sign off on the proposed requirements. This would not only increase the dependence on the already constrained availability of legal experts but also lead to substantially increased audit fees without commensurate benefit. We believe the teams of in-house attorneys, internal audit, compliance professionals and outside counsel appointed by publicly listed companies are best suited to monitor, identify, investigate, manage and report any potential violations of laws and regulations.
4. UK businesses compete for capital on the global markets and as such the FRC should help ensure that UK regulations are aligned with other international regulators. We are aware that the PCAOB proposed a similar change in August last year which received significant challenge and consequently the proposal is being re-evaluated.

We appreciate the opportunity to share our views and would be happy to discuss them in further detail.

Kind regards,



Philip Broadley (Jan 12, 2024 16:24 GMT+1)

Philip Broadley

Chair of the Audit Committee – AstraZeneca PLC



Mani Sharma (Jan 12, 2024 15:20 GMT)

Mani Sharma

Senior Vice President Finance – Group Controller & Head of Global Finance Services

AstraZeneca PLC

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