**Appendix 4: Audited Annual Sales Report – Voluntary Scheme**

Independent auditor’s report to [name of entity]

**Opinion**

We, [State name of audit firm], have audited the 2019 Voluntary Scheme for Branded Medicines Pricing and Access Annual Sales Report (the “Annual Sales Report”), of [name of entity] (the “Company”) for the [year/period] ended [period end date] as set out in the enclosed spreadsheet entitled Sales Report – Audited Annual and the related notes, including the special purpose basis of preparation and a summary of significant accounting policies, as set out in note 1 to the Scheme Member’s Declaration.

In our opinion the Annual Sales Report for the [year/period] ended [period end date] has been properly prepared, in all material respects, in accordance with the special purpose basis of preparation and accounting policies in [note 1] to the Scheme Member’s Declaration.

**Basis for opinion**

We conducted our audit in accordance with International Standards on Auditing (UK) (“ISAs (UK)”) issued by the Financial Reporting Council (“FRC”), including ISA (UK) 800 and ISA (UK) 805, and our engagement letter dated [date]. Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Annual Sales Report section of our report. We are independent of the Company in accordance with the ethical requirements that are relevant to our audit of the Annual Sales Report in the UK, which includes the FRC’s Ethical Standard, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

**Emphasis of matter – Special purpose basis of preparation**

We draw attention to note [1] to the Scheme Member’s Declaration which describes the special purpose basis of preparation and accounting policies. The Annual Sales Report is prepared to assist the directors in complying with the requirements of the 2019 Voluntary Scheme for Branded Medicines Pricing and Access. The Annual Sales Report has been prepared in accordance with a special purpose framework and, as a result, the Annual Sales Report may not be suitable for another purpose. Our opinion is not modified in respect of this matter.

**Explanation as to what extent the audit was considered capable of detecting irregularities, including fraud[[1]](#endnote-2)[[2]](#endnote-3)**

The risk of not detecting a material misstatement due to fraud is higher than the risk of not detecting one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control. The extent to which our procedures are capable of detecting irregularities, including fraud is detailed below.

* We obtained an understanding of the legal and regulatory frameworks that are applicable to the company and determined that the most significant are [Consider specific laws/regulations in relation to the 2019 Voluntary Scheme for Branded Medicines Pricing and Access]
* We understood how [XYZ] is complying with those frameworks by [insert details of the specific audit approach]
* We assessed the susceptibility of the Company’s financial statements to material misstatement, including how fraud might occur by [insert details].
* Based on this understanding we designed our audit procedures to identify noncompliance with such laws and regulations. Our procedures involved [insert details]

**Directors’ responsibilities for the Annual Sales Report**

As explained more fully in the Scheme Member’s Declaration, the directors are responsible for the preparation of the Annual Sales Report in accordance with the special purpose basis of preparation and accounting policies in [note 1] of the Scheme Member’s Declaration. This includes determining that the basis of accounting is an acceptable basis for the preparation of the Annual Sales Report and for such internal control as the directors determine is necessary to enable the preparation of the Annual Sales Report that is free from material misstatement, whether due to fraud or error.

**Auditor’s responsibilities for the Audit of the Annual Sales Report[[3]](#endnote-4)**

Our objectives are to obtain reasonable assurance about whether the Annual Sales Report is free from material misstatement, whether due to fraud or error, and to issue an auditor’s report that includes our opinion. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the Annual Sales Report.

A further description of our responsibilities is located on the FRC’s website at: www.frc.org.uk/auditorsresponsibilities. This description forms part of our auditors’ report, except for the section detailing an auditor’s responsibility in respect of the directors’ going concern assessment.

As the preparation of the Annual Sales Report does not involve an assessment of going concern by the directors, we have no responsibilities to assess going concern for the purposes of this report.

**Materiality**

The level of materiality applied in the audit of the Annual Sales Report has been determined as follows:

1. If the materiality applied in the audit of the Company’s financial statements is less than 0.5% of turnover, then materiality applied in the Audit of the Annual Sales Report will be 0.5% of turnover.
2. If the materiality applied in the audit of the Company’s financial statements is in the range 0.5%-1.2% of turnover, then that same level of materiality will be applied in the Audit of the Annual Sales Report.
3. If the materiality applied in the Audit of the Company’s financial statements is greater than 1.2% of turnover, the materiality applied in the audit of the Annual Sales Report will be 1.2% of turnover.
4. If the period subject to audit is less than a full year, the materiality applied in the audit is between 0.5% and 1.2% of the turnover disclosed in the entity's most recent annual financial statements.

We have agreed to report uncorrected misstatements in excess of 10% of the level of materiality applied in the audit of the Annual Sales Report to the directors of the Company.

**Subsequent events**

Once we have issued our auditors’ report we have no further obligation to perform any audit procedures in relation to the Annual Sales Report for that financial [year/period]. However, in accordance with ISA (UK) 560 ‘Subsequent events’, if afterwards we become aware of a fact that may have caused us to amend our auditor’s report had we known it before we signed it, we shall discuss the matter with the directors and the Department of Health and Social Care, who shall, together, consider whether the Annual Sales Report needs revision. The directors of the Company agree to inform us of any material event occurring after the date of our auditor’s report which may affect the Annual Sales Report.

**Use of this report**

This report, including the opinion, has been prepared for and only for the Company in respect of the Annual Sales Report in accordance with our engagement letter dated [date]. Without assuming or accepting any responsibility or liability in respect of this report to any party other than the Company, we acknowledge that the Company is required to share a copy of this report with the Department of Health and Social Care to facilitate the discharge by the Secretary of State for Health and Social Care of its functions in respect of the Annual Sales Report. Otherwise, this report, including the opinion, should not be given to any other party or referred to without our prior written consent. We do not, in giving this opinion, accept or assume responsibility for any other purpose or to any other person to whom this report is shown or into whose hands it may come including, without limitation, under any contractual obligation of the Company, save for where expressly agreed by our prior consent in writing.

**Documentation provided to the Department of Health and Social Care**

# In accordance with our engagement letter dated [date], we provided the Department for Health and Social Care with copies of our audit plan (including details of materiality and the reporting timetable) and our report to those charged with governance (including an update on the materiality used and any uncorrected misstatements) at the same time as they were provided to the Company’s directors. We have done so without assuming or accepting any responsibility or liability in respect to these documents to any party other than the Company, including the Secretary of State for Health and Social Care. Our responsibility and liability to the Company is set out in our engagement letter dated [date].

**[Audit firm’s name][[4]](#endnote-5)**

[Location]

[Date]

1. The location of this paragraph within the audit report is flexible and it may be combined with auditor’s responsibilities with or without a separate heading [↑](#endnote-ref-2)
2. Strict wording is not imposed in this section. This wording is suggested only and can be adapted. [↑](#endnote-ref-3)
3. 3 No opinion on Going Concern is included in this report. ISA (UK) 805 para 10 requires that the requirements of the ISAs (UK) are adapted when the subject of the audit is not a complete set of financial statements and, although ISA (UK) 805 para A10 states that ISA (UK) 570 will, in principle, be relevant, there is a strong argument in the case of a report on revenue information that it is not. [↑](#endnote-ref-4)
4. If the company is listed, in which case the requirement in ISA (UK) 700 para 46 applies, the report must include the name of the engagement partner – this can be fulfilled either by signing the report in the individual’s name or by including a statement in the auditor’s report identifying the individual, for example “The engagement partner on the audit resulting in this independent auditor's report is [name]”. For unlisted companies, firms may choose to include the name of the engagement partner. [↑](#endnote-ref-5)