

A guide to the assurance statement on non-financial reporting

1. Introduction

The Novo Nordisk Annual Report 2004 integrates financial and non-financial performance. The Annual Report is presented with two auditor's reports. The first covers the audit of all the information in the Annual Report, including all financial information in accordance with International Financial Reporting Standards, the Danish Financial Statement Act and additional Danish reporting requirements as well as information pertaining to Novo Nordisk's non-financial performance. The second concerns Novo Nordisk's commitment to sustainability and stakeholder engagement embodied in the principles of materiality, completeness and responsiveness of the AA1000 Assurance Standard (AA1000AS).

In agreement with Novo Nordisk management, we have prepared this 'guide' to our assurance statement on non-financial reporting. It sets out to provide a more full understanding of the assurance statement prepared in accordance with the AA1000AS and ISAE3000. As such this document provides in particular a more detailed outline of the work we have undertaken to prepare the assurance statement as well as the underlying conclusions on which the opinion in the statement is based. This document is addressed to the stakeholders of Novo Nordisk.

We stress that this document does not in any way present nor should be interpreted to represent a qualification of our assurance statement. We also stress that this document does not disclose the recommendations and underlying observations we have presented to Novo Nordisk¹. In accordance with the AA1000AS and ISAE3000 our recommendations address areas of weakness and improvement.

We do not accept or assume any liability or duty of care for any other purpose or to any other person to whom this document is shown or into whose hands it may come save where expressly agreed by our prior consent in writing.

2. The Assurance Statement

The assurance statement follows a simple structure: i) what is the objective and scope of the assurance engagement; ii) what work has been undertaken to accomplish the objective; and iii) what are the conclusions/the opinion.

What is the objective and scope of the assurance engagement?

The objective and scope of the engagement is stated at the top of the assurance statement.

¹ We note that the recommendations presented to Novo Nordisk do not represent qualifications of the assurance statement.

Subject, responsibilities, objective, and scope of assurance statement

We have reviewed Novo Nordisk's commitment to sustainability and stakeholder engagement embodied in the principles of the AA1000 Assurance Standard (AA1000AS).

Management of Novo Nordisk is responsible for defining stakeholders and for the collection and presentation of the non-financial information in the Annual Report. Our responsibility, as agreed with Management, is to express conclusions with limited assurance in relation to the principles of materiality, completeness and responsiveness of the AA1000AS and in accordance with the ISAE 3000.

Moreover, we have assessed Management's statement that the Annual Report meets the conditions for reporting 'in accordance' with the GRI's 2002 Sustainability Reporting Guidelines, and whether the reporting and underlying policies, systems and activities support Management's commitment to the United Nations' Global Compact.

The objective of the engagement is to review Novo Nordisk's commitment to sustainability and stakeholder engagement. Novo Nordisk has asked us to make this review against the three key principles of the AA1000AS, materiality, completeness and responsiveness. Consistent with statutory requirements Novo Nordisk as the reporting organisation decides to whom the information in the Annual Report is reported as well as what is important to report. As assurance providers we are asked to review the extent to which the reporting compares with the requirements of the AA1000AS; please see text box. As a professional auditing firm our conclusions must also, however, be in conformity with the ISAE 3000².

The AA1000 Assurance Standard

The AA1000 Assurance Standard is a generally applicable standard for assessing, attesting to, and strengthening the credibility and quality of organisations' sustainability Reporting, and their underlying processes, systems and competences.

The standard requires that the assurance provider

- States whether the Reporting Organisation has included in the Report the information about its sustainability performance required by its stakeholder for them to be able to make informed judgements, decisions and actions by assessing whether what is in the report is material for Novo Nordisk's stakeholders, and whether indicators and targets included in the Annual Report can be and are used in strategic and operational decision making tools and processes.
- Evaluates the extent to which the Reporting Organisation can identify and understand material aspects of its sustainability performance associated with activities, products, services, sites and subsidiaries for which it has management and legal responsibility.
- Evaluates whether the Reporting Organisation has responded to stakeholder concerns, policies and relevant standards, and adequately communicated these responses in its Report by assessing whether Novo Nordisk has decided how it intends to respond to stakeholder concerns and interests; whether Novo Nordisk has established associated policies, targets and indicators; whether Novo Nordisk has demonstrated that it has allocated resources to enable it to implement associated policies and commitments; and whether Novo Nordisk has communicated the above in the Annual Report in a manner that is both timely and accessible to stakeholders.

Source: AA1000 Assurance Standard, Accountability 2003

² The International Standard on Assurance Engagements (ISAE) 3000, "Assurance Engagements Other Than Audits or Reviews of Historical Financial Information" is issued by the International Federation of Accountants (IFAC). Accounting firms must follow this standard when performing the aforementioned assurance engagements.

In addition to providing assurance on the Annual Report, we have been asked to make an assessment of management's statement that Novo Nordisk's reporting meets the conditions for reporting 'in accordance' with the GRI Sustainability Reporting Guidelines, and to assess whether the reporting and underlying policies, systems and activities support Management's commitment to the United Nation's Global Compact.

What is the Basis of Opinion?

The basis of opinion outlines in more detail what kind of work including evidence-gathering procedures we have undertaken to provide a foundation for our opinion and recommendations.

Basis of opinion

We planned and performed our work based on the AA1000AS and in accordance with the ISAE 3000. Based on an assessment of materiality and risk, our work included a review of management systems, reporting structures and boundaries as well as enquiries, interviews and testing of registration and communication systems, data and underlying documentation. We tested whether data and the underlying components are accounted for in such a way as to fulfil the assertions of materiality, completeness, valuation, existence and cut-off in accordance with the Novo Nordisk accounting policies for non-financial data. Two major production sites were visited in Denmark, namely Bagsværd and Kalundborg.

We have assessed Novo Nordisk's statement that it reports 'in accordance' with GRI by checking that the reporting (the Annual Report and the supplementary information in the online report) contains the required information and indicators and by reviewing Novo Nordisk's own assessment of whether these are consistent with the eleven Reporting Principles of Part B in the GRI Guidelines.

With respect to the UN Global Compact we have reviewed Novo Nordisk's own assessment of how the reported information and the underlying policies, systems and activities are aligned to and support the principles of the UN Global Compact.

The nature and extent of our work is first and foremost defined by the level of assurance we are seeking to obtain. The AA1000 Assurance Standard does not currently provide definitions of level of assurance nor does it provide guidance on what evidence-gathering procedures need to be undertaken to pursue higher or lower levels of assurance. The Standard notes, however, that the level of assurance provided may depend on the extent and quality of, *inter alia*, sufficiency of evidence, underlying systems and processes, internal assurance systems and resources allocated for assurance by the Reporting Organisation³.

We have planned and performed our work with a view to obtain limited assurance based on the AA1000 Assurance Standard's assurance principles and in accordance with the ISAE 3000. The term limited assurance is derived from the ISAE 3000; please refer to text box below. In practice, limited assurance means that our evidence-gathering procedures and testing are more limited than for a reasonable assurance engagement⁴.

³ Please refer to the AA1000 Assurance Standard for a full account of issues that may impact the level of assurance.

⁴ The level of assurance is also a function of the auditability of the underlying systems, procedures and controls of reported data.

ISAE 3000

The International Standard on Assurance Engagements 3000 establishes basic principles and essential procedures for, and to provide guidance to, professional accountants in public practice for the performance of assurance engagements other than audits or reviews of historical financial information.

The ISAE 3000 distinguishes between two types of assurance engagements a assurance provider is permitted to perform; reasonable assurance engagement and limited assurance engagement with the former providing the highest level of assurance.

This difference in risk is expressed in the opinion where a reasonable level of assurance leads to a positive form of conclusion, e.g. 'in our opinion Novo Nordisk's system to measure CO₂ emissions is effective', while a limited level of assurance leads to a conclusion in negative form, e.g. 'Nothing has come to our attention that causes us to believe that Novo Nordisk's measuring of CO₂ emissions is not effective'

What work did we perform?

The work we performed was aligned to the requirements of the AA1000 Assurance Standard as well as the ISAE 3000. We undertook the following evidence-gathering procedures to form a basis for our conclusions:

- Interviewed in-person a number of Novo Nordisk executives, senior managers, and expert staff:
 - to develop a understanding of how sustainability objectives and priorities are set and key sustainability risks and opportunities managed
 - to assess how materiality is perceived at various levels in the organisation
 - to assess the extent to which sustainability is integrated throughout the organisation (geographically, business areas and business functions)

As part of this, we conducted a limited number of interviews with site managers at two major production sites located in Denmark (Bagsværd and Kalundborg) as well as a phone-interview with the General Manager of one non-Danish site.

- Reviewed Novo Nordisk's ex-post reasoning for determining materiality of reported data, including both qualitative and quantitative data.
- Reviewed a limited selection of Danish media sources with a view to i) check whether the Annual Report reflected issues of concern to key stakeholders, ii) check whether possible policy breaches were appropriately reflected in the Annual Report, and iii) check whether internal management mirrored external statements.
- Reviewed Novo Nordisk's stakeholder engagement activities, including the company's trend spotting activities through interviews with corporate staff with a view to determine whether Novo Nordisk has in place appropriate procedures to engage with stakeholders and their present and emerging concerns and interests.
- Reviewed a wide range of documents such as minutes from executive management meetings and meetings in relevant policy committees headed by members of executive managements; policy papers, strategy documents and guidelines on sustainability issues; internal balance scorecards; consolidated facilitation reports; and business plans with a view
 - to establish top management awareness of, involvement in and decision-making related to sustainability
 - to determine the existence of policies, indicators and targets related to reported information

- to ensure adequate evidence to support the information in the Annual Report as well as the robustness of the systems and procedures underpinning its production and application.
- Substantive testing of a significant number of reported quantitative indicators and their underlying processes and procedures, including review of accounting principles and their application, and review of data collection, reporting and control procedures to determine that reported data fulfil the assertions – in the sense of AA1000AS - of completeness, materiality, valuation, existence, and including in the proper period. As part of this we visited two major production sites in Denmark.
- Assessed Novo Nordisk management's statement that the Novo Nordisk reporting (that includes both the Annual Report and the supplementary information in the online Report) meets the conditions for reporting 'in accordance' with the GRI Sustainability Reporting Guidelines 2002 by checking that the reporting:
 - contains all information required in Section 1-3 of Part C of the Guidelines
 - contains a GRI Content Index
 - contains data (quantitative and qualitative) regarding performance against each of the GRI core indicators or explanations for omissions.
 - contains a statement signed by the board or the CEO confirming that the reporting has been prepared in accordance with GRI; and
 - by reviewing Novo Nordisk's own assessment of whether the reported information and indicators are consistent with the eleven Reporting Principles of Part B of the Guidelines.

It should be underlined that it is not the Annual Report in itself that has met the criteria for reporting 'in accordance' with GRI, but the Annual Report combined with the reporting on the Novo Nordisk web-site.

- Reviewed Management's own assessment of how the reported information (that includes both the Annual Report and the supplementary information in the online Report) and the underlying policies, systems and activities are aligned to and support the principles of the UN Global Compact.

Our Opinion

The opinion we express in the assurance statement is based on the work performed described in the preceding section, *Basis of Opinion*. We express our opinion in relation to the AA1000 Assurance Standard principles of materiality, completeness and responsiveness. Our opinion is expressed in a negative form to reflect that the level of assurance obtained is limited.

Opinion

Based on the work performed nothing has come to our attention that would cause us not to believe that

- the Annual Report includes information that is material to Novo Nordisk's corporate stakeholders and that the reported targets and indicators in respect of sustainability in general are used in strategic and operational decision-making;
- the Annual Report presents a fair and balanced account of Novo Nordisk's material sustainability performance, risks and impacts at the corporate level and that Novo Nordisk can identify and understand material aspects of its corporate sustainability performance;
- through the Annual Report Novo Nordisk is responsive to major issues raised by stakeholders and that Novo Nordisk has robust policies, programmes and procedures in place to address material issues raised by stakeholders.

Based on our work we consider that Novo Nordisk's policies, systems and activities taken as a whole support Management's commitment to the UN Global Compact. In addition, nothing has come to our attention that disproves Novo Nordisk's statement that it has met the conditions for reporting 'in accordance' with the GRI guidelines.

When forming our opinion we are required to consider a number of aspects; please refer to text box 1. In view of the brevity of the assurance statement, these aspects are not fully communicated in the assurance statement. Hence, below we have outlined the key conclusions that allowed us to form the opinion expressed in the assurance statement. The conclusions below do not and should not be viewed to represent a qualification of the assurance statement.

Materiality

- We are not aware of any information material to corporate stakeholders that has been excluded from the Annual Report. The sustainability issues that in general are considered material to the pharmaceutical industry have been addressed in the Annual Report, including issues related to access to health, business ethics, transparency in clinical trials and animal health. We have not undertaken sufficient work to form an opinion on to what extent the Annual Report meets the requirements of local stakeholders, however we note that it is the intention of Novo Nordisk to prepare individual site reports.
- We noted that Novo Nordisk's annual reporting is yet to be guided by a robust set of materiality criteria although Novo Nordisk presented fair and balanced reasoning for the materiality of the information in the Annual Report. It must be recognised at the same time that integrated financial and non-financial reporting in general is yet to develop a robust materiality criterion.
- We observed that many of the reported indicators are used in the corporate Balanced Scorecard as well as in business unit or site Balanced Scorecard. We also noted that neither environmental investment or cost indicators nor economic footprint indicators seem to be used for any business related purpose.
- Novo Nordisk organisational structure including functional committees headed by executive management allows that sustainability issues are raised with and decided upon by executive management.

Completeness

- Novo Nordisk Way of Management is a platform for Novo Nordisk's business. It outlines basic policies with respect to environmental impact and occupational health and safety, however it stops short of providing detailed guidance on performance. Hence, compliance with the policy will not necessarily ensure an even level of performance across production

sites, e.g. emission standards may vary as well as may safeguards with respect to the working environment.

- Novo Nordisk's efforts in areas such as environmental management and occupational health and safety have been focused on the Danish sites while less attention has been devoted to sites and affiliates outside Denmark.
- Novo Nordisk is addressing and reporting on a wide range of sustainability risks and opportunities along the value chain including risks and opportunities outside the boundaries of which it has legal or direct managerial control, e.g. Novo Nordisk is addressing animal health with Contract Research Organisations, social and environmental issues with suppliers, and various health needs of users and health care professionals through its National Diabetes Programme. We are not aware of issues material to the sustainability performance of the company and its stakeholders that are unaddressed.
- We observed that Novo Nordisk prepares a strategic detailed and direction guiding bi-annual business plan for sustainability. The business plan provides a solid basis for Novo Nordisk's work with sustainability and contributes to continuous improvements.
- Novo Nordisk is undertaking a wide range of activities with respect to diabetes prevention including the National Diabetes Programmes and the Oxford Vision 2020 project. We note that Novo Nordisk is yet to determine the objectives and targets for these activities.
- In 2004, Novo Nordisk decided to develop a policy on business ethics as well as to review all policies of the Novo Nordisk Way of Management to ensure consistency with business ethics.
- The use and/or clarity of existing procedures and controls could be improved to ensure more robust data collection, validation and reporting performance.

Responsiveness

- Novo Nordisk does not have a stakeholder engagement strategy in the traditional sense that it plans, performs and reports the number of stakeholder engagement it undertakes. We see this as evidence of the company having progressed towards the point where stakeholder engagement at corporate level is performed as an ongoing undertaking and where stakeholders are involved informally and formally in management of sustainability issues. Novo Nordisk's 'trend-spotting activities' support its stakeholder engagement strategy and activities.
- Novo Nordisk has established an ombudsman function that is accessible to all employees for all concerns.
- The Novo Nordisk planning and decision-making process provides a structured approach to ensure that identified issues eventually are underpinned by planning, policies, guidelines and process as required.
- We did not see evidence such as policies, guidelines, tools or internal reporting structures and procedures that would suggest that stakeholder engagement is fully integrated and

embedded throughout the business lines including non-Danish sites and affiliates. We also note that sustainability management seems to be centralised.

- Novo Nordisk uses the GRI 2002 Guidelines.

END