

Independent Assurance Report

**Internal Procedures at Bayer on Quality, Safety and Efficacy
of the Coppertone® product range**



AccountAbility

Setting the Standard for
Corporate Responsibility and
Sustainable Development

To Bayer HealthCare LLC, Consumer Health Division, New Jersey (USA)

BAYER HEALTHCARE, LLC Consumer Health Division (therein 'Bayer' or 'the Company') engaged AccountAbility to undertake an independent assurance of their internal processes, systems, controls, and performance guidelines relating to the labeling accuracy of its Coppertone® sun care product range for the United States market. Our responsibility in performing this work is to determine appropriate controls are applied around the product labelling accuracy for its over-the-counter (OTC) Coppertone® products, and that the standard operating procedures are appropriately applied at Bayer on the quality, safety and efficacy aspects of its Coppertone products, and that they are in accordance with the relevant regulatory guidelines applicable to the sun care product industry in the United States.

AccountAbility applied the International Standard on Quality Control 1 and accordingly maintains a comprehensive system of quality control including documented policies and procedures regarding compliance with ethical requirements, professional standards and applicable legal and regulatory requirements.

We have complied with the independence and other ethical requirements of the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants, which is founded on the fundamental principles of integrity, objectivity, professional competence and due care, confidentiality and professional behavior.

This Report has been prepared for the use of our client Bayer. We consent to the publication of this report in conjunction with Bayer's explanation to stakeholders regarding the purpose of this report, without accepting or assuming any responsibility or liability on our part to any parties other than Bayer unless expressly agreed by our prior consent in writing.

Sincerely,

AccountAbility 

Table of Contents

Objective	4
Assurance standards.....	4
Scope of the engagement and approach	4
Subject matter	5
Criteria.....	5
Our responsibility.....	6
Assurance procedures	6
Conclusions.....	8
Recommendations	9

Objective

The objective of our assurance procedures is to determine that standard operating procedures (“SOPs”) are applied as part of Bayer’s process in providing accurate labelling associated to its Coppertone® product range (the “Products”) based on quality, safety, and efficacy aspects.

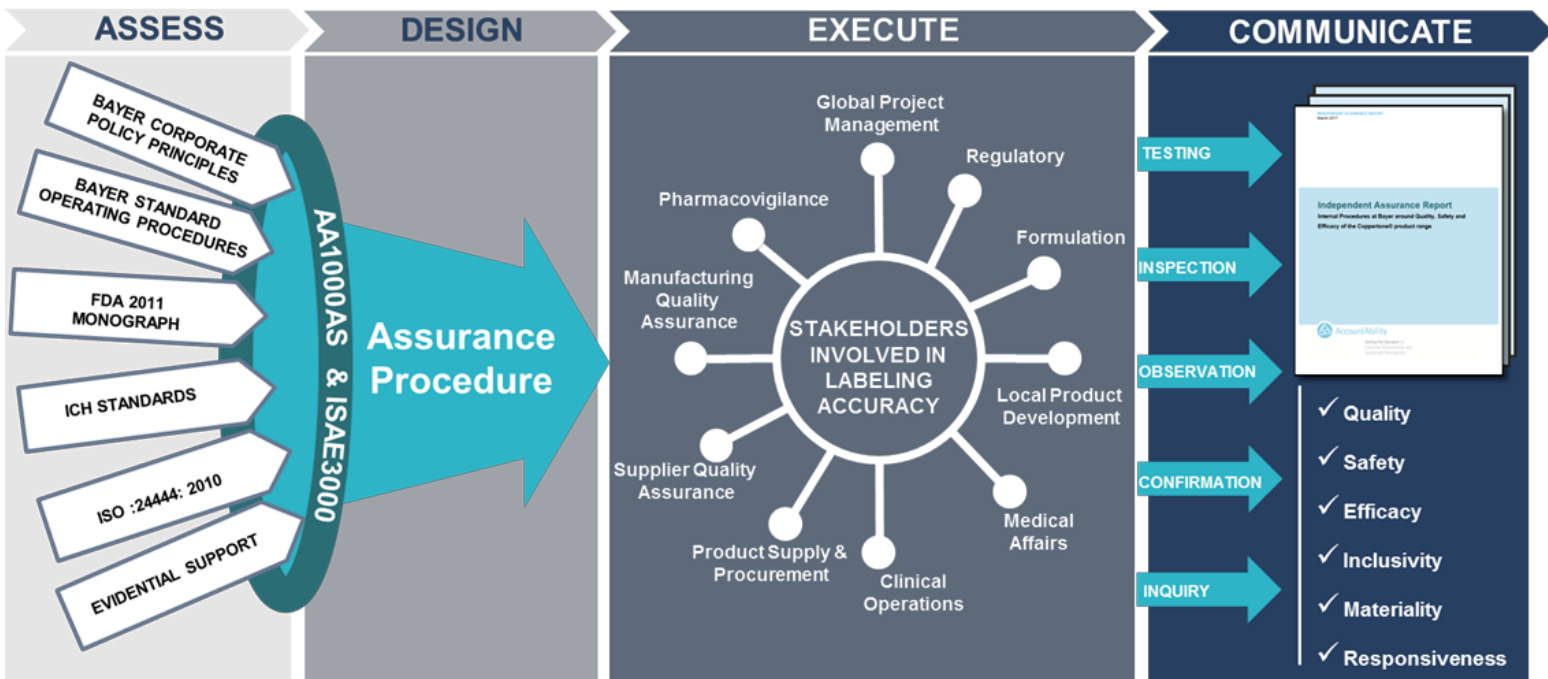
Assurance standards

We have performed limited assurance procedures in accordance with the International Standard on Assurance Engagement other than Audits or Reviews of Historical Financial Information – the ISAE3000 (Revised), as well as Type 2 Moderate assurance procedures in accordance with the AccountAbility Assurance Standard (2008) – AA1000AS to determine whether Bayer has applied appropriate SOPs and are in accordance with Bayer Compliance and national regulatory and industry guidelines to ensure that the accuracy of its Product labelling adheres with the principles of:

- ▶ *Inclusivity* – how Bayer identifies and includes participation of stakeholders in developing and achieving an accountable and strategic response to the subject matter.
- ▶ *Materiality* – how Bayer determines the relevance and significance of an issue to an organisation and its stakeholders.
- ▶ *Responsiveness* – how Bayer responds to stakeholder issues that affect its performance, realized through actions, decisions and communications.

Scope of the engagement and approach

The scope of our work focuses on the Product development and manufacturing quality assurance SOPs and control procedures in the United States for the period spanning January 1, 2016 through December 31, 2016.



Subject matter

Internal processes, systems, controls, and performance guidelines are required at Bayer to determine that quality, safety and efficacy are reflected in its processes in labelling the Products available in the United States market relating to the 2016 Fiscal Year period from January 1, 2016 to December 31, 2016. More specifically, this relates to:

- ▶ The guidelines, processes, systems and controls developed and enforced at Bayer to comply with market regulations in the United States related to the quality, safety and efficacy of the Products.
- ▶ The quality assurance processes and systems developed and enforced at Bayer to ensure the accuracy of the ingredients labelled and the claims made on the packaging of all product forms marketed in the United States based on the quality, safety and efficacy and performance of the Products.
- ▶ The supplier audit processes, controls and performance guidelines developed and enforced at Bayer to ensure third party testing labs and contract manufacturing organizations comply with market regulations in the United States related to the quality, safety and efficacy of the Products.
- ▶ The three AccountAbility Principles – *Inclusivity*, *Materiality* and *Responsiveness* with respect to the quality, safety and efficacy of the Products.

Criteria

The criteria used in developing our assurance procedures are based on the following for all Products, which include, **spray, lotion, stick, and whipped formulations**:

- ▶ testing results in final formulation performance data for sun protection factor (SPF), water resistance, stability and broad spectrum claims related to the Products
- ▶ internal regulatory interpretations, guidelines and controls related to the Products from:
 - United States Food and Drug Administration (FDA):
 - *Labelling and Effectiveness Testing: Sunscreen Drug Products for Over-the-Counter Human Use (2011)*.
 - *Contract Manufacturing Arrangements for Drugs: Quality Agreements Guidance for Industry (2016)*
 - International Standards Organization (ISO):
 - *In vivo determination of the sun protection factor (ISO:24444:2010)*
 - *Determination of sunscreen UVA photoprotection in vitro (ISO:24444:2012)*
 - International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH):
 - *Quality, Safety and Efficacy Guidelines (2005)*
- ▶ internal quality assurance process and systems for spray, lotion, stick, and whipped packaging and labelling of the Products
- ▶ internal supplier audit processes, controls and performance Data for third party testing labs and contract manufacturing organizations related to the Products
- ▶ internal standard operating procedures for pharmacovigilance and change controls related to the Products

Our responsibility

Our responsibility is to conduct a limited assurance engagement based on the scope and procedures outlined to Bayer Management and draw conclusions based on the work undertaken.

The accuracy and completeness of non-financial information and indicators are subject to inherent limitations given their nature and methods for determining, calculating and estimating such data and information. Our assurance report should therefore be read in connection with the internal processes, systems, controls, and performance guidelines at Bayer used to ensure the quality, safety and efficacy of its Products as well as regulatory guidelines as listed in “Criteria”.

The Company’s management is responsible for the proper development of processes, systems, controls and performance guidelines relating to the quality, safety and efficacy of its Products. This responsibility includes a rational and precautionary interpretation of market regulations in the United States and subsequent design of internal standard operating procedures that enable an appropriate compliance with the Company’s reasonable interpretation of market regulations in the United States.

Assurance procedures

We have performed the following limited and type 2 moderate assurance procedures to draw conclusion to our Report in determining that SOPs, industry guidelines and regulatory requirements are used as part of Bayer’s processes in providing accurate labelling associated to the Products based on quality, safety, and efficacy aspects:

- ▶ Gain an understanding of Bayer’s commitments, competencies, resources and internal controls and systems relating to its processes in addressing safety, quality and efficacy applied to adhere to the AccountAbility Principles of *Inclusivity*, *Materiality* and *Responsiveness* through inquiries and limited sample testing performed with the following departments:
 - Pharmacovigilance
 - Supplier Quality Management
 - Clinical Operations
 - Product Supply and Procurement
 - Medical Group
 - Clinical Operations
 - New Product Development Core Project Management
 - Local Product Development Group
 - Manufacturing Quality Assurance
 - Regulatory
- ▶ Inquiring, collecting and inspecting documentary evidence and management representations that support adherence to internal processes, systems, controls, and performance guidelines relating to the quality, safety and efficacy of the Products and the AccountAbility Principles of *Inclusivity*, *Materiality* and *Responsiveness*.
- ▶ Understanding the management of specified performance guidelines and information collection processes related to the quality, safety and efficacy of the Products.
- ▶ Selecting representation samples across all released SKUs in 2016 (covering all product forms, such as whipped, stick, spray, and lotion) to perform validation testing, and collect relevant documentary evidence to evaluate the processes, systems and controls used to adhere to Bayer’s interpretations of the regulatory guidelines to comply with the regulations in the United States related to the quality, safety, and efficacy of

the Products. Note, our sample selections include, both, Bayer and Merck developed Products, which were part of Bayer's acquisition of Merck Consumer Care Business in 2014. For all Merck developed Products, they are referred to as "legacy" Products

- ▶ Observing and inspecting, on a sample basis, the management practices, process testing and evidence gathering relating to the quality, safety and efficacy of the Products at Bayer's Consumer Health's division in Morristown New Jersey, and corporate Headquarter in Whippany, New Jersey.
- ▶ Inquiring regarding the scope and findings on the latest Global Quality Management audit of Bayer's Cleveland, TN manufacturing site of the Products in 2016 and that the findings from the audit were addressed, and the findings were not related to the Products' safety, quality and efficacy.
- ▶ Inquiring and performing limited inspection of supporting documents as related to the third-party lab results on water resistance, SPF, broad spectrum, and stability for the "legacy" Products that were not developed and formulated by Bayer.

AccountAbility did not perform or re-perform tests on the SPF, water resistance, stability, and broad spectrum data as well as quality assurance of its manufacturing facilities or third party suppliers for the Products.

Conclusions

Based on the assurance procedures performed and evidence obtained for the Bayer developed Products, nothing has come to our attention that causes us to believe that Bayer has not, for the scope period spanning January 1 2016 through December 31, 2016:

- ▶ Complied, in all material aspects, with its internal guidelines designed to ensure the quality, safety and efficacy of the Products.
- ▶ Accurately tested and implemented quality assurance procedures, based on its reasonable interpretation of market regulation for the United States, the ingredients, SPF, water resistance, stability and broad spectrum properties on the label and packaging of Bayer developed Products.
- ▶ Accurately verified the work undertaken by third party testing labs to comply with market regulations in the United States related to the quality, safety and efficacy of the Products.
- ▶ Accurately labelled the ingredients and made appropriate claims on the packaging of the Products
- ▶ Adopted, in all material respects, its SOPs and guidelines that adhere to the AccountAbility Principles (2008) - AA1000APS.

At the time of issuing this report, AccountAbility noted that Bayer is in the process of locating the FDA required spectrum critical wavelength testing results that were conducted by Merck prior to Bayer's acquisition for one of our selected "legacy" Product samples. Bayer's archiving of testing results conducted by Merck is part of an on-going post-integration process. Once located, Bayer will formally archive the testing results in its central file depository system and, once provided, AccountAbility will update this report.

Principle – Inclusivity

The Company's efforts to engage with both internal and external stakeholders related to the Products demonstrated adherence to the AccountAbility Principle of Inclusivity. The development process for new products identifies key internal stakeholders that represent teams with specific responsibilities and subject-matter expertise and requires their continuous input in shaping the product development strategy and approach to ensure the safety, quality and efficacy of Bayer's Products. In addition, a pharmacovigilance process identifies and monitors potential product risks, as well as adverse signals raised by academic studies, industry trends, and consumer groups. Bayer also has an [online campaign](#) to raise customer awareness on appropriate use of sun care product.

Principle – Materiality

The Company's undertaking of quality, safety, and efficacy procedures of the Products by interpretation of market requirements in the United States are coherent with the AccountAbility Principle of Materiality. Materiality is used as a core factor in the design and implementation of Bayer's internal procedures overall as demonstrated by the materiality assessment in the [2015 Annual Report](#), that identifies *Product & Process Innovation*, *Stakeholder Engagement*, *Business Ethics*, *Product Stewardship* and *Supplier Management* as very high material issues. These material issues underline the standard operating procedures that have been implemented at each stage of the Products' lifecycle from product development, formulation, clinical and medical testing, manufacturing and product release, quality assurance, and pharmacovigilance of the Products.

Principle – Responsiveness

The Company's integration of processes, systems, controls, and performance guidelines regulating the quality, safety and efficacy of its Products to ensure ultimate product labelling accuracy in accordance with relevant regulatory guidelines applicable to sun care products in the U.S. market demonstrate adherence to the AccountAbility Principle of Responsiveness. Standard operating procedures at Bayer are informed by various organizations including the [United States Food and Drug Administration \(FDA\)](#), [International Standards Organization \(ISO\)](#), and [International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use \(ICH\)](#). In particular, policies and governance structures pertaining to corrective action plans (CAPAs) and pharmacovigilance ensure responsiveness to both internal and external stakeholders issues and provides risk management framework to respond and address critical product issues in the consumer health sector that could have potential material consequences.

Recommendations

AccountAbility recommends Bayer establish a timeline for completing its archiving process of testing reports of legacy Products as part of its post-acquisition integration process. Once completed, AccountAbility will verify that spectrum critical wavelength testing reports are archived in Bayer's central file depository system.

In addition, as part of our assurance procedures, AccountAbility has provided Bayer management with suggestions in areas of continuous improvement to apply leading practices that could further strengthen the Company's internal processes. Some of the suggestions are:

- ▶ improving documentation references for easier access to records;
- ▶ improving certain inter-departmental synergies through more frequent follow-up and communications on status of project initiatives and timelines;
- ▶ developing certain required fields and/or templates for customers to provide Product feedback in order to enhance the information received and to efficiently process the issues.

AccountAbility

3 Lloyds Avenue, EC3N 3DS, London

United Kingdom



14 April 2017

AccountAbility has relevant experience in researching, standardizing and verifying corporate non-financial performance data, systems and processes. AccountAbility professionals have the appropriate professional and technical competencies and experience to conduct an assurance to the AA1000AS (2008). AccountAbility did not provide any services to Bayer during 2016 Fiscal Year that would conflict with the independence of this work.
© 2017 AccountAbility.org. All rights reserved.