

Independent Assurance Report

**Internal Procedures at Bayer on Quality, Safety and Efficacy of the
Coppertone® product range for the calendar period 2017**



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 over-the-counter 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 labeling accuracy for its Coppertone® products, and that the standard operating procedures (SOPs) 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. In addition, we have met all the license requirements as prescribed by the Assurance Standard (2008) - AA1000AS and is certified in the Certified Sustainability Assurance Practitioner (CSAP) program.

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 

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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 labeling associated to its Coppertone® product range (the “Products”) based on quality, safety, and efficacy aspects. Additional procedures include expanded sample testing around supplier audit procedures, pharmacovigilance and systems and controls. See section Assurance Procedures on page 7 for more details.

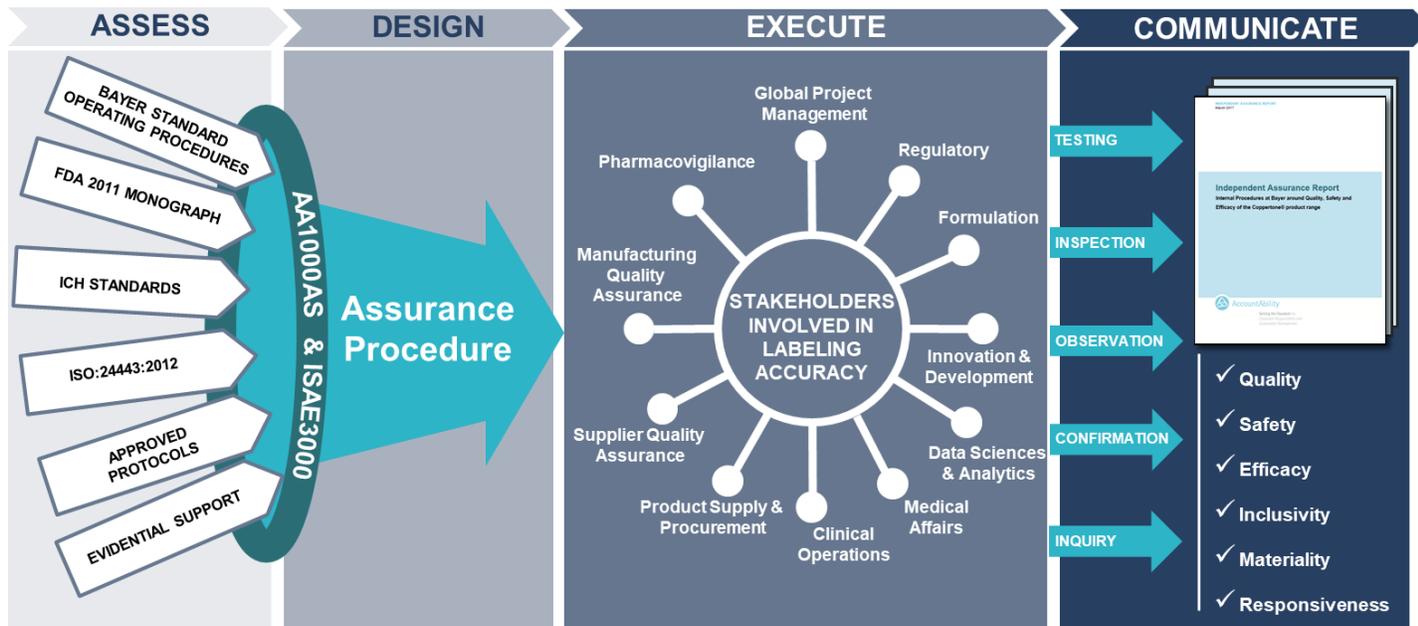
Assurance standards

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, national regulatory and industry guidelines to ensure that the accuracy of its Product labeling 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 Product release SOPs, control procedures and systems in the United States for the period spanning January 1, 2017 through December 31, 2017.



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 labeling the Products available in the United States market relating to the 2017 Fiscal Year period from January 1, 2017 to December 31, 2017. 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 labeled 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, clinical studies, raw material providers 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**:

- ▶ clinical study results of the final formulation performance data for sun protection factor (SPF), water resistance, stability (expiration period) 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):
 - *Labeling 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)*
 - *Stability Testing of New Drug Substances and Products Q1A(R2)*
- ▶ internal quality assurance process and systems for spray, lotion, stick, and whipped clinical studies protocol, packaging and labeling of the Products
- ▶ internal supplier audit processes, controls and performance data for third party testing labs, clinical studies, raw materials providers 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 reasonable and precautionary interpretation of market regulations in the United States and subsequent design of internal standard operating procedures that enable appropriate compliance with the industry regulations in the United States and internationally accepted guidelines.

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
 - Innovation & Development
 - Data Sciences and Analytics
- ▶ 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 2017 (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, Tennessee manufacturing site of the Products in 2017 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 selected Coppertone Products.

Additional assessments and procedures that were performed during the 2017 assurance process include the following:

- ▶ Expanding the number of vendors selected to determine regular on-site audits were performed and major issues were remediated. Vendors selected provide Research and Development and Commercial services and products to Bayer.
- ▶ Inquiring and obtaining evidence of Bayer's protocol review process to determine appropriate controls, systems and SOPs were implemented for SPF Assay.
- ▶ Observing additional systems and controls that were implemented manage and document Product Development, pre-market stability and final formulation approval processes.
- ▶ Inquiring and obtaining evidence that the missing critical wavelength studies noted in the 2016 Assurance Report have been located and that Bayer is proactively implementing a new system to track and maintain clinical studies records for all formulated Products.
- ▶ Obtaining actual pharmacovigilance report for the U.S. market from Bayer's system that tracks all reported cases from consumers and inquiring about the remediating actions, where required.
- ▶ Inquiring Bayer's literature review processes and procedures to determine if any safety findings resulted in changes to the product risk profile.

AccountAbility did not perform or re-perform tests on the ingredients, 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 2017 through December 31, 2017:

- ▶ 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 labeled 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.

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 has a dedicated [website](#) to provide product information and 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 [2017 Integrated 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. In addition, Bayer recognizes the need to engage with its suppliers and publicly disclosed its [Supplier Management](#) position as part of its long-term sustainability and business strategy.

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 labeling 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. A [dedicated website](#) is publicly available to receive all product complaints and compliments, so that Bayer may respond and action accordingly in a timely manner.

Recommendations

There were no issues that came to our attention as part of AccountAbility's assurance procedures to determine that standard operating procedures ("SOPs"), systems and controls are applied as part of Bayer's process in providing accurate labeling associated to its Coppertone® product range.

As part of our standard practice, 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:

- ▶ engaging with internal stakeholders to further improve internal system functions and interface to support productivity;
- ▶ creating more opportunities to engage with consumers to address common inquiries around the ingredients and their functions as well as providing them with product knowledge and sun care education;
- ▶ updating Bayer website more frequently with the latest product artwork and information;
- ▶ developing processes that could better support effective and timely monitoring of internal procedures and practices.

AccountAbility

3 Lloyds Avenue, EC3N 3DS, London

United Kingdom

30 March 2018



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 2017 Fiscal Year that would conflict with the independence of this work.
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