Greenhouse Gas Accounting Sector Guidance for Pharmaceutical Products and Medical Devices

Summary Document

November 2012

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This guidance has been reviewed by WRI for conformance with the GHG Protocol Product Life Cycle Standard

http://www.sdu.nhs.uk/pharma-md/

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For and on behalf of
Environmental Resources Management

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Signed:

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Date: 30 November 2012

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FOREWORD

The pharmaceutical and medical device sectors are central to healthcare combating greenhouse gas emissions and reducing our impact on the environment. In 2010 an estimated 22% of NHS England's greenhouse gas emissions were attributable to pharmaceuticals and 8% to medical devices.

I am therefore delighted to see the NHS, the pharmaceutical and medical device industries, international health experts, and greenhouse gas accounting specialists working together to produce these international guidelines. This guidance will form the cornerstone of our joint action to reduce environmental impact and provide a fantastic example to other sectors of how to tackle climate change and develop sustainably in partnership. It is the first international greenhouse gas life cycle assessment guidance for the pharmaceutical and medical device sectors, and only the second of its kind for any sector.

Measuring greenhouse gas emissions in a consistent manner across national boundaries will help us all understand where the emission "hot-spots" are, and consequently where we initially need to focus our attention to achieve the greatest possible impact.

This guidance marks an important first step. It will be a globally relevant, living document that is freely available, and continually revised and updated. It is international in its scope, encourages transparent and accurate reporting, and helps to create a common language and methodology that will form the basis for further development.

What is being proposed is in the interest of all of us, to gain a better understanding of what is good for business, good for health, and good for our common future.
I would like to thank all those involved from the different countries and different sectors in breaking new ground.

Sir Neil McKay CB
NHS CEO of NHS Midlands and East and Lead CEO for Sustainable Development, NHS England.

"NICE is committed to exploring methods for building sustainability into NICE guidance and to promoting sustainable growth in the life sciences industries. We warmly welcome this guidance. It represents an important extension of the scope and methods of carbon accounting. It's also a very practical support to industry efforts to reduce the carbon footprint of the drugs and medical devices that are so important to NHS patients."

Sir Andrew Dillon CBE
CEO of the UK National Institute for Health and Clinical Excellence

1 ACKNOWLEDGEMENTS

This guidance has been developed in conjunction with a steering group comprising representatives from a range of organisations involved in the production and administration of pharmaceutical products and medical devices, as well as representatives of Government, health care providers and other stakeholders. Acknowledgement is given to the invaluable input of the following individuals and organisations:

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GLOSSARY

API - Active Pharmaceutical Ingredient.

Attributable processes - Service, material, and energy flows that become the product, make the product, and carry the product through its life cycle.

Biogenic - Produced by living organisms or biological processes, but not fossilised or from fossil sources.

Carbon footprint - The sum of greenhouse gas emissions released in relation to a product or service, expressed as carbon dioxide equivalents (CO_2e).

Functional unit - The quantified performance of the studied product.

Greenhouse gas (GHG) - Gas released to the atmosphere that absorbs and emits infrared radiation, contributing to the greenhouse effect. Sources of GHGs include combustion, emissions from chemical processes, waste degradation, etc.

Life cycle - Consecutive and interlinked stages of a product system, from raw material acquisition or generation of natural resources to end-of-life.

Life cycle assessment - A method of assessing the environmental impacts of a product through the product's life cycle stages.

Non-attributable processes - Processes and services, materials and energy flows that are not directly connected to the studied product because they do not become the product, make the product, or directly carry the product through its life cycle.

Primary data - Data from specific processes in the studied product's life cycle.

Product - Any good or service.

Product GHG inventory - Compilation and evaluation of the inputs, outputs and the potential GHG impacts of a product system throughout its life cycle.

Product Rule - A document containing additional specifications needed to enable comparisons or declarations about a product or product category.

Product Standard - The title used throughout this guidance document to refer to the Greenhouse Gas Protocol Product Life Cycle Accounting and Reporting Standard.

Reference flow - The amount of studied product needed to fulfil the function defined in the unit of analysis.

Scope 1 - all direct GHG emissions from a company.

Scope 2 - Indirect company GHG emissions from the consumption of purchased electricity, heat or steam.

Scope 3 - All indirect emissions that occur in the value chain of a company (excluding Scope 2), including both upstream and downstream emissions.

Secondary data - Process data that are not from specific processes in the studied product's life cycle.

Unit of analysis - The basis on which the inventory results are calculated; the unit of analysis is defined as the functional unit for final products and the reference flow for intermediate products and processes.

2 INTRODUCTION

This is a brief summary of the greenhouse gas accounting sector guidance document for pharmaceutical products and medical devices. It provides a short overview and introduction to the sector guidance, why and how it has been developed, how and for what it is intended to be used. This brief summary follows the overall structure of the full guidance document which was publicly released at the end of 2012 and is available for download at http://www.sdu.nhs.uk/pharma-md.

2.1 THE PURPOSE OF THIS GUIDANCE

The objective of the guidance is to enable consistent quantification of the GHG inventory of pharmaceutical products and medical devices. It is relevant for all pharmaceutical products and medical devices and is applicable to products manufactured and administered in any geography.

A **pharmaceutical product** is a substance used for medicinal purposes, for the purpose of medical diagnosis, cure, treatment or disease prevention.

Examples include tablets and dry powder, creams and ointments, patches, administering devices, etc.

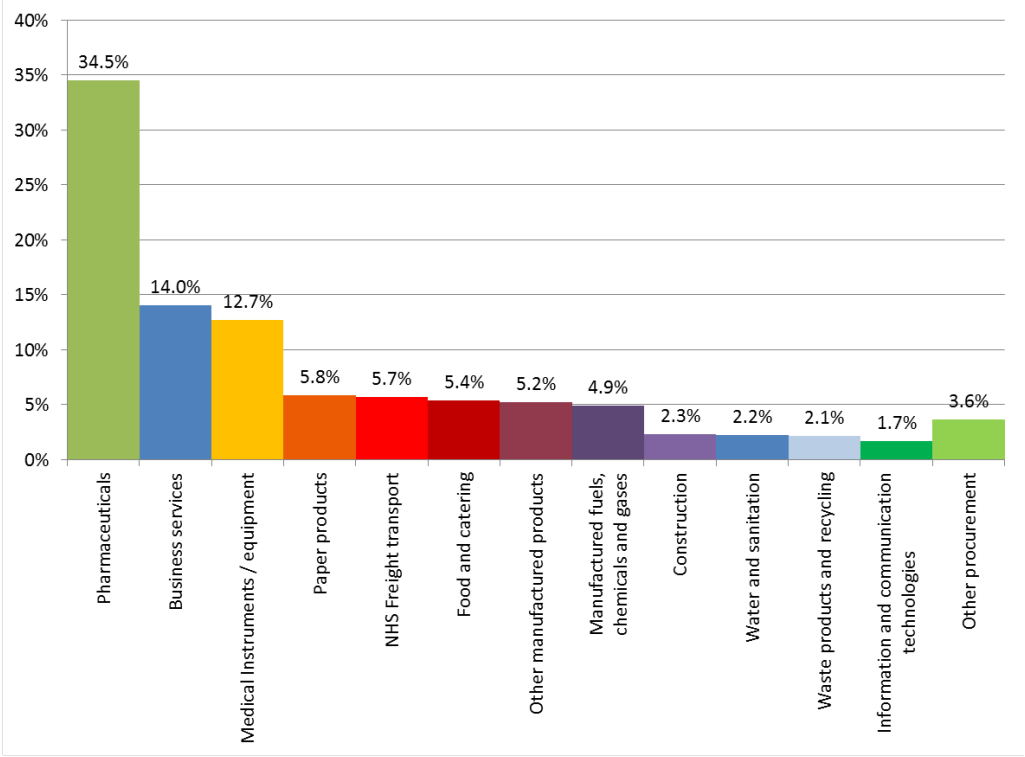
A **medical device** is a product intended to be used for medical diagnosis, cure, treatment or disease prevention, but which does not achieve its principal intended action in, or on, the human body by pharmacological, immunological or metabolic means.

Examples include instruments that may be active, passive, implantable, etc and can be used in such applications as the prevention, diagnosis or treatment of disease.

2.2 WHY THE GUIDANCE WAS DEVELOPED

Globally, pharmaceutical and medical device products contribute a large proportion of healthcare GHG emissions. Evidence for this comes from the National Health Service (NHS) Sustainable Development Unit (SDU) which, in 2009, carried out its first top-down carbon footprinting exercise. This concluded that procurement of goods and services from the NHS's supply chain accounted for 65% of the total GHG emissions of NHS England. Of these procurement-related emissions, approaching half were attributable to pharmaceutical products and medical devices.

Figure 1.1 Breakdown of the NHS England Procurement Carbon Footprint 2010



Source: http://www.sdu.nhs.uk/documents/publications/NHS_Carbon_Footprint_Published_2012.pdf

The SDU organised two summits (in 2010 and 2011), attended by healthcare and pharmaceutical industry experts, aiming to facilitate collaboration towards low carbon outcomes. During the 2011 summit, the need for guidance to aid in the GHG accounting across the life cycle of pharmaceutical and medical device products was agreed by the attendees.

Pharmaceutical product and medical device companies are increasingly making efforts to understand the environmental footprint of their businesses and products. Many pharmaceutical and medical device companies have reported the emissions associated with their business operations, for example through submission to the Carbon Disclosure Project [(1)]. Scope 3 emissions have been found to contribute as much as two thirds of the total emissions reported, demonstrating the importance of taking a life cycle approach.

(1) Further detail about the Carbon Disclosure Project can be found at https://www.cdproject.net/en-US/Pages/HomePage.aspx

3 HOW THE GUIDANCE WAS DEVELOPED

The development of this guidance was commissioned and funded by the NHS Sustainable Development Unit (SDU) in collaboration with a group of leading international pharmaceutical and medical devices companies.

3.1 STEERING GROUP

A steering group, comprising representatives from a range of organisations involved in the production and administration of pharmaceutical products and medical devices, as well as representatives of Government, health care providers and other stakeholders, has overseen development of the guidance. The steering group was chosen to include life cycle assessment expertise, international reach and manufacturing experience.

The steering group comprised a range of organisations and are listed in the Acknowledgements section.

3.2 TECHNICAL AUTHORSHIP AND REVIEW

Technical authorship of the guidance was undertaken by the sustainability consultancy ERM, who also co-ordinated the steering group meetings, public consultation and pilot testing.

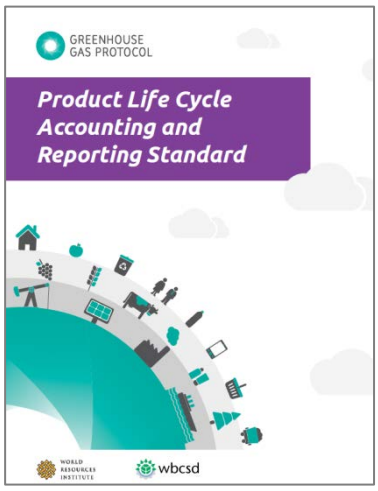
A final draft of the guidance was reviewed by WRI/GHG Protocol Secretariat to ensure conformity with the principles of the GHG Protocol Product Life Cycle Accounting and Reporting Standard.

4 USING THE GUIDANCE

4.1 WHAT IS THE GUIDANCE FOR?

The sector-specific guidance within this document builds upon the requirements of the Greenhouse Gas Protocol Product Life Cycle Accounting and Reporting Standard [1] (Product Standard), and it is intended for use alongside this standard.

Figure 3.1 GHG Protocol Product Standard



The 'Built on GHG Protocol' logo is affixed to the guidance document as confirmation that the document has been reviewed and approved by WRI and conforms with the guidance outlined in the Product Standard.

The intention of the guidance document is to complement the GHG Protocol Product Standard and to:

- clarify sector specific life cycle stage and process inclusions/justified exclusions;
- guide on challenging aspects of the inventory calculation process;
- provide further recommendations on primary and secondary data needs, sources and data quality appraisal; and
- give additional detail regarding reporting.

The GHG protocol product standard describes two types of supplementary documents: sector guidance and product rules. Sector guidance offers a route to assist the pharmaceutical and medical device sectors in completing product carbon footprints. Product rules provide additional specifications that enable valid comparisons of two or more products to be made. The document that has been developed provides sector guidance and this does not support product comparisons.

(1) GHG Protocol Product Life Cycle Accounting and Reporting Standard, http://www.ghgprotocol.org/standards/product-standard

It is hoped that product rules may be developed in the future to aid in these comparisons.

4.2 *WHO SHOULD USE IT?*

The document is intended primarily for use by practitioners carrying out GHG assessments of pharmaceutical and medical device products. Typical users are envisaged to be practitioners working for, or on behalf of, a company supplying pharmaceutical products/medical devices or components, with some understanding of carbon footprinting or life cycle assessment methods. However, there are elements of guidance that consider a wider audience and application as below.

Figure 3.2 Audience, Applications and Benefits of this Guidance

Carbon footprint or LCA practitioner (internal/expert)	• Specific guidance on boundary setting, unit of analysis, data requirements, calculation aspects, reporting and assurance. Details of the life cycle stages and processes that are required.
Producers within the sector or value chain	• As above, plus detailed descriptions of data needs and the data collection process.
Healthcare services / regulators /policy makers	• May be useful for wider stakeholders to understand the scope and scale of the assessment process, and data quality and transparency. It may serve as a useful educational tool and to indicate future data and information needs.
Procurement teams	• Not yet intended to support quantitative product comparison decisions. However, the document can be used to raise awareness and guide future efforts

4.3 *WHAT IS IN THE GUIDANCE?*

The guidance provides:

- details of the life cycle stages and processes that should be included when undertaking a GHG inventory assessment of pharmaceutical and medical device products;
- details of the life cycle stages and processes that may be justifiably excluded from an assessment (based on existing evidence of insignificance, or expert consensus of minor significance);
- specific guidance on challenging aspects of the inventory calculation process, such as multiple processing stages in organic API synthesis, and the use phase of multi-use medical devices;

- requirements, recommendations and guidance for users on primary/secondary data needs, sources and data quality appraisal; and
- specific additional requirements and recommendations with regard to reporting and assurance.

4.4 WHAT THE GUIDANCE DELIVERS TO THE USER

The guidance should assist users to take a consistent, transparent and thorough approach to quantifying GHG emissions across the life cycle of pharmaceutical and medical device products. This will put businesses and others in the healthcare value chain in a stronger position to introduce improvements in areas such as product design, materials choice, supplier screening, energy efficiency and waste minimisation. This will support efforts to:

- **reduce greenhouse gases emissions** - with associated reputational benefits and ability to differentiate;
- **help identify potential cost savings** - directly affecting the bottom line;
- **identify points of risk in the value chain** - and help to minimise them early;
- **inform customers** - stakeholders require robust and well-founded information to ensure confidence in current and future performance;
- **prepare** for any future questions from stakeholders, or for any strengthening of the relevant regulations; and
- **engage internal staff** - thereby involving them in the organisation's sustainability initiatives.

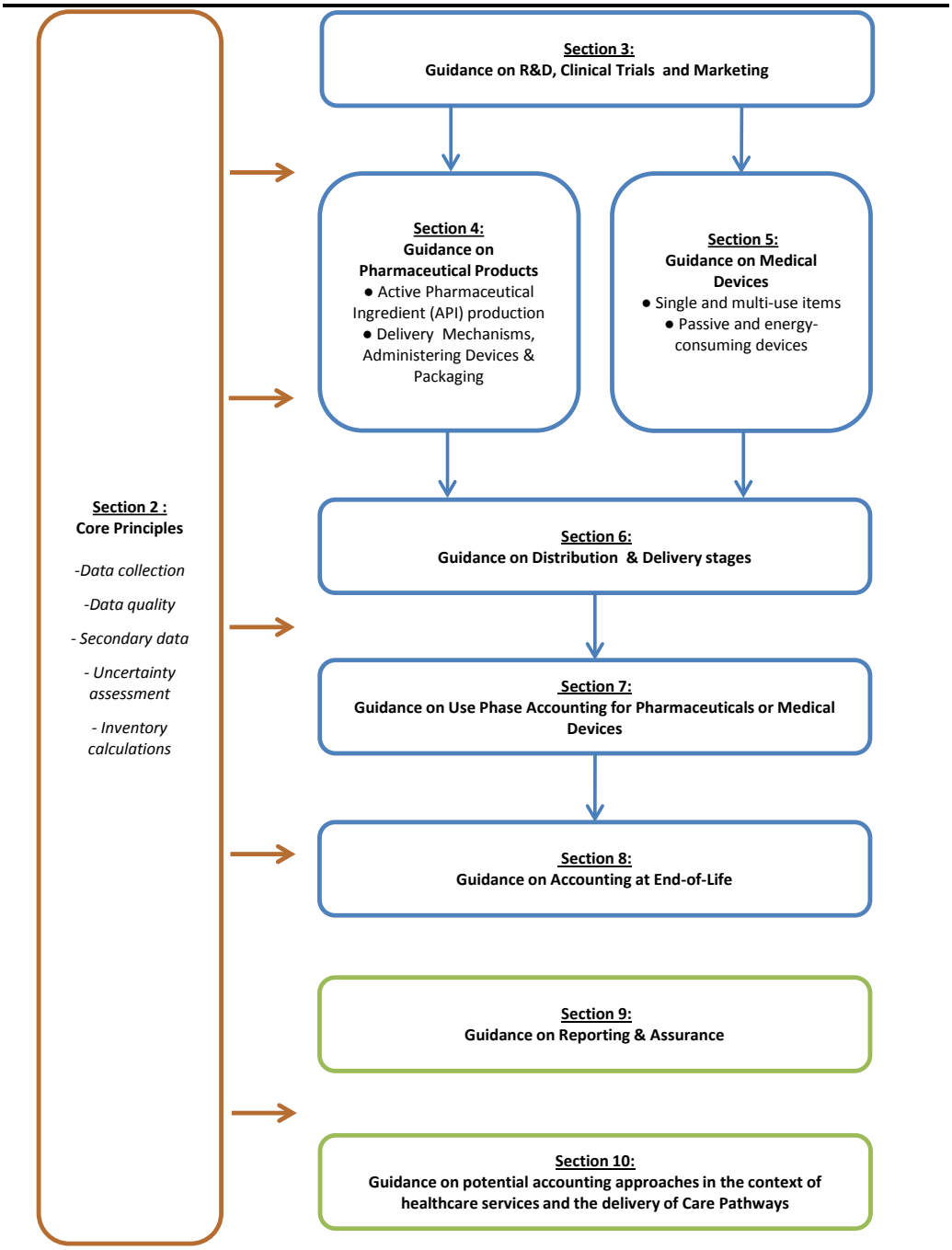
This document does not provide guidance for assessments that aim to externally report comparative assertions between products, or claims of favourable environmental performance of one product over another.

5 STRUCTURE OF THE GUIDANCE

The life cycle of pharmaceutical and medical device products includes various stages, including research and development (R&D), production of intermediates and final product, marketing, distribution and delivery, use and end-of-life. Some stages are specific to particular types of pharmaceutical or medical device; and some are common to all product systems.

The guidance has been developed using a modular approach that allows the guidance to be tailored to specific products, as outlined below.

Figure 4.1 Guidance Document Structure



Specific guidance modules address different life cycle stages and processes and can be combined in order to build a full life cycle profile for any type of pharmaceutical and medical device product.

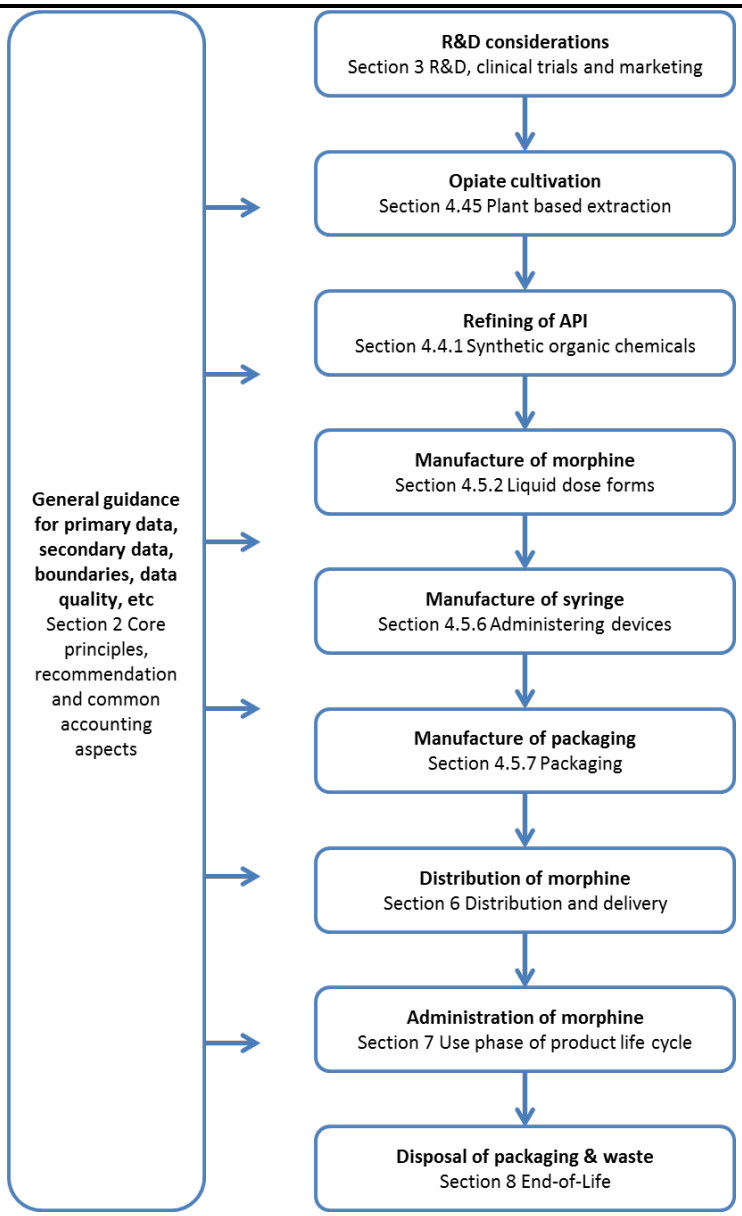
5.1 *INTRODUCTION (SECTION 1)*

The introduction Section includes information on the background to the document, the development process, the target audience, the intended application of the guidance and a detailed explanation of how the document should be used.

5.2 *CORE PRINCIPLES, RECOMMENDATION AND COMMON ACCOUNTING ASPECTS (SECTION 2)*

Specific guidance is provided to outline how the modular approach should be built up. An example of using the modules within the guidance (showing relevant Section references) to build up the life cycle for morphine production is below.

Figure 4.2 Using the Modules within the Guidance (Morphine Example)



This Section also provides additional information that may be applicable when making decisions during the appraisal for all products within the sectors. General guidance includes direction regarding:

- building a process map of the a product life cycle;
- the types of data available when developing the appraisal;
- choices between data and guidance on how to collect primary data
- secondary data sources;
- assessing the data quality of primary and secondary data through qualitative or semi-quantitative approaches;
- considering uncertainty within the data; and
- how to calculate the GHG inventory of a product including time period considerations and the inclusion of biogenic carbon.

A distinction is made between processes within the value chain that are attributable and non-attributable. Further sections in the guidance document recommend attributable and non-attributable exclusions and recommended exclusions from the value chain.

What is an Attributable Process?

"Service, material, and energy flows that become the product, make the product, and carry the product through its life cycle."

Examples of attributable processes may include manufacture of chemical feedstocks and solvents, energy used during processing and disposal of waste.

What is a Non-Attributable Process?

"Processes and services, materials and energy flows that are not directly connected to the studied product because they do not become the product, make the product, or directly carry the product through its life cycle."

Examples of non-attributable processes may include chemicals used during cleaning, sterilisation GHG emissions and in protective gear used by operators.

5.3 *Research and Development, Clinical Trials and Marketing (Section 3)*

Research and development, marketing and clinical trials are non-attributable processes and are excluded from GHG inventory calculations through this guidance document because of the complexity of product development, the difficulty in consistently and accurately quantifying GHG emissions associated with these activities and attributing to specific quantity of product in a specific year. Section 3 provides a further explanation of this exclusion.

R &D, marketing and clinical trials associated with the development of pharmaceutical products and medical devices are recommended to exclude from product assessments and included in Scope 3 appraisals.

5.4 PHARMACEUTICAL PRODUCTS (SECTION 4)

The production of pharmaceutical products can be broadly split into two major stages: API manufacture, and conversion with a suitable delivery mechanism for administration to patients. Each is covered in separate 'modules' of guidance, broken down according to the following.

Active pharmaceutical ingredient (API) manufacture including;

- **synthetic organic chemical** batch-processes that start from commercially available commodity and speciality chemicals;
- fermentation by use of microorganisms or **cell cultures**;
- **egg-based cultivation** for vaccine incubation;
- production of **conjugate vaccines**;
- **plant-based extraction** of chemicals for processing; and
- extraction of materials from **animal and human-derived** sources.

Delivery mechanisms including;

- **solid dose forms** such as tablets or a dry powder for use in a further delivery mechanism;
- **liquid dose forms** and suspensions for ingestion or use in other delivery mechanisms;
- **creams and ointments** for transferring APIs onto the skin;
- **patches** for API administration in doses through the skin;
- **gases** for inhalation;
- **administering devices** such as metered dose inhalers (MDI), dry powder inhalers, auto-injectors and nebulisers; and
- **packaging** such as vials, ampules and bags and packaging to protect and store the products before use.

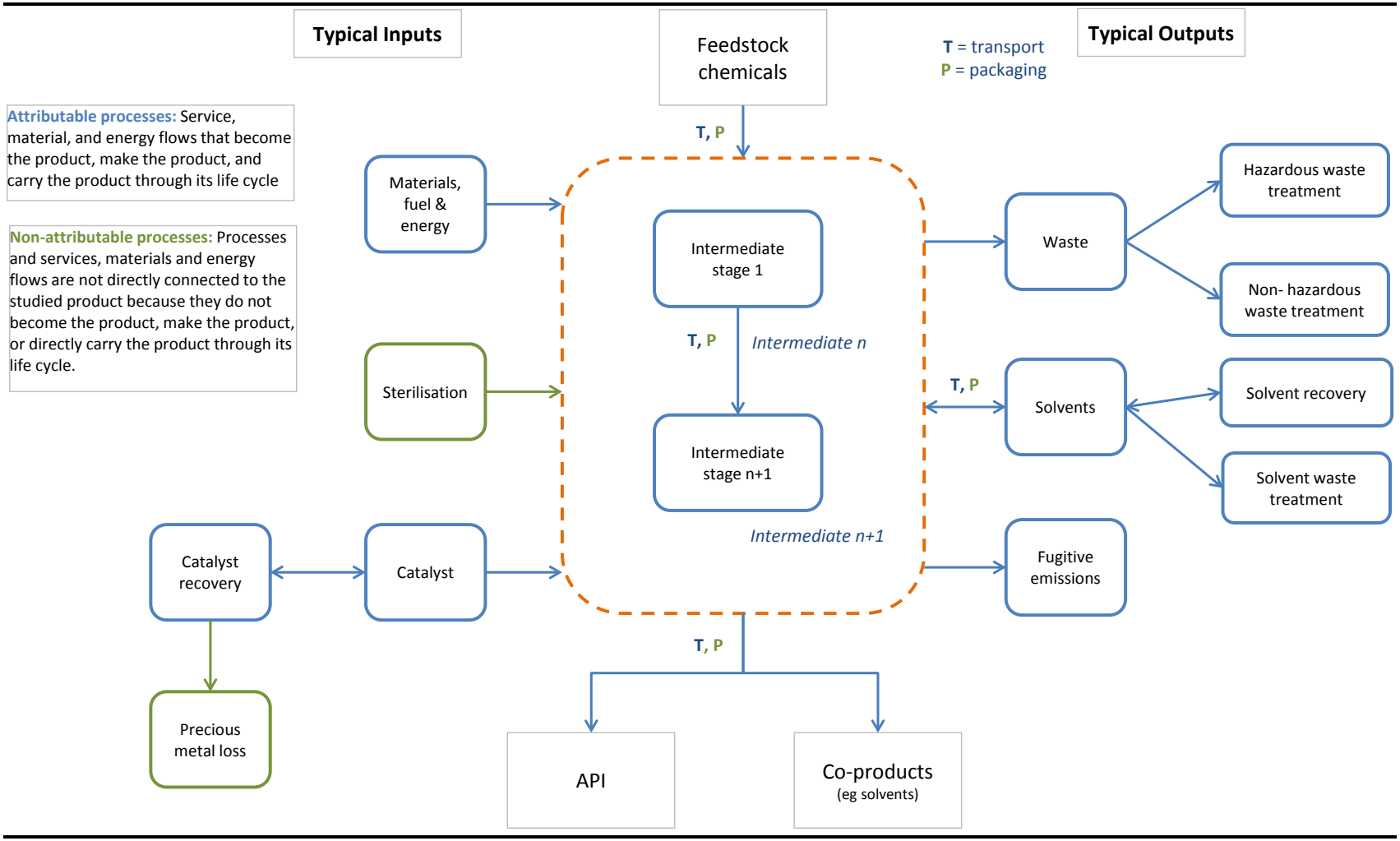
Each module provides specific information relevant to the life cycle stage for:

- module description;
- boundary setting;
- unit of analysis;
- primary data and allocation; and
- secondary data sources.

These categories are defined in the GHG Protocol Product Standard.

An example of the type of process map and attributable/non-attributable process inclusions and exclusions that are defined in the guidance is show below for synthetic organic chemicals.

Figure 4.3 ***Pharmaceutical Product Example Process Map (Synthetic Organic Chemicals)***



The following colour coded boxes are used within each module to provide recommendations on processes to include or exclude.

Figure 4.4 ***Pharmaceutical Product Example Inclusions and Exclusions (Synthetic Organic Chemicals)***

Include these attributable processes:

- Material and chemical inputs
- Material and chemical transport
- Energy/fuel generation and consumption
- Waste disposal
- Solvent manufacture, use and disposal
- Catalyst manufacture, use and disposal
- Solvent recovery and incineration
- Process emissions from synthesis

Include these non-attributable processes:

- Chemicals used for cleaning
- Sterilisation
- Refrigerant leakage associated with product manufacturing

Exclude these attributable and non-attributable processes:

- Packaging of material and chemical inputs
- Disposal of input packaging (eg IBCs, drums, pallets, etc)
- Production and disposal of consumables (eg gloves and protective clothing, filters, cartridges, etc)

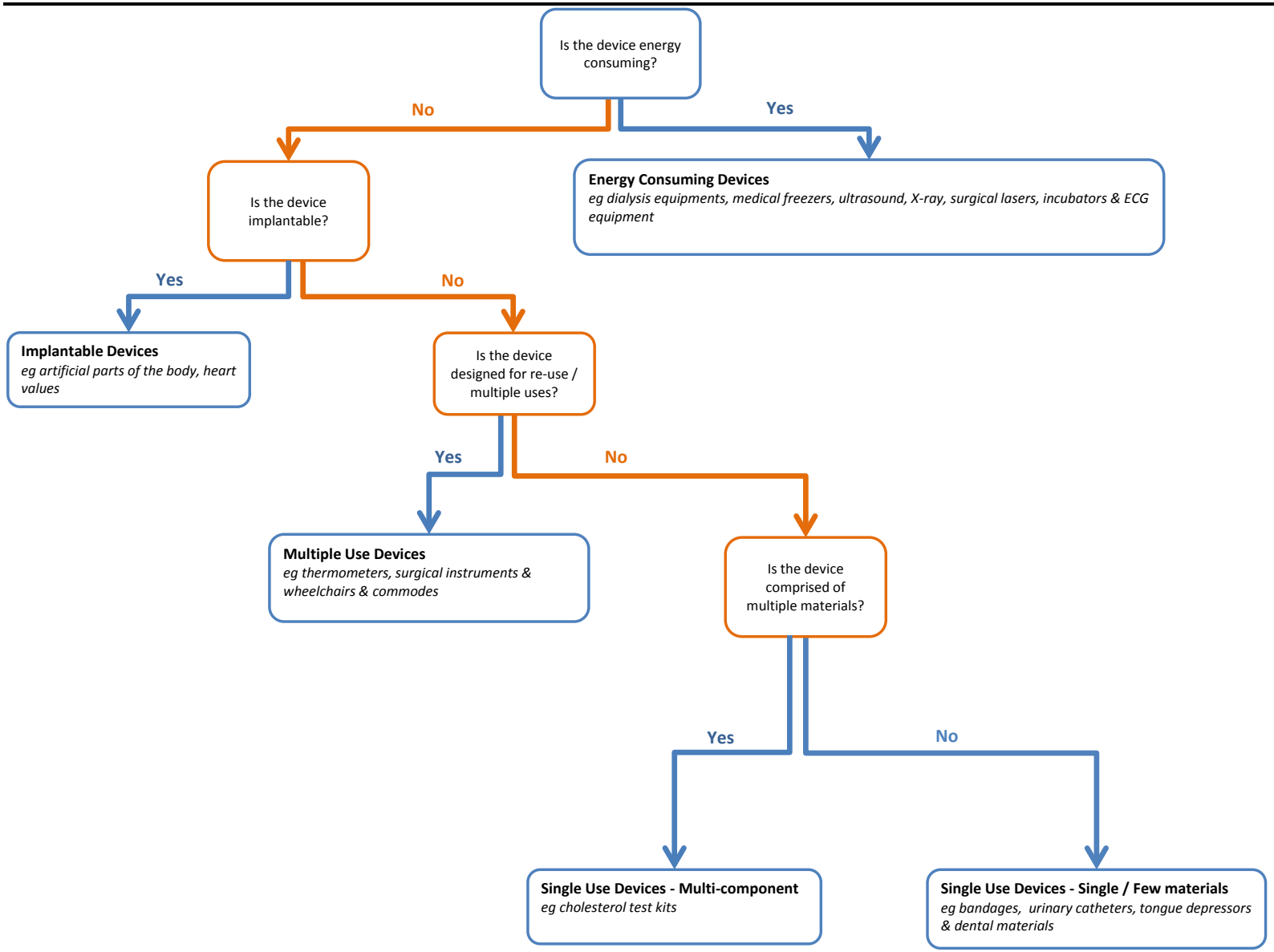
5.5 MEDICAL DEVICES (SECTION 5)

Similar to pharmaceutical products, modular guidance is provided for medical devices. These include the same categories of information within each module and the modules considered include:

- Passive, Single Use Devices with Multiple Components/Materials;
- Passive, Single Use Devices with Few or Single Components/Materials;
- Passive, Reusable Devices;
- Implantable Devices; and
- Energy Consuming Devices.

A decision tree for considering the relevant medical device modules is shown below.

Figure 4.5 *Decision Tree for Assessing Medical Products*



Attributable and non-attributable process inclusions and exclusions are also considered under the medical devices category. An example of process inclusions and exclusions for medical devices is shown in the boxes below.

Figure 4.6 Medical Device Example Inclusions and Exclusions

Include these attributable processes:

- Production, processing and transport of raw materials, including batteries and packaging materials
- Manufacture, sterilisation, packing, storage and distribution of the medical device product
- Production and distribution of energy, water and materials consumed by the medical device during operation
- Production of spare parts/materials, and energy required for refurbishment and repair of devices
- Waste management activities at end-of-life, including transportation

Include these non-attributable processes:

- Production and distribution of energy/water/chemicals for sterilisation of reusable devices
- Production and distribution of consumables required for the operation of a medical device for its intended purpose
- Sterilisation and cleaning chemicals
- Refrigerant leakage associated with product manufacturing

Exclude these attributable and non-attributable processes:

- Transport of staff involved in delivery, maintenance, refurbishment and repair
- Transport of patients to receive treatment
- General hospital/clinic/home infrastructure to support use of the medical device
- Software to run medical devices
- Ancillary products and equipment, eg protective clothing, etc. – with the exception of energy used for sterilisation (before distribution or during use)

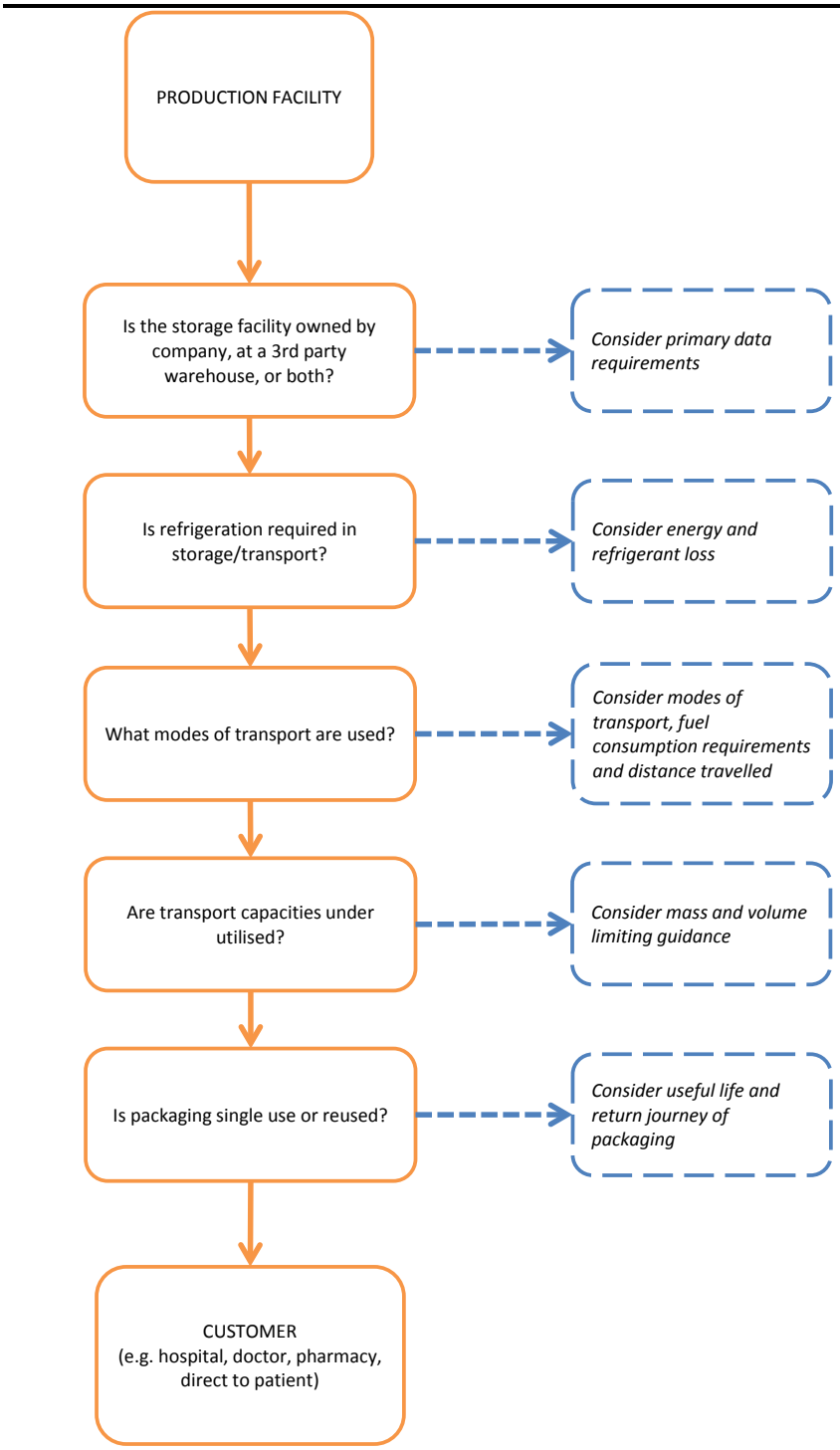
5.6 *Distribution and Delivery (Section 6)*

A module is provided for appraising the GHG emissions from distributing and delivering pharmaceutical products and medical devices. Undertaking a high level appraisal (screening) of this stage through the use of secondary data is recommended to determine its significance in the overall value chain and primary data should be collected if relevant. Additional consideration should be given to the

geography in which the product is sold and the functional unit determined for the product.

Some further considerations when understanding the distribution phase of a product are provided in the diagram below.

Figure 4.7 Example Questions When Appraising Distribution and Delivery



5.7 USE PHASE OF THE PRODUCT LIFE CYCLE (SECTION 7)

The burdens associated with the use phase of a product can be significant to the total GHG emissions through the value chain (particularly for some medical devices) and guidance is provided to consistently account for a product use phase.

This section considers the use, administration or consumption of pharmaceutical products and medical devices. Products are considered to be used at the following locations:

- local/regional/national hospital;
- local/regional/national clinic;
- local GP surgery; or
- patient home.

The document provides information on the inclusion of:

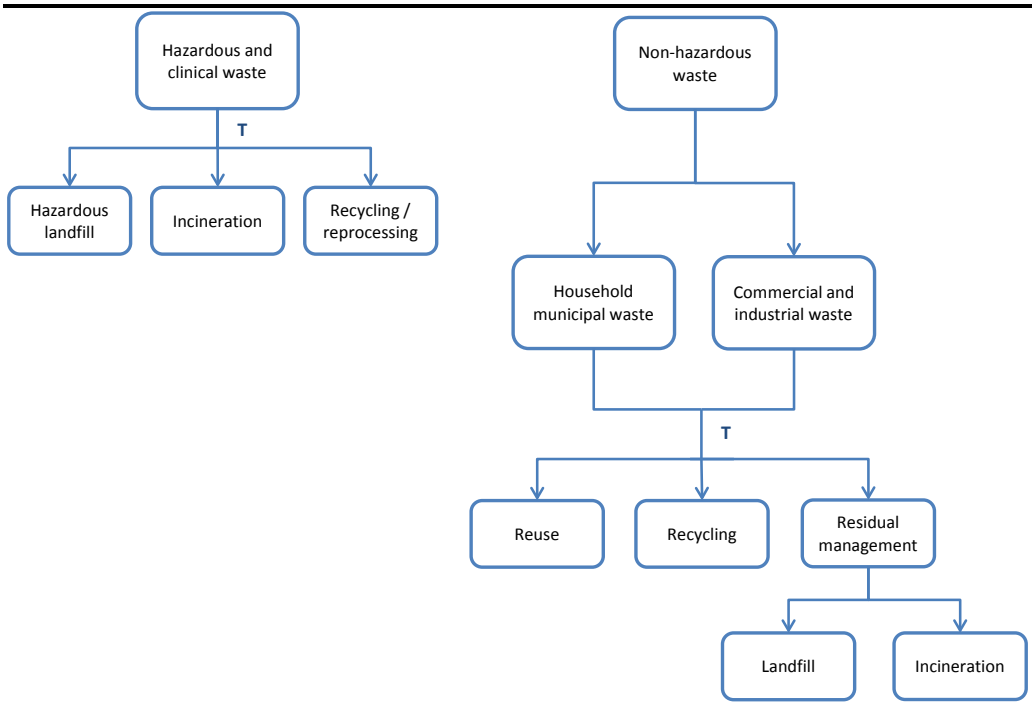
- energy consumption during use;
- additional material consumption during use;
- release of propellant;
- product refurbishment;
- sterilisation; and
- patient travel.

5.8 END-OF-LIFE (SECTION 8)

The end-of-life stage begins when the used product is discarded, and ends when the product is returned to nature as waste or enters another product's life cycle (eg in a reprocessing step). A number of key considerations for pharmaceutical and medical device end-of-life accounting are outlined in this section.

Information is provided in this section on accounting for the following disposal pathways. Guidance considers not just the disposal of product at end of its useful life but also the disposal of material throughout the value chain (e.g. waste material through manufacture).

Figure 4.8 *Type and Fate of Waste Material*



Specific guidance is provided for the differences between hazardous and non-hazardous waste and possible sources of secondary data are included.

5.9 COMMUNICATION, REPORTING AND ASSURANCE (SECTION 9)

Reporting and communication recommendations closely follow those provided in the GHG Protocol Product Standard. They give additional guidance on the information that should be included when publicly reporting within categories such as:

- general information and scope;
- boundary setting;
- allocation;
- data collection and quality;
- uncertainty;
- inventory results; and
- assurance.

As the GHG Protocol Product Standard describes, first and third party assurance can be undertaken.

- **First party:** Person(s) from within the reporting company but independent of the GHG determination process conducts internal assurance.
- **Third Party:** Person(s) from an organisations independent (different business entity from reporting company) of the product GHG inventory determination process conducts third party assurance.

The calculation of product GHG inventories by organisations demonstrates a commitment to understanding and managing GHG emissions. The assessments are

not appropriate for external product comparisons; therefore procurement requirements directed at the product GHG emissions inventory should not be specified. Procurement requirements should encourage product inventory development, public reporting, management of GHG emissions and demonstration of inventory reductions through the use of the guidance and conformance with the Product Standard.

5.10 CARE PATHWAYS (SECTION 10)

A care pathway describes the activities and interventions that need to occur for a patient with a particular condition as they move through the care system. It is evidence-based and multidisciplinary by nature and can involve the provision of assessment, treatment and monitoring clinics as well as the provision and use of pharmaceutical and medical device products. Care pathways can be considered a service in the context of the Product Standard and guidance document and are an optional element to an appraisal but may provide useful insight into the product.

Care pathways, due to the potential for variability in patient profile and response, combined with high levels of human activity introduce a complexity into assessments and the interpretation of results. The consumption of resources is likely to vary from patient to patient and as a result data requirements will be guided by the functional unit and the patient profile it defines. It can be difficult to define the unit of analysis for a care pathway, ideally elements need to be considered:

- the magnitude of the care pathway (eg an average adult patient requiring a certain service);
- the duration or service life of that function or service (eg one year); and
- the expected level of quality or outcome (eg effective management of condition with no unforeseen clinical or technological complications).

An example for haemodialysis treatment is below.

Example of a Unit of Analysis
An adult patient receiving in-centre maintenance haemodialysis provided by South London Healthcare NHS Trust for one year.

The guidance document provides further information on likely process inclusions and exclusions when appraising care pathways.

6 CONCLUSION AND WAY FORWARD

The guidance was developed in response to a study undertaken by the NHS in 2010 that identified the GHG emissions of pharmaceutical products and medical devices to be significant to the health sector. It was further identified that a guidance document would be beneficial to enable the consistent quantification of the GHG emissions of these products. A Steering Group was created including leading international pharmaceutical product and medical devices companies as well as health and carbon footprint experts, trade associations and other relevant members. This Steering Group collaborated to develop the guidance document in conjunction with World Resources Institute who reviewed the guidance document for conformance with their GHG Protocol Product Life Cycle Accounting and Reporting Standard.

The guidance document is freely available online and it is envisaged that the guidance will be used by pharmaceutical and medical device manufacturers, carbon footprint and LCA practitioners, healthcare services/regulators/policy makers and procurement teams. It is hoped that these users will adopt the guidance document as a means of understanding the GHG emissions of products within this sector and use the guidance as one avenue of promoting sustainable healthcare initiatives.

The guidance document has been created as a living document that will be updated and amended as carbon footprinting practices and information within the sector develop. The NHS has committed to act as secretariat for the document and the contributing members of the Steering Group have agreed to meet on a six-monthly basis to discuss and agree amendments to the document.

Further information and details about how to provide feedback on the document can be found at: www.sdu.nhs.uk/pharma-md

Published: November 2012

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