MSc Program
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Non-Financial Reporting with an Emphasis on Environmental Reporting

A Master's Thesis submitted for the degree of
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supervised by
DI Dr. Klaus Rapp

Jasmin Mercedes Ahmad,BEd

00649588

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Affidavit

I, **JASMIN MERCEDES AHMAD,BED**, hereby declare

1. that I am the sole author of the present Master's Thesis, "NON-FINANCIAL REPORTING WITH AN EMPHASIS ON ENVIRONMENTAL REPORTING", 66 pages, bound, and that I have not used any source or tool other than those referenced or any other illicit aid or tool, and
2. that I have not prior to this date submitted the topic of this Master's Thesis or parts of it in any form for assessment as an examination paper, either in Austria or abroad.

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Abstract

The impact on the environment coming from corporate activities increases constantly due to the human demand for growth. The environment and its overall health are extremely hard to measure due to a natural lack of uninterrupted and undisturbed laboratory conditions. In the last years, the strain on a group of corporations intensified not only coming from national but also from international institutions such as the United Nations and its subdivisions or the Global Reporting Initiative.

Taking actions and improving the negative trend of more and more pollution can only efficiently be done when there is an appropriate evaluation of the state of the art. Particularly in the chemical and pharmaceutical industry, the documentation of the hazardous substances is of greatest importance.

Therefore, this thesis will analyze the most recent developments of pharmaceutical chemicals in the environment. Moreover, the documentation of methods and substances as well as primary and secondary reactions needs to be supervised and set into a comparable framework. In an international setting, the approach to have international standards can be a positive remark.

Consequently, there will be an analysis of how the technical approach of environmental documentation, the environmental reporting developed in a multinational company. This analysis will correspondingly investigate the development of the environmental report in the light of the emerging integrated report.

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List of abbreviations

SDGs	Sustainable Development Goals
MDGs	Millennium Development Goals
UN	United Nations
GRI	Global Reporting Initiative
GSSB	Global Sustainability Standards Board
IIRC	International Integrated Reporting Council
EU	European Union
EC	European Commission
OECD	Organisation for Economic Co-operation and Development
CSR	Corporate Social Responsibility
ISO	International Organization for Standardization
KPI	Key Performance Indicator

1. Introduction

The overall framework of sustainable development in an economized environment is the balance between the three pillars of sustainability.

The three pillars of sustainability emerged from the holistic understanding of a sustainable cooperation between the main influencing factors in developed countries. The economy, the environment and the social aspects of the entire system. Often, the three pillars of sustainability are referred to as the three pillars of corporate sustainability. This logic deduction leads to the further consideration of the nexuses, respectively the bonds between these interwoven terms. Nonetheless, in the economic understanding of pre colonialized and pre industrialized times it was an implicitness to consider a "sustainable" lifestyle to be more vital. Therefore, the term was not frequently used by the public. In 1987, Gro Harlem Brundtland the Swedish politician established the term of sustainable development in her famous universal report, "our common future".

> *"Sustainable development is development that meets the needs of the present without compromising the ability of future generations to meet their own needs."* (Brundtland 1987)

The terms sustainability and sustainable development originated from the German forestry industry, where it was explained as a humble principle of not harvesting more that can sustainably grow back in time. Subsequently, after the *Brundtland Report* was made public in the year 1987 the term was used in a larger realization and awareness. Underlining the interlinkages among economy and ecology, the notion of sustainability enhanced recognition at a far-reaching audience. Terms like "intergenerational equity" which stands for primary resource depletion and "inequity" gained popularity. Future generations, not even born were taken into account and into consideration (United Nations 2013) to maintain intergenerational solidarity for a generation without any lobby. However, sustainable development, intergenerational solidarity and environmental protection are still a key to peace and security. Imbalance of these three often leads to either humanitarian or environmental catastrophes, often both. Environmental protection only works when the population can care about it. Implicating that hunger and other more vital demands are already covered. Sustainable development of economies may not be

mixed up with plain internalizing of the externalities. Moreover, the term sustainability is still discussed frequently and there are different concepts of it, for example, strong sustainability and weak sustainability, they mostly show the two sides of the medal. On the one side natural capital and on the other side manufactured capital. While natural capital is more valuable due to its irreversible value, this only means that once the natural aspect is turned and processed, the natural value is gone forever. A true value or a price tag cannot be placed on it, but vaguely be estimated. Many factors cannot be assessed in terms of money, factors like recreational power of a forest or the contribution of forests and oceans to clean air or the value of an ocean as a CO_2 sink. The commercial value of nature can only be estimated when it is either manufactured into commodities or consumables. However, the true value of habitats of flora and fauna are besides all immeasurable. Strong sustainability is based on the assumption that environmental and economic capital is complementary, but not interchangeable. Research shows that human activity mainly drives all sorts of environmental challenges concerning damages and degradations like climate change and pollution. (IPCC 2013) Environmental scientists developed the theory of planetary boundaries. This concept describes a framework in which a safe operating and economic activities are not destroying the livelihood of the planet. The limits of this system are described as the planetary boundaries that can in the long run not be supported. Economic growth and human development are key elements in this concept. (Öhman et al. 2013)

The scientists are describing the planetary boundaries as non-limiting to human development. Therefore, they are not per se rival to the economy. The nine boundaries are classified in three categories:

1) *"Boundaries defining a safe global level of depleting non-renewable fossil resources, such as energy (coal, oil, gas), and fossil groundwater;*
2) *Boundaries defining a safe global level of using the living biosphere, including exploitation of ecosystems, protection of biodiversity and consuming renewable resources, such as land use;*
3) *Boundaries providing a safe global level of Earth's capacity to absorb and dissipate human waste flows, including carbon, nitrogen, phosphorus, and toxic chemicals such as pesticides."* (Öhman et al. 2013)

With undeniable evidence like the acceleration of the melting of the pole caps, (Öhman et al. 2013) and the alteration of precipitation patterns, it is most likely, that humanity has arrived a new geological epoch, the Anthropocene. (Öhman et al. 2013) They further

argue that in multilateral negotiations, the parties hardly ever agree on everything (… due to the principle of unanimity) and therefore no common actions can be started.(Öhman et al. 2013)

Human activity and mainly corporate action have led to local resource scarcities. The loss of biodiversity due to heavy industrial pollution will be a great concern to the next generations.

Biodiversity management and the preservation of ecosystems is quite challenging, due to a long reaction time. (Öhman et al. 2013) The complex operations have to be planned accordingly and are of great complexity. (Öhman et al. 2013) The most difficult task is to find a common policy. (Öhman et al. 2013) Biodiversity cannot be assessed easily and therefore setting measurements is highly complex. Measurements set in the past often backfired due to a lack of understanding and knowledge. Many assumptions in large environmental set ups can only be seen as models, scientists can only build up models because the complexity of interdisciplinary knowledge is unassailable.

The same is true for the tropospheric ozone depletion, caused by rising temperatures and heavy pollution. The toxicity of polluted water threatens species in large areas as well as agriculture and food. (IPCC 2013) The global trend of growth will intensify these threats that are mainly caused by uncontrolled corporate activities. (IPCC 2013) Especially developing countries with a higher tendency of corruption, weak institutions and enforcement suffer from resource exploitation (Rodrik 2003) and uncontrollable exhausts of environmental pollution. The lack of environmental and general resource protection policies and laws maximizes corporate profits but minimizes local (sustainable) development. Long before there was a sophisticated definition of sustainability and sustainable development, it was clear to most species inhabiting the planet earth to economize their resources according to the conditions of their surroundings. Sustainability can be traced back to the earliest human civilizations. It can be further defined as the rise and fall of regional societies, in particular, the success of their true understanding of economic behavior. (Chesworth and Wright 2005) Already during the Neolithic revolution, humans had to, after finding arable land budget their manpower, their seeds and every other good. Between 10.000 and 8.000 years ago, the dependence on climatic stability and environmental conditions elevated due to permanent residency and agriculture. The transgression of these natural boundaries were either penalized with habitat loss or death of the respected society. (Chesworth and Wright 2005) Evidence found by scientists at archeological sites suggest that societies

in Mesopotamia were able to harvest their fields more than once due to a more “sustainable” way of farming. A slight overproduction of edibles enabled the first substantial settling and led the way to sustainable thinking and sustainable living. (Chesworth and Wright 2005) The transition from seeking to harvesting allowed settlers to live in larger groups and split up duties. This procedure developed differently around the world and led to different outcomes. In some areas, the progression resulted in malpractice of resources, in example, deforestation that caused catastrophes like flooding and soil degradation. In some civilizations, mismanagement might have been the reason why they (Diamond 2009) have fallen. While sustainability in the past was mostly about sustainable agriculture, small group farming in rural areas outlasted many centuries. (Diamond 2009) The balance between maintaining and spoiling a society may be the key to understanding how sustainability was ignored more and more during the emerging Anthropocene. Functionality became the new religion, leaving the well-being of nature behind. During the industrialization humans in many western civilizations took over the control over the environment and abandoned old values and knowledge about sustainable living. With the rise of technology in transportation, the need of fossil fuels increased exponentially. Another considerable factor was a constant population increase. Within 200 years, the population went from 500 million in the year 1650 to one billion in the year 1850. Europe was philosophically accompanied by the spirits of the Enlightenment, disregarding the change of mindset that caused technological progress, the change of mindset that caused substantial progress was sanitation and hygiene which led to an enormous increase in life expectancy. A conglomerate of natural sciences as we still know them developed during this period. Not all changes were appreciated by the contemporary philosophical society.

1.1 Research Questions

The thesis is segmented into four main parts in order to answer the three research questions. The main focus lays on the structure and outputs of non-financial reporting. Non-financial reporting underwent a long journey. From a United Nations resolution to the implementation of a European Commission directive into national law. Another focus lays on the interpretation of Corporate Social Responsibility and its influence on the development of integrated reporting, respectively integrated thinking in the companies and corporations. This thesis will further analyze the core of the history of approaches and concepts of non-financial reporting for example, the IIRC, Global Compact, the GRI and their philosophic principles.

The research questions: *How does Merck structure its environmental and sustainable reporting division in an international setting*; *Did Merck develop a technical solution to mitigate environmental challenges; Which hazardous substances that potentially derive from pharmaceutical production are globally monitored,* are answered subsequently in the chapters that approach Merck and their non-financial reporting. The further research is positioned around the non-financial reports of Merck, the analysis of their KPIs and tables are closing the gap between the theoretical approach and the practical displaying of the hard facts in an environmentally difficult production line.

Previous to the research output, the thesis comprehends three aspects: sustainability concepts, environmental and non-financial reporting concepts as well as the emergence of the pharmaceutical industry. The final part merges the analysis and the illustrative model, the international chem-tech company Merck.

1.2 State of the Art

> *"Business has a key role to play in addressing the SDGs."* (Global Reporting Initiative and UN Global Compact 2017)

Corporate reporting, with an emphasis on non-financial reporting has, thanks to the United Nations Sustainable Development Goals, gained greater significance. Moreover, large corporations, particularly companies in a potentially hazardous environment such as companies that handle hazardous chemical and pharmaceutical substances, were historically seen often in a predicament to not cause any danger to the environment. A philosophy that surely prevents a company from losing their facility and their employees very easily. A financial disaster often followed by a bankruptcy and in order to prevent these worst-case scenarios on a sustainable basis, a certain level of precaution developed. At least in the companies with a holistic approach on health, safety and the environment. From this approach and of course unfortunately many accidents and several backlashes, a system of rules and requirements emerged. This set of rules combined with the basic rules of sustainability shall help to merge the needs of the environment with the needs for medication and chemical utilities.

1.3 Methodical Approach

The thesis is divided into a theoretic part and a practical part. The theoretical approach involves the explanation of the emergence of sustainable development as well as various

concepts of sustainability and their relation to modern law concerning corporate social responsibility. An elaboration of the subject matter and the differences between mandatory and voluntary reporting in following the remarks on the scope of the legal framework of business reporting on the example of the European Union. On the basis of the *EU Directive 2013/34/* on non-financial reporting ("*Directive 2014/95/EU lays down the rules on disclosure of non-financial and diversity information by large companies. This directive amends the accounting directive 2013/34/EU. Companies are required to include non-financial statements in their annual reports from 2018 onwards.")* (EC 2017), the thesis itemizes the principles and obligations for European businesses. Scope and details are covered below.

Firstly, the research comprises how the Sustainable Development Goals evolved from the beginning of the United Nations Millennium Goals to the present,(EC 2017) with a closer look on the role today and an emphasis on the Sustainable Development Goal (SDG) number three. The SDG number three focusses on health and the development of health-related issues on an international basis of understanding. In addition, the Sustainable Development Goal Targets are to be compared to their practical and theoretical implementation. The main resource of research are the guidelines of the United Nations, secondary material and reports from the United Nations Sustainable Development Goals Departments. The background of the history of the emergence of the pharmaceutical industry, (Global Reporting Initiative and CSR Europe 2017) containing a brief description of the history of medicine and medicinal products. The discovery of the interlinkages of the health of a human population and the health of the surrounding environment (Global Reporting Initiative and CSR Europe 2017) is to be discussed in the chapter followed by the problematic side effects of mass production of chemicals and pharmaceuticals.

Milestones of the regulation of pharmaceutical products and mixtures are followed by the history of the establishment of the World Health Organization.

The quantitative part of the research, the demonstration of the material as well as the analysis of the data presented in the reports of Merck will be in the fourth part together with a brief history of the family-owned enterprise. The material used for the analysis comprises only publicly published material from the respected homepage of the company.

Further data and knowledge about the production of pharmaceuticals could be gained in a real tour with a process engineer and an interview with an Environment Health & Safety (EHS) manager at the largest production site of Merck in Darmstadt, Germany.

2. Framework of Reporting with an Emphasis on the Pharmaceutical Industry

Non-financial reporting was successfully implemented into union law and national law and went into force with the following original terms:

> "*The Directive on disclosure of non-financial and diversity information by certain large companies is now in force, with member states required to have legislation in place as of December 2016. It is expected that the first company reports will be published in 2018 covering financial year 2017-2018.*
>
> *The Directive introduces measures that will strengthen the transparency and accountability of approximately 6000 companies in the EU. These so-called 'public interest entities'* with more than 500 employees will be:*
>
> *Required to report on environmental, social and employee-related, human rights, anti-corruption and bribery matters;*
>
> *Required to describe their business model, outcomes and risks of the policies on the above topics, and the diversity policy applied for management and supervisory bodies;*
>
> *Encouraged to rely on recognized frameworks such as GRI's Sustainability Reporting Guidelines, the United Nations Global Compact (UNGC), the UN Guiding Principles on Business and Human Rights, OECD Guidelines, International Organization for Standardization (ISO) 26000 and the International Labour Organization (ILO) Tripartite Declaration.*
>
> *GRI and CSR Europe, supported by Accountancy Europe, have developed a publication which outlines the principal elements of the 28 Member States' laws, and provides insight on the direction non-financial reporting is headed in Europe."* (GRI 2016)

2.1 Sustainability reporting

State of the art of corporate reporting on the Sustainable Development Goals, is that due to the Agenda 2030, the United Nations acknowledged that "*business has a key role to play in addressing the SDGs*." (Global Reporting Initiative and UN Global Compact 2017) However, Corporate sustainability reporting has its roots in environmental reporting that

affected the chemical industry due to image problems. The people in the developed countries became more aware of environmental issue and environmental hazards because they could see that the effluents of large industry exhausts did change the surrounding environment. Inhabitants saw that rivers and streams were foamy and that certain species struggled with environmental pressures. During these years, Green Parties established and gained attention. It was historically seen a slight change of the focus, from economy and employment over everything to second thoughts towards the environment. However, in the system of the developed world, economic activities are part of reality and cannot be stopped in a way that can relieve all environmental pressures ad hoc. Hence, businesses must be integrated in the process to sustain and to rectify the condition of the environment.

> *"Business is a vital partner in achieving the Sustainable Development Goals. Companies can contribute through their core activities, and we ask companies everywhere to assess their impact, set ambitious goals and communicate transparently about the results."* (Ban Ki-moon 2016)

Initiatives helping the corporations to mitigate their impact on the environment developed around the United Nations. The United Nations "Global Compact" is the agency to help businesses identify their weaknesses and to discover their opportunities.

Global Compact has laid down ten principals within four disciplines that were derived from, the Universal Declaration of Human Rights, the International Labour Organization's Declaration on Fundamental Principles and Rights at Work, the United Nations Convention Against Corruption and the Rio Declaration on Environment and Development:

"Human Rights

Principle 1:

Businesses should support and respect the protection of internationally proclaimed human rights; and (United Nations Global Compact 2019)

Principle 2:

make sure that they are not complicit in human rights abuses."(United Nations Global Compact 2019)*"* (United Nations Global Compact 2019)

The principles on human rights in business galvanize corporations to put an emphasis on taking action to actively support human rights.

Taking action, on a voluntary basis may bring out much better ideas to a positive contribution to protect human rights "…*whether through core business, strategic social investment/philanthropy, public policy engagement/advocacy, and/or partnerships and other collective action."* (United Nations Global Compact 2019) Global Compact underlines the high rank of importance to pay enough contribution to *"vulnerable groups including women, children, people with disabilities, indigenous peoples, migrant workers, older persons etc."* (United Nations Global Compact 2019)

Respect and thoughtful interacting towards human rights can improve stability and strengthen the relationship among the stakeholders. Global Compact underlines the importance of a good relationship to the employees in order to receive more loyalty. Bringing up respect and dignity can motivate employees on a different level and enhance their intrinsic productivity. (United Nations Global Compact 2019) Loyalty in this context can bring also more safety and compliance to a company, this in return can increase the overall success and performance.

"Human rights and inclusive business models can also be a source of innovation for new products or services, access to new markets, help strengthen the social license to operate and to make the business a valued member of the community and society." (United Nations Global Compact 2019)

Labour

Principle 3:

> *"Businesses should uphold the freedom of association and the effective recognition of the right to collective bargaining;"* (United Nations Global Compact 2019)

Principle 4:

> *"the elimination of all forms of forced and compulsory labour;"* (United Nations Global Compact 2019)

Principle 5:

> *"the effective abolition of child labour; and"* (United Nations Global Compact 2019)

Principle 6:

> *"The elimination of discrimination in respect of employment and occupation."* (United Nations Global Compact 2019)

> *“Moreover, the guarantee of representation through a "voice at work" facilitates local responses to a globalized economy, and serves as a basis for sustainable growth and secure investment returns. The results help bridge the widening representational gap in global work arrangements, and facilitate the input of those people, regions and economic sectors — especially women and informal sector workers — who otherwise may be excluded from participating in processes that build decent work environments”.* (United Nations Global Compact 2019)

All principles associated with labour follow a similar intention, the freedom of the employee or worker to choose and to negotiate their terms and conditions of their contracts without suppression. The right to collective bargain is of course a voluntary process, but Global Compact argues that it enables better relationships between management and employees, hence increases productivity on both sides. “*An important part of the effective recognition of the right to collective bargaining is the "principle of good faith". This is important for the maintenance of the harmonious development of labour relations.”*(Global Reporting Initiative and UN Global Compact 2017) The development of a good basis, a good working atmosphere and a respectful cooperation can not only improve the specific output of a company but also help to retain managers, employees or workers from psychological or also physiological health problems, which again implies that there is less need of medication and less pollution via the sewage systems.

Environment

Principle 7:

> *“Businesses should support a precautionary approach to environmental challenges;”* (United Nations Global Compact 2019)

Principle 8:

> *“undertake initiatives to promote greater environmental responsibility; and”* (United Nations Global Compact 2019)

Principle 9:

> *“encourage the development and diffusion of environmentally friendly technologies.”* (United Nations Global Compact 2019)

As stated in principle seven, the UN Global Compact refers to the “Precautionary Principle” that was promoted and also laid down in the Rio Declaration in the year 1992. Due to emerging technological development, the regulation of law regarding the environment has to function in scientific uncertainty. Effects and longtime damages can

remain undiscovered a long time and therefore sometimes follow unconventional rules. The environment, respectively the planet and all its interlinked functions do not follow laboratory conditions. Good scientific practice can therefore not be the basis of all environmental policy. *"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." Principle 15* (UN General Assembly 1992) Global Compact offers a wide range of possibilities to support a precautionary approach. On the one hand, to minimize potential threats, spills, accidents and generally dangerous situations and on the other hand, an environmental threat can easily become an economic threat. A business, that had carelessly jeopardized the health and lives of its surrounding environment, neighbors or any species, has a greater likelihood to fail its economic goals, to experience great loss or to be fined. All of which endangers the success of a company and its stakeholders. The UN Global Compact suggests these precautionary arguments in order to avoid unwanted and unforeseen risks:

- *"Develop a code of conduct or practice for its operations and products that confirms commitment to care for health and the environment*
- *Develop a company guideline on the consistent application of the approach throughout the company.*
- *Create a managerial committee or steering group that oversees the company application of precaution, in particular risk management in sensitive issue areas*
- *Establish two-way communication with stakeholders, in a pro-active, early stage and transparent manner, to ensure effective communication of information about uncertainties and potential risks and to deal with related enquiries and complaints.*
- *Use mechanisms such as multi-stakeholder meetings, workshop discussions, focus groups, public polls combined with use of website and printed media.*
- *Support scientific research, including independent and public research, on related issues, and work with national and international institutions concerned.*
- *Join industry-wide collaborative efforts to share knowledge and deal with the issue of precaution, in particular in regards to production processes*

and products around which high level of uncertainty, potential harm and sensitivity exist." (United Nations Global Compact 2019)

Global Compact does not only give advice about challenges of today, but also tries to broaden the view on the development of new technologies. Technologies that may be safer, cleaner and more efficient. (United Nations Global Compact 2019) Investing in research and development are costly but are an investment in the future. "*They include a variety of cleaner production processes and pollution prevention technologies as well as end-of-pipe and monitoring technologies."* (United Nations Global Compact 2019)

The implementation of technologies that are more environmentally friendly could help companies to use and need less raw materials and therefore be more successful. (United Nations Global Compact 2019)

UN Global Compact suggests setting concrete measurements to mitigate environmental degradation via corporate action. The points are:

"At the basic factory site or unit level, improving technology may be achieved by:

- *Changing the process or manufacturing technique; changing input materials; making changes to the product design or components; and reusing materials on site. Strategic level approaches to improving technology include:*
- *Establishing a corporate or individual company policy on the use of environmentally sound technologies*
- *Making information available to stakeholders that illustrates the environmental performance and benefits of using such technologies*
- *Refocusing research and development towards 'design for sustainability'*
- *Use of life cycle assessment (LCA) in the development of new technologies and products*
- *Employing Environmental Technology Assessments (EnTA)*
- *Examining investment criteria and the sourcing policy for suppliers and contractors to ensure that tenders stipulate minimum environmental criteria*
- *Co-operating with industry partners to ensure that 'best available technology' is available to other organizations" (United Nations Global Compact 2019)*

Anti-Corruption

Principle 10:

> *"Businesses should work against corruption in all its forms, including extortion and bribery."* (United Nations Global Compact 2019)

Crucial events have led to the enshrinement of anti-corruption laws and passages into international environmental agreements and legislation. "*Corruption can take many forms that vary in degree from the minor use of influence to institutionalized bribery."* (United Nations Global Compact 2019) The tenth UN Global Compact principle on corruption and every aspect of it often goes at the expense of the weakest link in a system. A system without or with only a small lobby.

2.1.1 Millennium Goals and SDGs with an emphasis on health and pharmaceutical products

The SDGs are a successor of the Millennium Development Goals, a set of Goals established by the all UN member states as well as the World Bank, the International Monetary Fund and the Development Assistance Committee of the Organization for Economic Cooperation and Development to achieve from the year 2000 to the year 2015. (UN 2019) The eight Millennium Development Goals specifically approached certain matters in order to raise awareness, to enhance education and to start a process of worldwide collaboration in thinking of a more sustainable worldwide economy. Goal number six, for example "To combat HIV/AIDS, Malaria and other diseases was in fact a primary goal. Since of course it is difficult to analyze the given information, it is unclear if there was enough access to affordable medication in the regions. (UN Millennium Goals 2015)The monitoring of compliance, especially in developing countries without institutions and law enforcement is a bureaucratic unsatisfying task that consumes more resources than necessary. Nevertheless, the executive summary of the Millennium Goals suggests that although the monitoring was imperfect and painted an unsatisfying picture, the effort made paid off. The report summarizes that the internationally made effort to supply essential medicine worked. It was not only a matter of supply but also of price. An affordable price is as important as the comprehensive price of the respected pharmaceutical product. The use of, if available less expensive generics can also lead to more efficient distribution and less costs. However, by the end of September 2015,

the eight goals were further developed to 17 wider defined goals, the Sustainable Development Goals. (UN Millennium Goals 2015)

2.1.2 The Sustainable Development Goals

Dense population and growing cities led to a development of new technologies to nourish growing nations. These new technologies allowed an enormous population growth and impacted the environment accordingly. From the year 1850 to the year 2018, the population went from approximately 1.2 billion to approximately 7.5 billion people, (Connection-Population 2016) bringing the planet in troubles. *There were several concepts developed in order to mitigate the decreasing livelihood, scientists and the United Nations called them: "carrying capacity", "sustainable consumption and production", "guardrails", "tipping points", "footprints", "safe operating space" or "planetary boundaries".* (Öhman et al. 2013) The concept of planetary boundaries was then chosen because it was the best fitting concept in order to depict the *"global adding-up constraints"* (Öhman et al. 2013)

The theories however named, stand for what is described as unsustainable ecologic behavior. Underlining that there is an irreversible path to destroying livelihood for the inhabitants of the planet. Environmental scientists believe that the planet earth can handle the changes due to mankind, but mankind will not survive the planets reaction to this. (Öhman et al. 2013) A major issue rolling towards present challenges are the transitioning countries, these countries with a rising standard of living will soon consume as much energy, goods and resources such as oil, and consumables as the developed countries. (Öhman et al. 2013) The scientists further postulate that in history, there were always underutilized resources such as fresh water, fossil fuels or land, there was always room for improvement. But with the growing number of people on the planet, the pressures on the eco system differ.

The United Nations describe the Sustainable Development Goals as a blueprint for a sustainable future for everyone. The SDGs approach all challenges humanity faces on a holistic level (S. UN 2019) including issues related to environmental degradation, poverty, inequality, climate change and prosperity as well as justice and peace. (S. UN 2019) In this rounded description of the SDGs, clearly the focus lies on the achievement of the respected Goals. When tackling and comprehending these entwined issues certainly is one side of the medal, then monitoring and supervising the eradication of them is the other side of it. The 17 Sustainable Development Goals and 169 targets that

act as organizing principles to work towards a global sustainable development path shall be measured by 232 indicators, containing specific conditions of which actions have to be taken to change, or which steps have to be taken in order to fulfil the targeted SDG.

Potential threats to solve some of the Goals are sometimes as trivial as a simple misunderstanding, sometimes technically sophisticated due to complex structures that were not designed but grew over time, sometimes a matter of cultural misbehavior towards the environment. But there is a possible remedy for some of them connected to fraud and corruption. Surveillance. Since large scale satellite surveillance is becoming more and more inexpensive due to better and more efficient technology, monitoring has risen to another level. "*There is, however, an issue: "There is no single, uniform methodology for measuring and reporting business progress and impacts on the SDGs."(GRI Standards 2017)* However, there are several guidelines of good practice and principles to follow. A harmonized set of indicators would increase the transparency on a global basis and could guarantee a certain standard. The Global Reporting Initiative laid down possibilities to be compliant with the Sustainable development goals: The GRI underlines that the being compliant with the Sustainable Development Goals and their respected targets can improve the businesses communication with authorities and governments. (GRI 2016) Moreover, even receiving help and assistance from the local governments or municipalities could be one of the positive outputs. Reporting on a national level and informing the public about recent sustainability measures engages the companies to interact with their public environment. The main goal of the compact reporting principles published by the GRI is to establish a *"common language"* (Global Reporting Initiative 2016) and to contribute to accelerate the advancement of sustainable innovations towards the SDGs. (Global Reporting Initiative 2016)

With a high number of different species, an ecosystem can withstand many external pressures. Resilience, a strength that not only describes the boundaries of a system, but also its self-healing capacity. The planet and all its inhabitants are resilient because, whenever there was or is a stress or a pressure, this was the moment to reinvent themselves. Reinvention and resilience are the drivers of evolution and development. Protecting biodiversity is a priority in fighting habitat loss, sustaining biomes and in keeping ecosystems healthy. Before humankind interfered so profoundly with nature, the efficient self-sustaining system was able to recuperate.

2.1.3 The Sustainable Development Goal "health" with its respected targets

SDG 3 "Ensure healthy lives and promote wellbeing for all at all ages" (UN SDGs 2016)

"The goals within a goal: Health targets for SDG 3" (UN SDGs 2016)

Target: 3.1

"By 2030, reduce the global maternal mortality ratio to less than 70 per 100 000 live births." (UN SDGs 2016)

Target: 3.2

"By 2030, end preventable deaths of newborns and children under 5 years of age, with all countries aiming to reduce neonatal mortality to at least as low as 12 per 1000 live births and under-5 mortality to at least as low as 25 per 1000 live births." (UN SDGs 2016)

Target: 3.3

"By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases." (UN SDGs 2016)

Target: 3.4

"By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being." (UN SDGs 2016)

Target: 3.5

"Strengthen the prevention and treatment of substance abuse, including narcotic drug abuse and harmful use of alcohol." (UN SDGs 2016)

Target: 3.6

"By 2020, halve the number of global deaths and injuries from road traffic accidents." (UN SDGs 2016)

Target: 3.7

"By 2030, ensure universal access to sexual and reproductive health-care services, including for family planning, information and education, and the

integration of reproductive health into national strategies and programmes." (UN SDGs 2016)

Target: 3.8

"Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all." (UN SDGs 2016)

Target: 3.9

"By 2030, substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination." (UN SDGs 2016)

Target: 3.a

"Strengthen the implementation of the WHO Framework Convention on Tobacco Control in all countries, as appropriate." (UN SDGs 2016)

Target: 3.b

"Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all." (UN SDGs 2016)

Target: 3.c

"Substantially increase health financing and the recruitment, development, training and retention of the health workforce in developing countries, especially in least developed countries and small island developing States." (UN SDGs 2016)

Target: 3.d

"Strengthen the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks." (UN SDGs 2016)

2.1.4 The implementation of the SDG Targets

The WHO could report of two scenarios, one in which the quite “ambitious” targets could be reached and another scenario, the WHO calls it the “progress” scenario where the respected countries were able to reach about two thirds or more of the desired targets. (World Health Organization 2017) Both of these scenarios base on the believe that employing more personnel and an increase of monetary means are necessary. The concepts build on the theory that 75per cent of the costs are to be invested in the building of new clinics, the education of health workers and their salaries as well as equipment for medicinal use. Only 25 per cent of the remaining costs are used for medicines such as vaccines, therapies and treatments. (World Health Organization 2017) The WHO released the very impressive number of 97 millions of preventions of premature death that could be prevented. These numbers include about 50 million of stillborn children (World Health Organization 2017) plus premature death under the age of five and also 20 million losses from non-communicable diseases. The WHO calculated that the life expectancy would increase between approximately three and 8 years if lifestyles are adjusted across 67 countries. (World Health Organization 2017)

3. Legal framework of reporting in the EU

3.1 Scope of the Reporting Framework

"Organisations must produce a non-financial report if they:

(Global Reporting Initiative and CSR Europe 2017)

1."Are a large undertaking, as defined by Directive 2013/34/ EU, defined as exceeding 2 out of 3 of the following criteria for 2 successive accounting periods

- *a balance sheet total of EUR 20 million, or*
- *a net turnover of EUR 40 million, or*
- *average number of employees of 250*" (Global Reporting Initiative and CSR Europe 2017)

2. "*Are a public-interest entity, meaning any entity which is:*

- *Trading transferable securities on the regulated market of any Member State, or*
- *A credit institution, or*
- *An insurance undertaking, or*
- *Designated by a Member States as a public interest entity" (Global Reporting Initiative and CSR Europe 2017)*

3. "Have an average number of employees exceeding 500 during the financial year." (Global Reporting Initiative and CSR Europe 2017)

In *Figure 1*, a simple picture of the reporting framework is drawn to easily explain the interlocking of the different reporting approaches and acts as a visualization of the EC directive below.

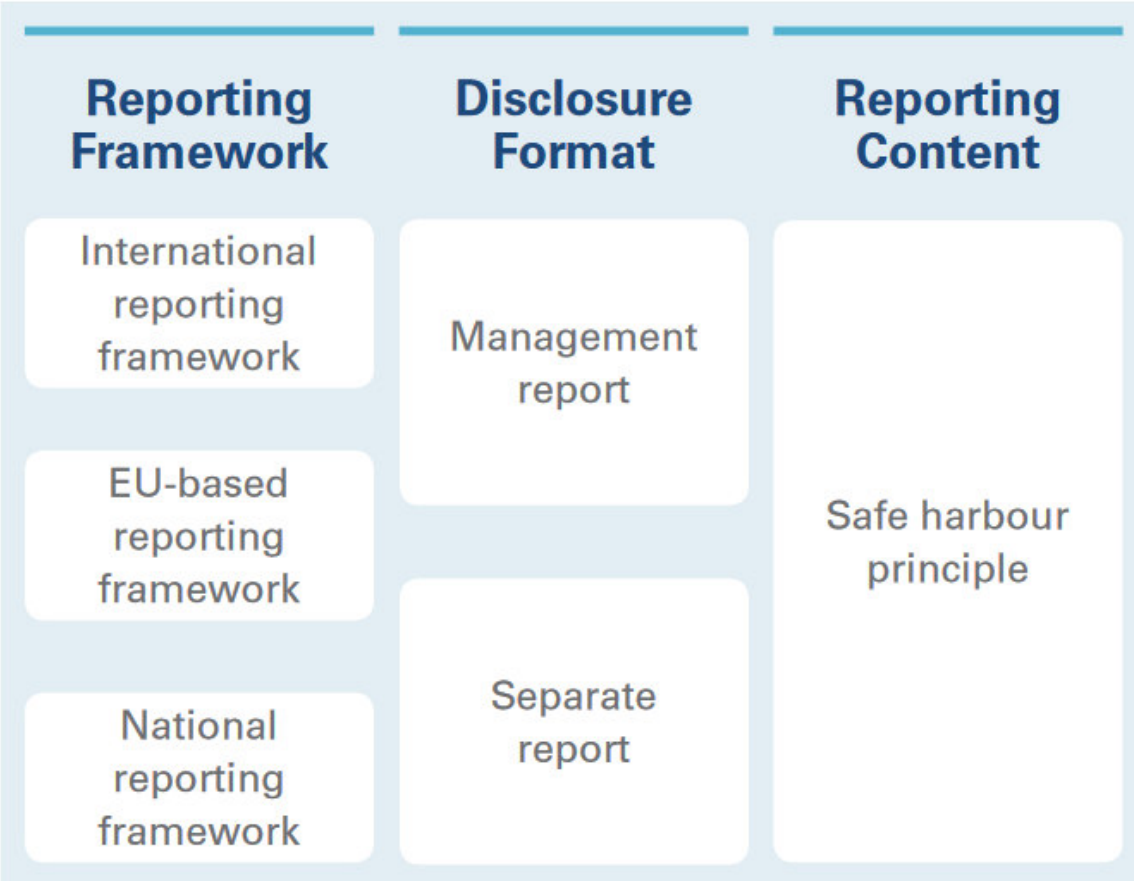

Figure 1

(Global Reporting Initiative and CSR Europe 2017)

"EU law requires large companies to disclose certain information on the way they operate and manage social and environmental challenges." (European Commission 2019) *"Comply and Explain":* This principle calls out for a general explanation on the non-financial report of a corporation. (European Commission 2019) The consolidated versions and statements have to be clear why they are

not listing every aspect. The tracked issues have to be provided in clear and reasonable explanation. (European Commission 2019)

"Safe Harbour" : This principle allows the management to prevent its advisory body and management to experience seriously detrimental (Global Reporting Initiative and CSR Europe 2017)developments and determines the members and employees that are responsible for the negotiations for the exceptional cases to not pursue policies in relation to one or more of the listed matters. (Global Reporting Initiative and CSR Europe 2017) It is the decision of the member states to allow material concerning future developments to be absent in exceptional cases only. (Global Reporting Initiative and CSR Europe 2017)

The following transposition table depicts measurements concerning the definition of a large undertaking- size of corporation, the definition of a public interest entity- possible hazard or danger for the public, the report topics and content, the reporting framework- which guidelines were followed, the disclosure format, the auditor's involvement- statutory or audit firm check, non-compliance penalties, the use of the safe harbor principle and whether there is diversity reporting required. (Global Reporting Initiative and CSR Europe 2017)

In *Figure 2* the transposition summary table is depicted. Showing the respected European countries and their definitions and decisions in implementing the Directive concerning undertakings and transpositions regarding also exceptional cases on not to pursue policies and certain requirements.

Transposition summary table

Country	Definition of a Large Undertaking	Definition of a Public Interest Entity	Report Topics and Content	Reporting Framework	Disclosure Format	Auditor's involvement	Non-compliance Penalties	Safe Harbour Principle	Diversity Reporting Required
Austria	=	o	=	=	o	=	o	=	o
Belgium	o	o	=	=	o	o	o	=	=
Bulgaria	=	o	=	o	o	o	o	=	o
Croatia	=	o	=	=	o	=	o	=	o
Cyprus	=	o	=	=	=	=	o	=	o
Czech Republic	o	o	=	=	o	=	o	=	=
Denmark	o	o	=	o	o	o	o	✖	o
Estonia	o	=	=	=	o	=	✖	✖	o
Finland	=	=	=	=	=	=	o	=	=
France	=	o	=	=	o	o	o	✖	=
Germany	=	o	=	=	o	=	o	=	=
Greece	o	o	o	=	o	=	o	=	=
Hungary	=	o	=	=	o	=	o	=	=
Iceland	o	o	=	=	o	o	o	=	o
Ireland	=	=	=	=	=	=	o	=	o
Italy	=	o	=	o	o	o	o	=	=
Latvia	=	o	o	=	o	o	o	=	=
Lithuania	=	o	o	=	o	=	o	=	o
Luxembourg	o	o	=	=	=	=	o	=	=
Malta	=	=	o	=	o	=	o	=	=
The Netherlands	=	o	=	=	o	o	✖	=	=
Norway	=	o	=	=	o	=	o	✖	=
Poland	=	o	=	o	=	=	o	=	=
Portugal	o	o	=	=	=	=	o	=	=
Romania	o	o	o	=	=	o	o	=	=
Slovakia	=	o	=	o	o	=	o	✖	=
Slovenia	=	=	o	=	o	=	o	=	o
Spain	=	o	o	o	o	=	✖	=	=
Sweden	o	o	o	=	o	=	o	=	=
United Kingdom	o	=	=	=	o	o	o	=	=

Legend

= Requirements are the same as in the Directive

✖ Requirements have been omitted

o Requirements have been adapted

Figure 2

(Global Reporting Initiative and CSR Europe 2017)

Stakeholders such as investors, employees, consumers as well as policy makers can evaluate the non-financial performance of a large company more easily.(Global Reporting Initiative and CSR Europe 2017) The EC further suggests that large companies can develop a *"responsible approach"* to business when looking into their own non-financial structures. The non-financial report "*directive 2014/95/EU lays down the rules on disclosure of non-financial and diversity information by large companies. This directive amends the accounting directive 2013/34/EU. Companies are required to include non-financial statements in their annual reports from 2018 onwards."* (European Commission 2017)

3.1.1 Mandatory reporting

The European Union ordered that the mandatory non-financial reporting only applies to large corporations that are of public interest and that have more than 500 employees. These applies throughout the European Union to approximately 6000 companies. (European Commission 2012)

"For these companies, non-financial reporting is mandatory:

- *Listed companies*
- *Banks*
- *Insurance companies*
- *Other companies designated by national authorities as public-interest entities"* (EC 2017)

3.2 Related reporting topics

"The Directive 2014/95/EU Directive ruled that large companies have to publish reports on the policies they implement in relation to:

- *"Environmental protection*
- *Social responsibility and treatment of employees*
- *Respect for human rights*
- *Anti-corruption and bribery*
- *Diversity on company boards (in terms of age, gender, educational and professional background)"* (EC 2017)

3.3 Mandatory Reporting – Methodical Approach

In Directive 2014/95/EU, the European Commission describes how the companies are obliged to report. Companies may use international, European or national guidelines (European Commission 2012) to produce their respected statements, they can rely on various guidelines such as:

- *"The UN Global Compact*
- *The OECD guidelines for multinational enterprises*
- *ISO 26000"* (European Commission 2012)

"In June 2017 the European Commission published its guidelines to help companies disclose environmental and social information. These guidelines are not mandatory and companies may decide to use international, European or national guidelines according to their own characteristics or business environment." (EC 2017) Non-financial statements reconcile the impact of corporate activity and are therefore a relevant disclosure of a company. (EC 2017) The modality of the impacts may differ, but all material publications respectively disclosures ought to cover possible the modalities. "*The non-financial statement is expected to reflect a company's fair view of the information needed by relevant stakeholders."* (EC 2017) However, the European Commission set a range of rules that must be assessed.

There are different rules for concrete situations (EC 2017) but they depend on the company's circumstances. "*Companies within an industry are likely to share similar environmental, social and governance challenges, for instance because of the resources they may rely upon to produce goods and services, or the effects they may have on people, society and the environment."* (EC 2017)

The key principles from the European Commission as stated in the *guidelines* for non-financial reporting:

"A number of factors may be taken into account when assessing the materiality of information." (EC 2017) *These include:*

- *"Business model, strategy and principal risks: a company's goals, strategies, management approach and systems, values, tangible and intangible assets, value chain and principal risks are relevant considerations."* (EC 2017)
- *"Main sectoral issues Similar issues are likely to be material to companies operating in the same sector, or sharing supply chains. Topics already identified by competitors, customers or suppliers are likely to be relevant for a company (1)."* (EC 2017)
- *"Interests and expectations of relevant stakeholders: companies are expected to engage with relevant stakeholders and seek a good understanding of their interests and concerns."* (EC 2017)
- *"Impact of the activities: Companies are expected to consider the actual and potential severity and frequency of impacts. This includes impacts of their products, services, and their business relationships (including supply chain aspects)."* (EC 2017)
- *Public policy and regulatory drivers: Public policies and regulation may have an effect on the specific circumstances of a company, and may influence materiality."* (EC 2017)

In chapter 3.5 of the guidelines of non-financial reporting, stakeholder-oriented reporting is advised as companies are expected to report in a way that all relevant stakeholders are evenly informed. The focus needs to stay on the side of the stakeholders in order to perform on a sustainable base. The stakeholders should be seen as a collective group. The focus must not lay on the preferences of an individual stakeholder or a group with excessive reporting demand. (EC 2017) Appropriate target group of stakeholders are: *"…investors, workers, consumers, suppliers, customers, local communities, public authorities, vulnerable groups, social partners and civil society."*(EC 2017) The engagement with stakeholders can contribute to the explanation of the process of decision making and should therefore be enclosed. (EC 2017) The European Commission suggests further KPIs, they are listed in the guidelines.

3.4 Voluntary reporting systems

The determination of impact on society and the environment is not easy to assess, therefore, it is necessary to find a strategy to encompass where a corporation or company stands in terms of a sustainable behavior. (Todorova 2011) Producing and presenting information on business achievements (Todorova 2011) in the field of sustainable development, compliance and transparency can be increased, this can in turn increase the confidence of the stakeholders in the company. (Todorova 2011) To put emphasis on the benefits that every company is aware of is already an advantage. Then talking advantage of these mechanisms and use them for reporting their corporate activities in the grounds of CSR. (Todorova 2011) The voluntary reporting is therefore considered more valuable because the necessary monetary resources are spent in a more productive way, always with an eye on a more sustainable basis to reuse the outcomes. (Todorova 2011)

3.5 Integrated reporting and environmental reporting

Integrated reporting has many purposes, one of the most important purposes is the explanation of the value creation and its flows. The holistic report should provide the stakeholders with information about financial capital and the creation of value over a certain time period. (The IIRC 2013) The creation of non-financial value can be mapped. This value of and for stakeholders is then measurable. Integrated reports should be beneficial to all stakeholders and therefore thoughtfully composed. (The IIRC 2013)

3.5.1 Principles of the IIRC

The “Guiding Principles” of the IIRC help to prepare the reports in order to present information:

- *“Strategic focus and future orientation*
- *Connectivity of information*
- *Stakeholder relationships*
- *Materiality*
- *Conciseness*
- *Reliability and completeness*
- *Consistency and comparability”* (The IIRC 2013)

3.5.2 The core idea of IIRC

The core idea of IIRC is the creation of value. While the business model and its inputs, activities, outputs and outcomes are in the center of attention, governed by strategy and “efficient” resource allocation versus risks and opportunities on the one hand and on the other hand, contemporary performance and outlook to the future. The flow of inputs to outputs fluxes into the six outflows. These outflows enter the external environment, and split up in natural outflow, social and relationship outflow, human outflow, intellectual outflow, manufactured outflow and financial outflow. The created value now flows back into the company, because all the created outflow streams reenter the system as valuable reciprocity and fertilizes the business model of the company. Corporations invest financial and non-financial means into business model infrastructures that do not per se create measurable outputs, it can be challenging to really understand some of the key positions. Depicted in *Figure 1*, the flow model of value creation:

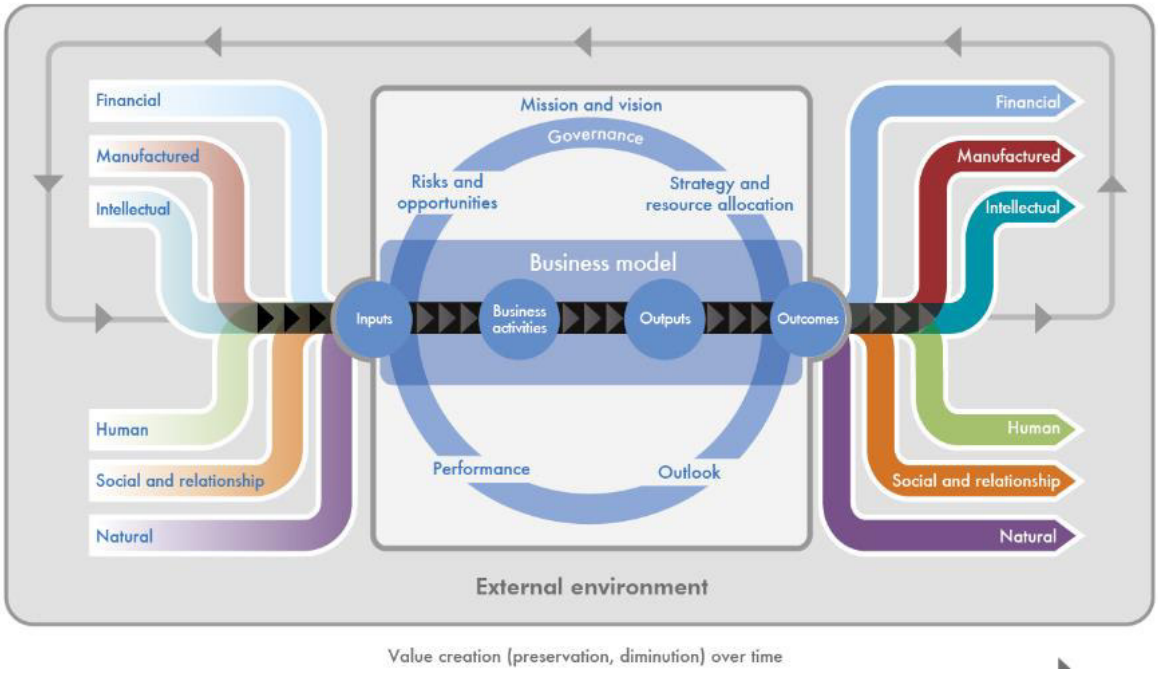

Figure 3

(The IIRC 2013)

Encouraging the participating of all stakeholders in various phases of the business cycle, from planning to manufacturing and also from marketing to selling is often a key to the utilization of deep knowledge and the deployment of specialized skills. (The IIRC 2013) The introduction of new technologies can mitigate or minimize the adverse effects on the environment and help to find alternative uses for unused outputs. (The IIRC 2013)

3.6 The GRI

The GRI standards were developed to find and speak a common language and to enable the communication about impacts of the economy on the environment. The standards were designed to "*enhance the global comparability"*.(Global Reporting Initiative 2016) It was also meant to establish a standard quality of the published "business reports". With the upcoming trend of compliance structures, transparency gained importance for stakeholders. "*The GRI Standards are structured as a set of interrelated standards. They have been developed primarily to be used together to help an organization prepare a sustainability report which is based on the Reporting Principles and focuses on material topics*." (Global Reporting Initiative 2019)

The GRI Standards developed from the latest version of the GRI Guidelines, the "G4". These Guidelines were the product of a 15 year "*global multi-stakeholder development process."* (Global Reporting Initiative 2019) The G4 Guidelines are newly structured and split into modules with interrelated standards. (Global Reporting Initiative 2019) The new Standard, the "GRI Standards" were designed to work on a global base. (Global Reporting Initiative 2019)

> "*The communications of the European Commission (EC) on its policy agenda over the past year reveal one major priority:*
>
> *The United Nations' SDGs. The 17 SDGs that are part of the United Nations' 2030 Agenda for Sustainable Development, provide a coherent, holistic framework for addressing the world's most urgent sustainability challenges – such as climate change, human rights, corruption, poverty, inequalities and justice, naming just a few – to help create a better future for all. As such, the SDGs cover all areas of the EC's work."*(Global Reporting Initiative and CSR Europe 2017)

3.7 Corporate Social Responsibility (CSR)

CSR can be defined as corporate behavior beyond good compliance (McWilliams and Siegel 2001) and should engage in actions that achieve social well-being, beyond interests of a corporation and also beyond of what is required by law. (McWilliams and Siegel 2001) McWilliams and Siegel further elucidate, that CSR developed from academic disciplines including economics, psychology, political science, management, marketing, and environmental management. (McWilliams, Siegel, and Wright 2007) There are several theories of what CSR is really about. Some even suggest it is only for the sake of the manager, others postulate that it is *"a moral imperative for managers to do the right thing."* This theory, developed by Donaldson in 1990, called stewardship theory, appeals to the strong intrinsic motivation of managers to follow their own path, a path that leads to just the right output. Donaldson assumes that *"given a choice between self-serving behavior and pro-organizational behavior, a steward will place higher value on cooperation than defection. Stewards are assumed to be collectivists, pro-organizational, and trustworthy."* (Donaldson and Davis 1991) Intelligent stewardship is the approach chosen by Merck to mitigate negative impacts on the environment. The Company follows this EHS policy:

"…CSR Europe played an active role in engaging companies in the different steps: negotiations, transposition and implementation across the 28 Member States. The European Directive is now mirrored in local laws which provide companies with a more stable framework for transparency. These laws support corporate reporting as a means towards better integration of sustainability within business models." (Global Reporting Initiative and CSR Europe 2017) The GRI organization states that they could assist the Member States of the EU with the implementation of the *"key elements"* of the directive into national law. (Global Reporting Initiative and CSR Europe 2017)

4. Basics and history of the pharmaceutical industry

The emergence of pharmaceutical chemistry and pharmacology and the rise of the pharmaceutical industry started in the years between 1870 and 1930 in Europe. (American Chemical Society 2005) In ancient times, pharmacy was a basically the use of plants against diseases, it was a discipline within the scope of medicine. The success of modern pharmacy can be traced back to two sources.

Firstly, the increasing popularity of morphine products and furthermore the malaria prophylaxis quinine as well as strychnine. (American Chemical Society 2005) Secondly, during this time apothecaries became wholesalers and thus were able to invest in the production of the desired drugs. Throughout the 19th century, chemical companies were able to establish chemical laboratories. (American Chemical Society 2005) The history of Merck, one of the largest international chemistry and pharmaceutical corporations started in 1668 in Darmstadt, where it also started as a small apothecary shop. The transition into a larger laboratory only began about two centuries later in the 1840ies. (American Chemical Society 2005)

4.1 Emergence of modern medicinal products

However, with the emergence of chemistry and pharmacology as separate disciplines a scientific approach as well as research and cooperation across Europe and the U.S. led to the discovery of many findings. (American Chemical Society 2005) Pharmaceutical companies in Europe and the U.S. were able to launch common academic facilities. This academic exchange and the new possibilities of research resulted in more findings and methods.(American Chemical Society 2005) By the beginning of the 20th century, the isolation of hormones and other synthetic drugs increased dramatically.

The successful history of vaccines, antibodies and antitoxins can be seen as a successful history against premature death and the emergence of systematic therapies. The regulation of medicines surely comprises an intelligent approach, medicines can also be a part of culture and tradition. Many regions in the world evolved with regionally typical supplements and potions. These traditional mixtures can date back hundreds of years.

Throughout the first third of 20th century and also before, the flourishing pharmaceutical industry market remained completely unregulated and the most mixtures were not

patented. (American Chemical Society 2005) These mixtures would not withstand a formal quality control. In modern medicine standardized quality plays an important role but it was not implemented into law as late as the 1540ies (Lembit and et al. 2010) when in England the *"manufacturing of a medication called Mithridatium was subjected to supervision under the Apothecaries Wares, Drugs and Stuffs Act."* (Lembit and et al. 2010) This statute was one of the first legislative acts on the control of pharmaceutical products. This first legislative act was the first of its kind in the pharmaceutical business. (Lembit and et al. 2010)

4.2 First regulations of pharmaceuticals

The governmental regulation of medicines started after a *"breakthrough process in life sciences"* (Lembit and et al. 2010) in the 19th century. After World War II, research and development among international partners flourished. The main fields of this research enthusiasm as chemistry, physiology and pharmacology. (Lembit and et al. 2010)

However, it was inevitable to set quality standards on an international level. The understanding of diseases and their derivatives gained a broader perspective. The development of appropriate education and training of the medical personnel become more relevant. The efforts became more sophisticated and a need for scientific training was needed in order to take rational decisions about safety and health related issues. (Lembit and et al. 2010) Using medicine that leads to therapeutic failures can cause extreme harm or even end lethal. Poor quality or wrong ingredients cause exacerbation of disease. The resistance to some drugs can also be traced back to these failures. (Lembit and et al. 2010) On the way to a functioning public health care system, it is highly ineffective to waste resources and financial means on unsafe medication.

4.3 Establishment of the World Health Organization (WHO)

Hence, a development of the approval procedures was essential. *"Medicines regulation demands the application of sound scientific (including but not limited to medical, pharmaceutical, biological and chemical) knowledge and specific technical skills, and operates within a legal framework. The basic elements of effective drug regulation have been laid down in several WHO documents."*(Lembit and et al. 2010)

The establishment of the WHO. The Constitution was adopted by the *"International Health Conference"* which took place in New York in 1946 "…and was signed *by the*

representatives of 61 States and entered into force on 7 April 1948." (WHO 2017) A crucial step for the continuous control was the establishment of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP).

The committee was established during the first World Health Assembly in 1948 to "*provide advice"* to WHO and its Member States. (WHO 2017) The goal was a normative development of guidelines. A set of rules and standard to endorse quality assurance and control. The constitutional paper contains a large part to ensure quality. (WHO 2017) The WHO as a globally thinking initiative was able to set a legal framework to identify standards that are applicable in all Member States:

> "*Operations of the pharmaceutical industry are guided by the legal requirements in force in the target markets. In a globalized marketplace this often means that high quality medicines are being produced for use in stringently regulated environments, while fewer requirements and lower standards are applied for medicines used elsewhere. Moreover, as starting materials and services are sourced from across the globe, local weaknesses in norms and standards regulatory control can have global impact."* (WHO 2017)

4.3.1 Identification of Interlinkages between the Environment and Human Health

Local weaknesses in standards regulatory control can lead to major environmental catastrophes, many substances used in large or small quantities, released into the environment can have an impact on humans and nature. Endocrinal substances for example can alter the hormone system of species, extinction and biodiversity loss are possible outcomes.

The WHO has identified these issues and supports Member States, that have gaps in their regulatory development. *"Today all the world's regulatory authorities, including the well-established ones – are calling for cooperation and convergence of standards to close the regulatory gaps. These developments have been shaping the need for comprehensive WHO guidance on medicines quality assurance that can be implemented in all Member States."* (WHO 2017) Without the constant examinations of the production standards, the quality assessment is a fundamental step.

"*When modern medicines regulation started to develop in the 1960s it was recognized that quality cannot be "tested into a product". Instead it must be built into a product at every step of development and production. The regulatory paradigm has shifted from quality control of the finished product to control of the manufacturing processes, as verified in inspections."* (WHO 2017) The ECSPP *"Expert Committee on Specifications for Pharmaceutical Preparations"* consists of experts who develop norms as well as standards on the manufacturing of pharmaceutical products.

4.3.2 Good Manufacturing Practice (GMP)

In 1969, the WHO presented their first set of rules and guidelines on the GMP. These rules determined a basis of the inspection body and its inspection convention. The continuous revise of these guidelines led to a constant improvement of standards. Different management systems, and their respected guidelines could be updated and supplemented on specific types of products. A functioning product management system that identifies risks, hazards and quality aspects can be a constant management tool for the entire life cycle of a product. (WHO 2017) Another branch of the guidelines is the classification of deficiencies (WHO 2017) that can be a support for the relationship with an inspecting body. (WHO 2017)

4.4 Side effects of Mass Productions

With the positive effect of regulation and the progress of safer medicines for consumers, the adverse effects of emerging pollutants, traces of pharmaceuticals and the detectives work to determine and prove the presence and influence of the emerging pollutants, it is clear that scientists are always running behind. Scientific prove of emerging pollutants is a lengthy process and the long-term consequences are not fully understood. However, *"pharmaceuticals enter the environment during various stages of the product lifecycle from their production and consumption to disposal."* (UNESCO and HELCOM 2017) The greatest challenge even when wastewater is treated in WWTP. The oxidation and denitrification with bacteria is not enough when it comes to reducing complex chemical compounds in water. (UNESCO and HELCOM 2017)

In a large scale study of 2017, emerging pollutants were subject to examination in the Baltic Sea, this site is also a victim to annually deadly algae blooms (ESA 2015) and therefore well observed. The study observed a wide range of popular pharmaceuticals, respectively emerging pollutants and their pathways to final sinks.

5. Merck- Healthcare, Technology and Life Science

The Merck KGaA is a company of partnership limited by shares. "…*the partnership limited by shares (Kommanditgesellschaft auf Aktien, KGaA) combines the structures of a stock corporation (AG) and a limited partnership (Kommanditgesellschaft). It connects the entrepreneurial commitment and personal standing of the individually liable shareholders (general partners) with the function of the AG as a public company and source of capital."* (Germany Trade & Invest 2019)

The organizational chart of the corporation concerning the EQ function of the corporation:

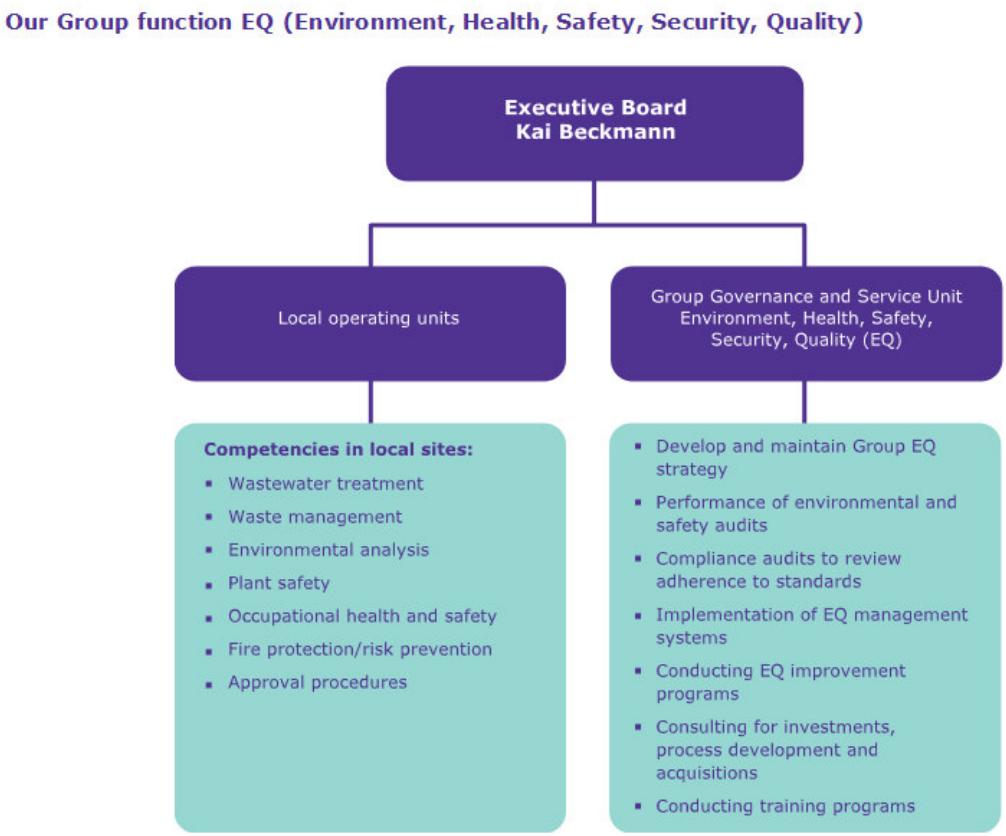

Figure 4

(Merck 2019)

The competences are divided into tasks intended for the single operational units and responsibilities for the strategic corporate EQ department. The competences at the local sites contain waste intensive tasks for instance wastewater treatment, (United Nations Global Compact 2019) wastewater management further covering environmental analysis along with the health and safety of the workers and employees. The overall plant safety with fire protection and risk prevention are also part of the "on site" management teams

in addition to the approval procedures. On the other branch of the organizational chart, the strategic development department with its responsibilities corresponding with environmental performance and safety and compliance audits. Merck uses audits as regular internal compliance and safety checks. Another task is consistent with compliance audits, the review of the adherence to the standards. Chemical and pharmaceutical production sites need high standards in maintenance and even higher standards in technical hygiene and production. Merck is a German chemistry and pharmaceutical but also life science and technology company that started their business 350 years ago, sustainable development led to innovative development in many fields. Now the company signed a fundamental strategy for environmental sustainability, explaining their sustainability and stewardship approach:

> *"Our approach to environmental stewardship is built on our Corporate Environment, Health and Safety Policy, which we updated in 2016. This policy is now aligned more closely with the stipulations of the chemical industry's Responsible Care® Charter, as well as environmental management standard ISO 14001, and it emphasizes our management's responsibility toward environmental stewardship, health and safety. Moreover, it addresses our suppliers, encouraging them to adopt similarly high standards for environmental sustainability and safety. In doing so, our Corporate Environment, Health and Safety Policy complements the Responsible Sourcing Principles of our Group Procurement function."* (MERCK 2018)

The company has an environmental protection program, following an environmental stewardship in order to protect stakeholders and of course the sustainable development of their business within a healthy environment.

> *"As a science and technology company with manufacturing operations, we utilize resources and materials that could have a potentially negative impact on the environment if not handled properly. To mitigate this effect, all our sites meet a strict set of environmental requirements. A holistic approach is needed to minimize negative impacts on the environment and sustainably preserve resources in the long run. Intelligent environmental stewardship reduces resource use and lowers costs."* (MERCK 2018)

5.1 Environmentally problematic substances

The company has been dealing with hazardous substances for approximately 350 years. A sustainable handling of hazardous chemicals was of great importance due to a high risk of loss of trust of business partners such as patients but also the loss of the trust of the stakeholders. Corporate action, especially when there are chemicals involved that can cause long term detrimental effects to the health of humans and nature needs to be supervised accordingly. Chemical spills via vapors or fumes are uncontrollable due to weather and wind. Secondary reactions with other chemicals can cause unforeseen damages to the environment. Liquids such as acids that are used as solvents can change their aggregate state and thus become gaseous and uncontrollable. Liquids though, can also percolate into the soil and degrade ground water that can travel uncontrollably. Merck has therefore laid down their own principles as:

> *"We continuously seek to reduce our environmental footprint, which requires us to utilize resources such as raw materials, energy and water both sparingly and efficiently while also cutting emissions and waste."* After identifying threats, the company decided to set up the structure as: *"The Group function Environment, Health, Safety, Security, Quality (EQ) is in charge of steering all environmental measures Group-wide. At our individual sites, each site director is responsible for environmental stewardship as well as occupational health and safety at the operational level. At larger facilities, the site directors receive day-to-day support and advice from Environment, Health and Safety managers, with EHS coordinators performing this role at smaller facilities. Ultimate responsibility for environmental stewardship is borne by Kai Beckmann, Executive Board member and Chief Administration Officer."* (MERCK 2018)

5.2 Environmental Reporting at Merck

The latest integrated report published by Merck, follows the natural business year 2018. The published general disclosure includes the GRI Standards which are tagged in a way according to the corporate activity, thus, the activity can be traced back to certain standard in the GRI family via the respected GRI code.

Aspect: Environmental matters

Within our Group, environmental matters fall under environmental stewardship. In the following section, we report on the measures implemented to further environmental stewardship, enhance plant and process safety, and address pharmaceutical and chemical residues in the environment (incl. abandoned hazardous waste).

Issue	Concepts incl. due diligence processes and outcome of activities
Environmental stewardship	▪ Organizational structure of the Group function EQ ▪ Standards and standard operating procedures for environmental stewardship ▪ Assessing environmental impacts, auditing our sites and reporting violations ▪ ISO 14001 Group certificate and certification of new sites ▪ Stakeholder dialogue ▪ Goals and progress: Environment
Pharmaceutical and chemical residues in the environment (incl. abandoned hazardous waste)	▪ Type and amount of provisions for environmental impact mitigation ▪ Remediation of contamination at Gernsheim site
Plant and process safety	▪ Organizational structure: Plant and process safety within EQ ▪ EHS standards and processes ▪ Tracking EHS performance indicators ▪ „Risk Management Process" ▪ Employee training and sharing lessons learned ▪ EHS Incident Rate ▪ Substance spills and environmental impacts

Figure 5

(MERCK CRR 2019)

For a comparable picture: *"The following GRI content index provides an overview of general disclosures, the GRI Standards and management approaches that were identified to be relevant. It also indicates where the corresponding information can be found. The GRI content index, as a part of the CR report 2018, has received an independent audit certificate after undergoing a limited assurance audit."*(MERCK CRR 2019)

5.3 Environmental Stewardship

Environmental stewardship - introduced in the analyzing chapters is the concept that the Merck KGaA chose to responsibly handle their environmentally hazardous production sites and plants. Merck included their commentary chapters in the integrated corporate report as part of the non-financial reporting. *"… with manufacturing operations, our activities have an impact on the environment, generating air emissions, wastewater and waste. Even the materials we utilize could adversely affect the environment if not handled properly. To mitigate these impacts, all our sites meet a strict set of environmental regulations and continually adapt their processes to new regulatory requirements.*(Merck KGAa 2017) Moreover, the use and development emerges toward energy efficiency, Merck emphasizes in their reports their goal on lowering resource and energy needs:

> *"Climate change is one of the most pressing challenges of the 21st century. Because our operations also generate greenhouse gas emissions, we endeavor to reduce these emissions to mitigate our impact on the climate, a course of action expected by our customers and stakeholders. Although stricter regulatory requirements may lead to planning and investment uncertainty, burgeoning regulations and rising energy costs are making climate impact mitigation an increasingly smart investment."* (MERCK CRR 2019)

Environment

Environmental stewardship

Goal: Incorporate all production sites into our Group ISO 14001 certificate for environmental management systems

Action(s):	By:	Progress by end of 2018:	Status:
At newly acquired production sites, introduce environmental management systems in line with our Group ISO 14001 certificate and certify them accordingly.	Ongoing	In 2018, two sites transferred their environmental management system to our Group certificate. All sites pertinent to the Group certificate have thus been transitioned to the new version of ISO 14001:2015.	

Climate action

Goal: 20% reduction in our direct and indirect greenhouse gas emissions (Scope 1 and 2) relative to the 2006 baseline

Action(s):	By:	Progress by end of 2018:	Status:
Systematically examine the energy consumption at our individual production sites.	End of 2020	In 2018, we conducted an energy audit at a production facility in Hamburg (Germany).	

Figure 6

Training on energy efficiency	End of 2018	In partnership with TU Darmstadt, our Darmstadt site offered day-long workshops on energy efficiency. The six workshops were attended by 80 people who play a major role in enhancing energy efficiency (such as plant engineers).	
Identify and implement potential energy savings.	End of 2020	In 2018, we implemented 34 Edison projects with a view to cutting carbon emissions by 75,000 metric tons in the medium term. Multiple projects had to be postponed until 2019.	
Reduce process-related emissions.	End of 2022	In 2018, we initiated two further projects aimed at lowering process-related emissions, one of which was completed in 2018, and yielded 10,000 metric tons of carbon savings. The second project is scheduled to run until 2022. Based on production volume in 2018, we are expecting to save roughly 40,000 metric tons of CO_2 in this period. A third project is currently in the planning stages.	
Renewable energy	End of 2020	Full integration of the purchase of electricity from renewable sources is our goal.	

Figure 7

(MERCK CRR 2019)

GRI 302: ENERGY 2016		
103-1	Explanation of the material topic and its Boundary	Environmental stewardship Climate action Sustainable product design Materiality analysis
103-2	The management approach and its components	
103-3	Evaluation of the management approach	
302-1	Energy consumption within the organization	Climate action Indicators: environment
302-2	Energy consumption outside of the organization	Climate action
302-3	Energy intensity	Climate action Indicators: environment
302-4	Reduction of energy consumption	Climate action Indicators: environment
302-5	Reductions in energy requirements of products and services	Sustainable product design

Figure 8

(MERCK CRR 2019)

GRI 305: EMISSIONS 2016		
103-1	Explanation of the material topic and its Boundary	Environmental stewardship Climate action Materiality analysis
103-2	The management approach and its components	
103-3	Evaluation of the management approach	
305-1	Direct (Scope 1) GHG emissions	Climate action Indicators: environment
305-2	Energy indirect (Scope 2) GHG	Climate action Indicators: environment
305-3	Other indirect (Scope 3) GHG emissions	Climate action Indicators: environment CDP
305-4	GHG emissions intensity	Indicators: environment

Figure 9

(MERCK CRR 2019)

5.4 Implementation and Conclusion

The tables representing the measurements and actions taken in the following fields: “Waste and Recycling”, “Water Management”, “Plant and Process Safety” and “Biodiversity”. The conclusions on the topics are implemented in the following chapters.

5.4.1 Waste and recycling

Waste and recycling

Goal: Reduce the environmental impact of our waste disposal (Merck KGaA Waste Score) by 5% by 2025 (baseline 2016)

Action(s):	By:	Progress by end of 2018:	Status:
Establish Waste Expert Network Groups.	End of 2018	We established a Group-wide and a U.S.-based Waste Expert Network Group comprising specialists from various areas who work together to integrate waste scoring and promote best practice sharing.	✓

Figure 10

(MERCK CRR 2019)

GRI Standards and Disclosure Number		Comment	Reference
GRI 301: MATERIALS 2016			
103-1 103-2 103-3	Explanation of the material topic and its Boundary The management approach and its components Evaluation of the management approach	In all our endeavors, we attempt to efficiently utilize materials and recycle as much as possible. Where feasible, we use recycled materials (in packaging, for instance). Overall, our company considers material consumption a major concern. There are few opportunities to use recycled material in our production processes because our business model puts us at the start of the value chain. We therefore do not collect such data at the Group-level. Individual data and measures are reported under the respective chapters.	Sustainable product design Packaging and recycling Environmental stewardship Waste and recycling Materiality analysis
301-1	Materials used by weight or volume	See GRI 301: 103	Waste and recycling Sustainable product design Packaging and recycling
301-2	Recycled input materials used	See GRI 301: 103	Waste and recycling Sustainable product design Packaging and recycling
301-3	Reclaimed products and their packaging materials	Owing to the multitude of products we supply and the minimal comparability of our various initiatives, we do not collect quantitative data at the Group level. The individual measures taken by our various businesses are reported in the respective chapters.	Waste and recycling Sustainable product design Packaging and recycling

Figure 11

(MERCK CRR 2019)

Emissions are determined partially based on measurements and partially based on calculations or estimates. Only some sites are required to measure individual parameters.

Hazardous and non-hazardous waste

metric kilotons	2015	2016	2017	2018[1]
Total waste	**324[2]**	**256[2]**	**255[2]**	**244**
Hazardous waste disposed[3]	55	47	43	44
Non-hazardous waste disposed[3]	35	38	33[2]	54
Hazardous waste recycled[4]	77[2]	82[2]	72[2]	74
Non-hazardous waste recycled[4]	157	89	107[2]	72

1 Excludes Consumer Health
2 Figure retroactively adjusted.
3 Disposed = incineration (without energy recovery) and landfill
4 Recycled = incineration (with energy recovery) and material recycling

Exported/Imported hazardous waste

metric kilotons	2015	2016	2017	2018[1]
Exported[2]	5.1	4.6	4.9	4.5
Imported[3]	0.010	0.010	0.005	0.000

1 Excludes Consumer Health
2 Disposal within the EU and the United States.

In 2018, approximately 4% of hazardous waste was shipped internationally.

Figure 12

(MERCK CRR 2019)

The company's concluding remark on the produced waste: *"as in previous years, the total waste generated continues to be heavily influenced by the waste from construction and remodeling activities. Construction, excavation and demolition waste accounted for 31% of our waste in 2018. Around 40metric kilotons of construction, excavation and demolition waste was recycled."* (Merck 2019) However, it is clear that the collected and assorted waste can contain valuable but also hazardous raw materials and substances. Moreover, should construction waste and materials that are obviously ending their lives at the landfill be designed in a more thoughtful way. Modules that can be recycled or even reused could prevent these actions.

5.4.2 Water management

GRI Guidance for assessing the impacts that corporate activities can have on water bodies:

> *"When assessing impacts, it is important that the organization consider its future impacts on water quality and availability, as these factors can change over time.*
>
> *Tools and methodologies for identifying impacts can include life cycle assessments, environmental impact assessments, water footprint assessments, scenario analysis, and stakeholder engagement. If information is estimated or modeled, rather than sourced from direct measurements, the organization can explain its estimation or modeling methods."* (Global Reporting Initiative 2018)

In order to measure the impacts on water management systems, Merck implemented a functional color-coded system to breakdown all desired points.

The relevance of sustainable water management in the chemical and pharmaceutical industry is enormous. Water is a valuable resource to every living being, but to the chemical industry it is vital. "*A key raw material."* (The European Chemical Industry Council AISBL 2018) The increasing level of concerns regarding the quality as well as the amount of available freshwater are already a constraining factor to some industries. *"Therefore, the chemical industry is committed to advancing sustainable management of water. Furthermore, growing concerns on water scarcity and water quality have increasingly highlighted sustainable water management as a strategic issue for chemical companies."* (The European Chemical Industry Council AISBL 2018)

Water management

Goal: Introduce a sustainable water management system at 24 of our manufacturing facilities with high water use by 2020

Action(s):	By:	Progress by end of 2018:	Status:
Meet the "progressed" requirements set out in the CEFIC flagship self-assessment tool (stage 2). This involves creating transparency regarding the situation in the vicinity of the respective sites and beginning the evaluation of the sites' influence on their environment.	End of 2018	During stage 2 of the self-assessment, we created transparency regarding the water situation in the vicinity of our individual sites. We successfully analyzed the results by the end of 2018.	✓
Meet the "advanced" requirements set out in the CEFIC flagship self-assessment tool (stage 3): This will assess our sites' impact on the water situation in the vicinity of each individual site.	May 2020	During stage 3 of the self-assessment, we will assess the environmental impacts arising from our discharged water. This process began in 2018, and will continue until May 2020 without an interim audit.	▶

Figure 13

(Merck 2019)

Wastewater volume and quality

	2015	2016	2017	2018[1, 2]
Total wastewater volume (millions of m^3)	**12.5**[3]	**12.9**[3]	**13.1**[3]	13.5
Chemical oxygen demand (metric tons of O_3)	1,240[3]	1,535	1,669[3]	1,589
Phosphorous (metric tons)	10	12	8	9
Nitrogen (metric tons)	487	379	234[3]	258
Zinc (kg)	491	448	351	–[2]
Chromium (kg)	42	34	34	–[2]
Copper (kg)	78	48	61	–[2]
Nickel (kg)	29[3]	29[3]	32[3]	29
Lead (kg)	32[3]	31[3]	35[3]	28
Cadmium (kg)	9[3]	7[3]	6[3]	6
Mercury (kg)	2	2	1	0
Arsenic (kg)	5	4	3	–[2]

1 Excludes Consumer Health

2 In alignment with ICCA reporting requirements specified by Cefic, we track heavy metal emissions from lead, cadmium, nickel, and mercury. These heavy metals are considered to be directly toxic to organisms and are also hazardous to human health due to their carcinogenic properties and their ability to cause harmful effects even in minute quantities. Due to having adopted ICCA reporting standards, we stopped tracking arsenic, chrome, copper, and zinc as of 2018.

3 Figure retroactively adjusted.

The wastewater volume includes indirect discharge into both public and Merck-owned wastewater treatment plants, as well as direct discharge (such as rainwater and cooling water).

The wastewater treatment plant at our Gernsheim, Germany site also treats wastewater from the neighboring municipality of Biebesheim. The communal wastewater from Biebesheim is included in the wastewater volume as well as in the emissions stated in the table.

Figure 14

(Merck 2019)

"Worldwide, the number of areas suffering from water scarcity is on the rise, yet our various facilities are dependent on a regular supply of water. At the same time, legislation governing water conservation is growing increasingly stringent. Our wastewater may contain traces of substances such as heavy metals or pharmaceutical active ingredients, which makes sustainable water management a key focus of our environmental stewardship." (Merck 2019)

5.4.3 Plant and process safety

The safe use of mutagenic, carcinogenic and reprotoxic chemicals often is inevitable. The impact of these chemicals and substances on the employees and on the environment could easily become a catastrophe.

Therefore, the handling at the workplaces requires high attention and strict procedures to follow. *"Currently, the EU regulatory framework offers two separate directives: on the one hand, a directive to manage the Carcinogenic and Mutagenic substances (set by the Carcinogens and Mutagens Directive) and, on the other hand, rules for managing reprotoxic substances (set by the Chemical Agents Directive)."* (The European Chemical Industry Council AISBL 2018)

Merck currently has more than 50000 employees, due to high security and internal safety standards, the employees are an asset themselves and hold a large almost not quantifiable share of the corporation. *"The safety of our plants and processes is a key element of our environmental stewardship efforts. This approach allows us to protect both our workforce and the people in the vicinity of our sites. Furthermore, high performance safety systems help minimize production errors, which in turn lowers the risk of financial losses."* (Merck 2019)

5.4.4 Biodiversity

As part of the non-financial statement, Merck reports their key figures according to the GRI:

GRI Standards and Disclosure Number	Comment	Reference

GRI 304: BIODIVERSITY 2016			
103-1	Explanation of the material topic and its Boundary		Biodiversity Materiality analysis
103-2	The management approach and its components		
103-3	Evaluation of the management approach		
304-1	Operational sites owned, leased, managed in, or adjacent to, protected areas and areas of high biodiversity value outside protected areas	Land use planning takes impacts on bioversity into account, with appro-priate measures being taken on a case-by-case basis.	Biodiversity
304-2	Significant impacts of activities, products, and services on biodiversity		Biodiversity
304-3	Habitats protected or restored		Biodiversity
304-4	IUCN Red List species and national conservation list species with habitats in areas affected by operations	Land use planning takes impacts on bioversity into account, with appro-priate measures being taken on a case-by-case basis.	Biodiversity

Figure 15

"The increasing loss of biodiversity is a global challenge that impacts our company as well. After all, we depend on ecosystems for natural resources such as raw materials. Prime examples include red algae (Polysiphonia elongata), whose cytoplasm is used in our cosmetic active (…) and the seeds of the common poppy (Papaver rhoeas), whose extracts can be found in our cosmetic (…). We therefore have a vested interest in preserving and promoting biodiversity."(Merck 2019) The actual measures to preserve biodiversity at the sites are mostly connected to how a site is constructed and planned. Soil sealing and the review of important ecological aspects are part of the projects. The EHS unit, is part of the planning team. The EHS unit correspondingly performs "*detailed environmental impact assessments for large-scale projects."* (Merck 2019)

6. Conclusion

An integrated report is displaying many aspects of the corporate activities, including the environmental measurements and thoughts undertaken in every business year. Merck refers in their non-financial report to the GRI. The GRI helps to implement the most important measures as well as a leitmotif to position a company. Merck has a tradition for non-financial reporting to keep up with the need for balance between employees and managers as well as nature and sinks. It is a matter of mind set and compliance in terms of how far exploitation goes. Taking responsibility and the commitment to environmental protection as well as the treatment of employees and workers, a divers staff and a divers company board (EC 2017) are the pillars of a sustainable economy and therefore well known to large structured companies with the financial possibilities and means to act in a responsible way. The three pillars of sustainability, CSR and very other principle described and analyzed in this thesis led to the conclusion that sustainable development in businesses is a matter of balance. Corporate social responsibility (CSR) derives from the need of a holistic approach towards sustainable corporate activities. Coming from the theory of business ethics, CSR can be a measurable value when it comes to comparing within a branch. Its self-regulating power influenced all sorts of businesses. Due to a large variety in policy for corporate behavior, internationally seen, corporate action can also be seen as cultural heritage, it is rather difficult to organize the economical approach of each country and its citizens because each and every country in the world has its own history and other resources.

Therefore, there cannot be a global theory to solve all exploitation and pollution issues magically. There are certain threats to the environment that are worth to be mentioned in this further conclusion on the pathways of pollution. The upcoming of emergent pollutions expresses a novel challenge on water quality. Pharmaceuticals are possibly a severe threat to humans and furthermore to the entire environment with all interlinkages. Emerging pollutants are found in all kinds of waters like rivers, coastal waters and even in further regions in oceans.

Due to the ongoing prolonging of human life in the western world, the highest ranked countries have an approximate expectancy of life at more than 80 years. (Connection-Population 2016) That suggests that there are not only more humans born every day, they also stay on the planet longer. This further implies that the possibility to use and consume more pharmaceutical products raises every day. Which leads to further and additional pollution.

Another hazard may be a significant amount of unmetabolized or even unused quantities of medicinal products and chemical byproducts. (UNESCO and HELCOM 2017) Untreated wastewater being discharged into the sewage system coming from agriculture and aquaculture are linked to possible pollution pathways. *These pollutants reach coastal and sea waters, as ultimate sinks."* (UNESCO and HELCOM 2017)

The "recycling" of the possibly mutated pollutants is an elusive risk to the biome of the planet. Various "primary" substances that are directly discharged pollutants which may develop and alter themselves into "secondary" pollutants that derive from the mix of substances, for example with pollutants from agriculture.

In conventional farming, the use of antibiotics and disinfecting solutions is widely spread. (Mateo-Sagasta et al. 2017) With more pollutants in the environment resulting from human action, the concerns grow. The impact on human health due to these emergent pollutants stemming also from pharmaceutical pollution, is causing risk to the biota. (UNESCO and HELCOM 2017) In fact, there are three common pathways or routes of pollutants entering the environment.

"*Pharmaceuticals also enter the environment via agriculture, aquaculture and veterinary practices. Awareness is growing that pharmaceuticals may have harmful effects for wildlife."*(UNESCO and HELCOM 2017) (*The WHO presented two drugs that were used in large quantities 17a-ethinylestradiol and the anti-inflammatory drug diclofenac*).

"The hormone 17a-ethinylestradiol has been reported to be responsible for the feminization of male fish at concentrations that can be found in surface waters downstream of sewage treatment plants." (UNESCO and HELCOM 2017)

The feminization of the male population of many species is an emerging issue due to many hormone active substances in the biosphere. The case of Bisphenol A, a substance that mimics female hormones is widely reported. Bisphenol A is a used in the production of plastics and is one of the most sold chemicals on the market. It has reached popularity due to its use in baby products. Growing organisms are disproportionately more affected by hormone active substances because: *"…during the first six months of the infants' lives, exposure to the substance is the highest, especially if infant formula is the only source of nutrition. Also, during this period the infants' system builds up and does not have the capacity to eliminate BPA."*(European Commission 2011)

Another commonly used drug, and OTC medicinal product is diclofenac. It is one of the most studied drugs worldwide due to its high amount of usage. However, the compounds used in Diclofenac are often detected in WWTP effluents. (UNESCO and HELCOM 2017) The biodegradability of the compound is very low, hence the removability is very small. (UNESCO and HELCOM 2017) Scientist and engineers are currently designing and researching on new technologies such as membranes and innovative oxidation technologies. Diclofenac is also widely used for veterinary purposes in Southeast Asia where it has almost extirpated the local vulture population. (UNESCO and HELCOM 2017)

The need of environmental policy and reporting is obvious, because next to the maximization of profits the compliance with international rules and policies is of importance. However, for certain industries, environmental reporting is substantial due to its importance for stakeholders and shareholders. The pharmaceutical industry in this case has great interest in environmental reporting as well as environmental laws and international agreements because it could directly affect their annual profits. Trust and consistency are of great importance in this field. Stakeholders and the environment are extremely vulnerable to mismanagement, corruption and compliance breaches. Corporate responsibility and the publication of environmental reports can lead to more sustainable efficiency.

Bibliography

American Chemical Society, News. 2005. “EMERGENCE OF PHARMACEUTICAL SCIENCE AND INDUSTRY.” Chemical and Engineering News. 2005. http://pubs.acs.org/cen/coverstory/83/8325/8325emergence.html.

Ban Ki-moon. 2016. “Business Key to Achieving SDGs, Says Ban Ki-Moon.” 2016. https://www.un.org/sustainabledevelopment/blog/2016/01/world-of-business-must-play-part-in-achieving-sdgs-ban-says/.

Brundtland, Gro Harlem. 1987. “UN WCED 1987 Brundtland Report.Pdf.”

Chesworth, Ward, and Ronald Wright. 2005. “A Short History of Progress.” Geoscience Canada.

Connection-Population. 2016. “Www.Populationeducation.Org.” Population Connection. 2016. https://worldpopulationhistory.org/map/2034/mercator/1/0/25/.

Diamond, Jared. 2009. Guns, Germs and Steel. 829-831, The Fates of Human Societies. W. W. Norton & Company. https://doi.org/10.1046/j.1467-8330.2003.00357.x.

Donaldson, Lex, and James H Davis. 1991. “Stewardship Theory or Agency Theory:” Australian Journal of Management. https://doi.org/doi.org/10.1177/031289629101600103.

EC. 2017. “Communication from the Commission: Guidelines on Non-Financial Reporting (Methodology for Reporting Non-Financial Information) (2017/C 215/01),” no. December 2014: 1–20. http://ec.europa.eu/finance/company-reporting/non-financial_reporting/index_en.htm#related-documents.

ESA. 2015. “Algal Bloom in the Baltic Sea - Environment Hazards - Earth Watching.” 2015. https://earth.esa.int/web/earth-watching/environmental-hazards/content/-/article/algal-bloom-in-the-baltic-sea.

European Commission. 2011. “Bisphenol A: EU Ban on Use in Baby Bottles Enters into Force next Week,” no. May: 31–32. http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm064437.htm.

European Economic and Social Committee and the Committee of the Regions “Report from the Commission to the European Parliament, the Council, the: The Implementation of the Soil Thematic Strategy and Ongoing Activities.” Com (2012) 46 Final, 15. https://doi.org/10.2771/44682.
Accessed 2019-04-05

European Commission. 2019. “Corporate Social Responsibility.” European Commission Internal Market, Industry, Entrepreneurship and SMEs Industry. http://ec.europa.eu/growth/industry/corporate-social-responsibility/.
Accessed 2019-05-05

Germany Trade & Invest, GTAI. 2019. “GTAI - Partnership Limited by Shares (KGaA).” https://www.gtai.de/GTAI/Navigation/EN/Invest/Investment-guide/Establishing-a-company/Company-forms/Corporations/partnership-limited-by-shares-kgaa.html.
Accessed 2019-08-05

Global Reporting Initiative. 2018. “GRI 303: Water and Effluents.” GRI Standards.

Global Reporting Initiative, and CSR Europe. 2017. “Member State Implementation of Directive 2014/95/EU.” CSR Europe and GRI 2017, 36. https://www.csreurope.org/sites/default/files/CSR Europe GRI NFR publication_0%281%29.pdf.
Accessed 2019-06-05

Global Reporting Initiative, GRI. 2016. “Gri 101: The Founding.”

GSSB and GRI. 2019. Questions and Feedback. https://www.globalreporting.org/standards/gssb-and-standard-setting/.
Accessed 2019-04-08

Global Reporting Initiative and UN Global Compact. 2017. “Analysis of the Goals and Targets.” https://www.globalreporting.org/resourcelibrary/GRI_UNGC_Business-Reporting-on-SDGs_Analysis-of-Goals-and-Targets.pdf.
Accessed 2019-04-09

GRI. 2016. “Sustainability Reporting in the EU.” 2016.
https://www.globalreporting.org/information/policy/Pages/EUpolicy.aspx.
Accessed 2019-04-16

GRI. 2017. “GRI Standards.” Global Reporting Initiative, 1–25.
https://doi.org/10.1029/95GL01432.

IPCC. 2013. “Summary for Policymakers. In: Climate Change 2013: The Physical Science Basis. Contribution of Working Group I to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change.” CEUR Workshop Proceedings.
https://doi.org/10.1017/CBO9781107415324.004.

Mateo-Sagasta, Javier, Sara Marjani, Hugh Turral, and Jacob Burke. 2017. “Water Pollution from Agriculture: A Global Review.” FAO y IWMI, 35.
https://doi.org/http://www.fao.org/3/a-i7754e.pdf.

McWilliams, Abagail, and Donald Siegel. 2001. “Corporate Social Responsibility: A Theory of the Firm Perspective.” The Academy of Management Review, Vol. 26, No. 1. 117-127, doi: 10.2307/259398

McWilliams, Abagail; Donald S. Siegel, and Patrick M. Wright. 2007. “CSR: International Perspectives.” Working Papers in Economics, Department of Economics Rensselar Polytechnic Ins., no. 0704.

Merck. 2019. “Corporate Report 2018.”
https://www.merckgroup.com/content/dam/web/corporate/non-images/investors/reports-and-financials/earnings-materials/2018-q4/en/2018-Q4-Report-EN.pdf
Accessed 2019-04-15

MERCK. 2017. “Environmental Stewardship - Merck Corporate Responsibility Report 2016.” 2017. http://reports.merckgroup.com/2016/cr-report/environment/environmental-stewardship.html.
Accessed 2019-04-13

MERCK CRR, 2019. “General Disclosures - Merck Corporate Responsibility Report 2018.” 2019. https://www.merckgroup.com/en/cr-report/2018/facts-figures/gri-content-index/general-disclosures.html#gri-id13.
Accessed 2019-04-15

MERCK, Global. 2018. “Merck Global History.” MERCK HP. 2018. https://www.merckgroup.com/en/company/who-we-are/history.html.
Accessed 2019-04-15

Merck. 2017. “Environmental Stewardship Handbook.” October, no. February: 86–102. http://reports.merckgroup.com/2017/cr-report/servicepages/downloads/files/environment_merck_crr17.pdf.
Accessed 2019-04-16

Öhman, Marcus C, Johan Rockström, Jeffrey D Sachs, and Guido Schmidt-Traub. 2013. “Sustainable Development and Planetary Boundaries Draft for Discussion,” Sustainable Development and Planetary Boundaries BACKGROUND RESEARCH PAPER, Sustainable Development Solutions Network issue March 2013

Rägo, Lembit and Santoso, Budiono. 2010, “Drug Regulation: History, Present and Future.” https://www.who.int/medicines/publications/en/ https://www.who.int/medicines/technical_briefing/tbs/Drug_Regulation_History_Present_Future.pdf
Accessed 2019-13-06

Rodrik, Dani. 2003. “What Do We Learn From Country Narratives?” In Search of Prosperity. Analytic Narratives on Economic Growth. citeseerx.ist.psu.edu/viewdoc/summary?doi=10.1.1.353.8816
Accessed 2019-04-19

The European Chemical Industry Council AISBL, CEFIG. 2018. “Water Framework Directive - Cefic.Org.” 2018. https://cefic.org/policy-matters/health-safety-environment/water-framework-directive/.
Accessed 2019-05-2

The IIRC. 2013. “The International Integrated Reporting Framework.” The International <IR> Framework, 37.

Todorova, Dessilava. 2011. “Voluntary vs. Mandatory Sustainability Reporting, by Guest Author: Dessislava Todorova, CSR Bulgaria.” 2011. https://www.globalreporting.org/information/news-and-press-center/Pages/Voluntary-vs-mandatory-sustainability-reporting-.aspx.
Accessed 2019-04-5

UN General Assembly, UN. 1992. “REPORT OF THE UNITED NATIONS CONFERENCE ON ENVIRONMENT AND DEVELOPMENT.” 1992. https://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm.
Accessed 2019-05-16

UN Millennium Goals, UN. 2015. “Taking Stock of the Global Partnership for Development - Executive Summary,” 1–92. https://www.un.org/millenniumgoals/pdf/MDG_Gap_2015_E_web.pdf
Accessed 2019-05-05

UN SDGs, WHO. 2016. “WHO | Sustainable Development Goal 3: Health.” WHO. https://www.who.int/topics/sustainable-development-goals/targets/en/.<
Accessed 2019-04-04

UNESCO and HELCOM. 2017. Pharmaceuticals in the Aquatic Environment of the Baltic Sea Region. https://doi.org/10.1038/nature01065.
Accessed 2019-05-05

United Nations. 2013. “Intergenerational Solidarity and the Needs of Future Generations Report of the Secretary-General,” no. August.

http://sustainabledevelopment.un.org/content/documents/2006future.pdf.
Accessed 2019-04-03

United Nations Global Compact, UN. 2019. “The Ten Principles | UN Global Compact.” 2019. https://www.unglobalcompact.org/what-is-gc/mission/principles.
Accessed 2019-04-06

WHO. 2017. “70 Years of WHO Standards on Medicines Quality Expert.” WHO Drug Information 31 (1): 15–26.

World Health Organization, WHO. 2017. “Global Price Tags.” WHO.
https://www.who.int/choice/globalpricetags/en/.
Accessed 2019-04-06

List of Figures

ANNEX

Interview with EHS Manager Merck KGaA

Annex 1

Interview (shortened)

Q: In an international setting: is it possible to keep up with the standards established in the EU?

A: *Yes, this is possible if a strong EHS Corporate Culture is established with own company standards which enforcement is supported by the Management and which is regularly supervised by internal company audits.*

Q: Best practice examples and greatest success, is Merck a pioneer in an environmentally related topic?

A: *Waste Score which was developed for Merck and which obtain the Hessian Environmental Award in 2018 to track the waste consumption for the entire company.*

Q: How can environmental management be quantified in key figures, what is an environmental department or division worth in numbers?

A: *Quantification is possible via our environmental aspect evaluation which quantifies our environmental impact.*

Q: Which hazardous substances that potentially derive from pharmaceutical production are globally monitored?

A: *The major risk to the environment are our active pharmaceutical ingredients (APIs) which may be discharged to wastewater and which may be disposed into natural waterbodies if the wastewater treatment is not efficient.*

Q: What are the challenges in implementing the GRI, ISO 14001 etc.?

A: *The GRI is not known in production surrounding (mainly used by corporate structures); challenge on 14001 is to ensure continuous improvement in a restricted environment of a pharmaceutical production.*

Q: Does unified environmental reporting lead to a sustainable use of pharmaceutical products?

A: *No, as the environmental footprint of pharmaceutical products depends on restrictions from research and development, furthermore quality obligations are more important.*