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Haute école de gestion  
Genève

# **The Effectiveness of the Swiss and Canadian Antibiotic Distribution System Compared**

**Bachelor Project submitted for the degree of  
Bachelor of Science HES in International Business Management**

by

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# Executive Summary

The aim of research paper was to explore the current antibiotic distribution system in Switzerland, as well as all the important players of this complex industry. In order to better understand how this industry functions. It is important to get a big picture by understanding the implication of pharmaceutical companies, health insurance companies, hospitals, doctors, pharmacies and drugstores, and finally the role of the government and other higher instances. The pharmaceutical world is a highly regulated and complex environment and to better understand how the pharmaceutical industry functions, it was important to understand the regulations and guidelines to follow. Furthermore, Canada was use throughout this paper as a comparison. The aim was to understand the Canadian key players, how their system functions.

The global health care market was an estimated worth of more than US\$ 8'452 billion in 2018 and is dominated by few key players such as Novartis, Roche, Pfizer (Businesswire 2019; Mikulic 2020). These key players are responsible for medication supply throughout the world, including antibiotics. Antibiotics have revolutionized society, when discovered in the early 20s, by Alexander Fleming. They have since helped fight several deadly infections. Antibiotics were a great contribution to the medical world; however, bacteria have, over the years, started to show resistance to certain antibiotic treatment. Scientifics and medical professionals are raising alarm bells to tackle antimicrobial resistance (AMR).

The Swiss antibiotic distribution system is highly regulated and conducted in two different ways. One part of Switzerland dispenses antibiotics solely through doctors, the other part only through pharmacies, whereas 2 cantons are exceptions, and have a dual distribution system. Furthermore, an estimate 30 percent of total medication is wasted yearly in Switzerland (Tornare 2017). The Swiss health sector is seeing its prices and costs rise year over year and inefficiency arise. Politicians try to address the inefficiency problem, but their means are only limited.

This paper intends to give a clear overview of the complex Swiss health care system. It will also compare the Swiss health care system and its key stakeholders with Canada to understand what is done differently and where there could be improvements. A combination of primary and secondary data will be used to address the effectiveness of the Swiss and Canadian antibiotics distribution system.

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## Abbreviations

AMR	Antimicrobial resistance
AMU	Antimicrobial use
ANDS	Abbreviated New Drug Submission
BTC	Behind the counter
CARSS	Canadian Antimicrobial Resistance Surveillance System
DDD	Defined Daily Doses
DIN	Drug Identification Number
EMA	European Medicines Agency
EU	European Union
FDA	Food and Drug Act
FDHA	Federal Department of Home Affairs
FOPH	Federal Office of Public Health
GDK	Swiss Conference of cantonal Ministers of Public Health
NAPRA	National Association of Pharmacy Regulatory Authorities
NDS	New Drug Submission
NOC	Notice of Compliance
OECD	Organization for Economic Co-operation and Development
OFAS	Office fédéral des assurances sociales
OTC	Over-the-counter
SL	Speciality list
US	The United States of America
VIPS	Swiss trade association for pharmaceutical companies
WHO	World Health Organization

## Canton Abbreviations

AG	Aargau
AI	Appenzell Inner Rhoden
AR	Appenzell Outer Rhoden
BE	Berne
BL	Basle-Country
BS	Basle-City
FR	Fribourg
GE	Geneva
GL	Glaris
GR	Graubünden
JU	Jura
LU	Lucerne
NE	Neuchatel
NW	Nidwalden
OW	Obwalden
SG	St. Gallen
SH	Schaffhausen
SO	Solothurn
SZ	Schwyz
TG	Thurgau
TI	Ticino
UR	Uri
VD	Vaud
VS	Valais
ZG	Zug
ZH	Zurich

# 1 Introduction

This report is concentrating on antibiotics in pill format and exclusively for outpatient treatment. Other forms or dispensing methods will be shortly described to better understand the current setting. Furthermore, this report will mainly compare Canada and Switzerland, a short profile of both countries can be found in Table 1.

## 1.1 The History of Medicine

Up to the end of the Middle Ages, magic, beliefs and religions or spirits played a crucial role in healing humans (Hajar 2015). In the beginning, mostly herbs and plants were used to treat diseases, some of which are still used nowadays (Thomson, Richardson 2020). Ancient Egypt<sup>1</sup>, India and China were pioneers when it came to the use of herbs and plants to heal the human body. Ancient Egyptian doctors were the first ones to record 200 diseases (Hajar 2015). On the Asian continent, India is the mother of the ayurvedic practices, which are still very popular in today's society. Staying on the Asian continent, Chinese doctors have developed and practiced acupuncture for several millenniums (Thomson, Richardson 2020). Later in history, came the Greeks who used the ancestral practices from ancient Egypt as well as India or China (Goldiner 2012). Their time was marked with the "Father of Medicine" Hippocrates and his many critical observations and understanding of how the human body was healing (Goldiner 2012; Thomson, Richardson 2020; *Hippocrates - body* [no date]).

The medical world observed a significant setback and stagnation in the Middle Ages era, which can be explained by the fall of the Roman Empire<sup>2</sup> (Hajar 2015). This era was also highly dictated by the Roman Catholic Church and superstition, which had; as a result, the hunting of "witches" (Hajar 2012). During the Middle Ages, several devastating diseases like the plague<sup>3</sup> and leprosy killed millions of people throughout Europe (Goldiner 2012). Some historians also call the Middle Ages the "golden age of bacteria" (Benedictow 2005), which can mainly be explained by the surge in population density as well as the beginning of modernization in Europe including the increased boat traffic due to trading and discovering uncharted lands and territories (Benedictow 2005).

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<sup>1</sup> The ancient Egypt era lasted from 3100BC to 30BCE (Tyldesley 2015)

<sup>2</sup> The Roman empire fell in the fifth century CE (Wasson 2018)

<sup>3</sup> The Black plague was one of the deadliest pandemics ever known and vanished about 60 percent of Europe's population. It was believed to be the consequences of human sins and Gods punishment. Doctors at that time could just helplessly watch the people dying all over Europe and had no other cure available than prayers and Gods faith (Benedictow 2005).

The fastest evolution observed in the medical world happened in the 17<sup>th</sup> century and onward. Some events that considerably impacted the medical world include the first observation of bacteria in water by Antonie Van Leeuwenhoek in 1676 (BBC [no date]) or the discovery of vaccination during the 18<sup>th</sup> century which helped eradicate, amongst other things, smallpox.

The 19<sup>th</sup> century, as the two previous ones, came with numerous life changing discoveries such as the verification of the germ theory by Louis Pasteur, Joseph Lister and Robert Koch<sup>4</sup>, which later led to discover pasteurization (the Editors of Encyclopedia Britannica 2020; Thomson, Richardson 2020). This had lifechanging improvements, especially for the agricultural world (Thomson, Richardson 2020). Other notable discoveries include Koch's findings in the bacterial world, where he demonstrated what could be done with bacteria, ranging from isolating, cultivating and examining leading him to discover tuberculosis and cholera organisms (Thomson, Richardson 2020).

The dramatic growth in medical and health discoveries helped increase the quality of life by the 20<sup>th</sup> century. With Alexander Fleming accidentally discovering antibiotics, greatly contributed to the rise of life expectancy with sometimes adding more than 20 years in one's lifespan by the 1980s (Thomson, Richardson 2020).

It is clear that healing the human body has been a priority since the dawn of time. it is interesting to see the improvements the medical world achieved in the latest centuries, helping humanity eradicate deadly diseases as well as to render harmless certain diseases that used to be fatal.

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<sup>4</sup> The verification of the germ theory consisted in a series of experiments to prove that microorganisms were responsible for the souring of milk and fermentation of wine. (*History of medicine - Malignant disease* 2020)

## 1.2 The Global Pharmaceutical Industry

### 1.2.1 Canada and Switzerland Profiles

**Table 1 – Country Profiles**

	<b>Canada</b>	<b>Switzerland</b>
Founded or Independence Day	1 <sup>st</sup> July 1867 (independence)	1 <sup>st</sup> august 1291 (founded)
Population in 2020	37.7 million	8.6 million
Official languages	English, French	German, French, Italian, Romantsch
Government	Confederation with parliamentary democracy	Federal republic
Size	9.98 million sq km	41'285 sq km
Regions	13 provinces	26 cantons
Capital	Ottawa	Bern
Major cities	Toronto, Montréal, Vancouver	Zürich, Geneva
Legal system	Common law	Civil law legal system
Health care system	National health Insurance Model	Bismarck Model
Unemployment rate 2019	5.67 %	4,58 %
GDP per capita 2019	US\$ 46'195	US\$ 83'717
Total expenditure on health in 2014 in US\$	US\$ 4'641	US\$ 6'468
Total expenditure on health as % of GDP in 2014	10.4 %	11.7 %
Main industries	Transportation equipment, chemicals, processed and unprocessed minerals, food products; wood and paper products; fish products, petroleum and natural gas.	Machinery, chemicals, watchmaking, textiles, precision instruments.
Currency	Canadian Dollar (CAD)	Swiss franc (CHF)
Exchange rate to US \$ average over 5 past years	CA\$ 1 = US\$ 0.75	CHF 1 = US\$ 1.05

(One World Nations Online [no date]; Plecher 2020a; BBC News 2019; *Canada Population (2020) - Worldometer* [no date]; Canada 2017; *Legal System* [no date]; Duffin 2020; One World Nations Online [no date]; Plecher 2020b; 2020c; BBC News 2020; *Switzerland Population (2020) - Worldometer* [no date]; Bovey 2006; *WHO | Canada 2020*; *WHO | Switzerland 2020*)

### **1.2.2 Introduction**

Pharmaceutical companies play an essential role in today's society. They are in charge of researching and developing new medication, which they produce and sell through different channels in various countries around the world. In some cases, the exported medicine represents an important pillar in the trade balance for the countries where the pharmaceutical company is headquartered. The pharmaceutical industry has observed a continuous growth since the early 2000, due to an ever-expanding, but also ageing population (ReportLinker 2020). In 2019, more than US\$ 1'250 billion were spent worldwide on pharmaceutical products (*Pharmaceutical market worldwide 2019*, p. 2). The pharmaceutical industry has been in a challenging situation in the past years as it has to deal with a rapidly evolving, as well as a highly regulated environment (ReportLinker 2020).

Furthermore, pharmaceutical companies are under innovation and discovery pressure for developing new drugs in their R&D departments (Ambrosus 2018). An estimated 17 percent of pharmaceutical revenue is spent in R&D (Investopedia 2019). The industry sometimes also comes with frustrations regarding marketing new drugs. Finding a new molecule, that passes all the testing phases successfully is rare, the process can take several years, if not decades, and the amount invested in R&D is enormous in comparison to the small success rate (Investopedia 2019).

### **1.2.3 Global Pharmaceutical Market Overview and Market Leaders**

In 2018, the pharmaceutical industry was an estimated net worth of US\$ 1'055 billion, with two Swiss companies, Novartis and Roche, ranking in the top five (Flury, Geiger, Sandmeier, Wüthrich 2019, pp. 38–39). It is to be discussed which pharmaceutical company was leading the market in 2019 since several sources were found that showed varying rankings based on revenue. For this paragraph, the priority will be given to the data published on Statista. Based on this information, the five worldwide leading pharmaceutical companies in 2019, based on their revenue, were Roche, Novartis, Pfizer, Merck & Co, and Johnson & Johnson. Their individual revenue was at least US\$ 40 billion (Mikulic 2020).

As already mentioned before, R&D is the living stone of a pharmaceutical company, as discovering a new molecule that is later successfully introduced to the market will result in an important source of revenue. But before being able to enjoy the money inflow, several billion US\$ have to be spent by pharmaceutical companies until they can market a new drug (Investopedia 2019).

### **1.2.3.1 The Canadian Pharmaceutical Industry**

#### **1.2.3.1.1 The History of the Canadian Pharmaceutical Industry**

The first pharmaceutical company in Canada opened in 1879. Soon after followed the first subsidiary which was owned by a U.S. firm called Park, Davis and Company. The main reason, foreign-owned companies opened plants in Canada was to take advantage of the Canadian tariff law and to sell their products at a lower price than foreign-based competition. The Canadian tariff law was mainly introduced to protect domestic manufacturers (Lexchin 2015).

It is only in the 1940s that the Canadian industry went through an important transformation. Until then, most of the drug preparations happened directly in the drugstores, but with potent new drugs being rapidly manufactured and marketed, more and more pharmaceutical preparation started to be produced in the factories. By using a more advanced technology, enabled the pharmaceutical companies to maximize production for lower costs (Lexchin 2015). Concentrating production in a few dedicated locations also helped to reduce medication expenses significantly. This, however forced domestic companies of a smaller scale, to be bought out by more prominent foreign companies, as they could not keep up with the production rate (Lexchin 2015). Many Canadian-controlled generic drug companies emerged in the 70s and 80s, most of them owned by foreign companies.

The association created in 1914, now renamed, Canada's Research-Based Pharmaceutical Companies (Rx&D) regroups the interest of more than 50 brand-name companies, whereas most of them are subsidiaries of well-known multinationals. The other major association is called the Canadian Generic Pharmaceutical Association (CGPA) and is made up of ten companies, most of them being owned by foreign corporations (Lexchin 2015).

#### **1.2.3.1.2 The Canadian Pharmaceutical Industry in Numbers**

The pharmaceutical companies based in Canada regroup several activities, going from R&D to marketing to selling for branded and generic drugs. Today, most pharmaceutical companies active in Canada are foreign owned (Lexchin 2015). The manufacturing companies can be split in three different categories:

- Foreign multinational subsidiaries producing branded drugs
- Generic companies producing drugs ineligible for patent
- Small biotechnology companies mostly concentrating on early-stage R&D with only a small number of marketed products.

(Lexchin 2015)

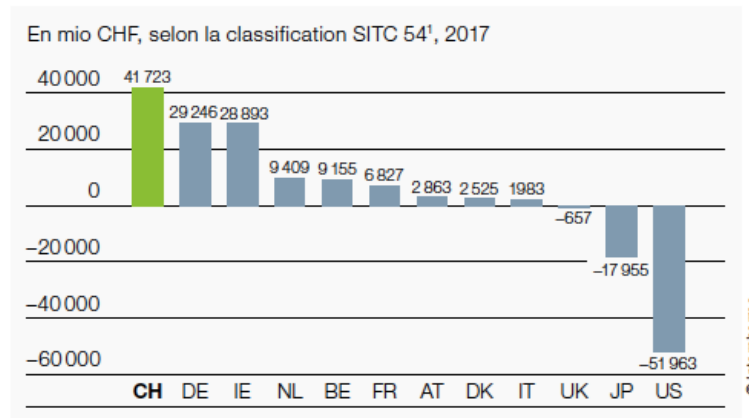
In 2013, the Canadian prescription pharmaceutical market was estimated at CA\$ 29 billion. In the same year, 574 million prescriptions were recorded, roughly 66 percent of which are for generic drugs. However, in terms of spending, it only accounted for 24 percent, since generics are less expensive than branded medication (Lexchin 2015). The only Canadian owned company is Apotex with sales around CA\$ 1.2 billion, whereas the Canadian market leader Johnson & Johnson accounts sales for more than CA\$ 1.75 billion (Lexchin 2015). The pharmaceutical sector has observed a decrease in employment by seeing it drop from about 30'000 in 2006 to 26'950 in 2013. From a geographical point of view, most of the Canadian pharmaceutical industry concentrates on the east part of Canada in Toronto and Montréal (Lexchin 2015).

### **1.2.3.2 The Swiss Pharmaceutical Industry**

The Swiss Pharmaceutical market is a key pillar of the Swiss economy and keeps growing over the years. With the introduction of new medicine amongst others for cancer and multiple sclerosis, enabled a steady development (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 38). Pharmaceutical products are the most important exports for the Swiss economy, with their primary destination being Europe. It is interesting to observe, that between 2017 and 2018, total exports went from CHF 84 billion to 88.4 billion, however, in terms of export volume, the numbers went down from 38 percent to 29 percent. This means that the total exports for Switzerland, in terms of volume, were more important than the total amount (Flury, Geiger, Sandmeier, Wüthrich 2019, p. 40; Enderli, Käch, Sandmeier, Wüthrich 2018, p. 62). Switzerland being the absolute leader in pharmaceutical exports, the country is highly competitive in the pharmaceutical industry and is the homeland of pharmaceutical multinationals like Novartis and Roche, which highly contributes to Switzerland's leading position on a global scale.



**Figure 1 – Switzerland’s Exports in CHF**



Source: UN Comtrade Database, 2019 (conversion en CHF par Interpharma).

<sup>1</sup> La Standard International Trade Classification (SITC) est une classification statistique utilisée pour classer les marchandises pour les statistiques du commerce extérieur.

Source: (Flury, Geiger, Sandmeier, Wüthrich 2019, p. 45)

The graph above shows the trade surplus for Switzerland compared to the other countries. This means that Switzerland exports more medication than it has to import. The US, on the other hand, have a significant trade deficit as they have to import a substantial amount of medicine compared to what they export. The pharmaceutical industry exports account for at least one-third of Switzerland’s total exports (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 72). Not only is Switzerland a major producer and exporter of pharmaceutical products, but it is also an important employer. Directly employing about 45’500 people in 2016, it also contributed to more than 180’000 indirect jobs in Switzerland (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 66).

Switzerland is also a major R&D hub, where CHF 6.8 billion were invested in 2017, mainly by companies headquartered in Switzerland like Roche and Novartis (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 68). Out of these investments, 63 percent were made by private industries, and only 24 percent were made by the public sector including federal government and cantons (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 78). Furthermore, Switzerland is a worldwide leader in innovation but has recently slightly fallen behind with clinical research. The Federal Council has decided to boost Switzerland’s competitiveness by approving a master plan destined for biomedical research and technology (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 74). Switzerland also enjoys a high reputation amongst its peer countries when it comes to scientific publications and is often cited and regarded as high-value content.

### **1.2.3.3 Branded Medication**

#### **1.2.3.3.1 Introduction**

Branded medicine is the original drug produced by the developing pharmaceutical company. If the pharmaceutical company wants the sole right to produce that drug, it will apply for a patent<sup>5</sup> (HealthEngine 2009). Once that patent granted, the pharmaceutical company will be the only one allowed to sell that drug for the next 20 years (DrugPatentWatch 2018). Patents are a way for the pharmaceutical company to recover some of its expenses spent during the previous steps of marketing the drug. Since pharmaceutical companies make about 80 percent of their revenue through patented medication, they often try to extend their patent for a few more years in order to keep the exclusivity (DrugPatentWatch 2018).

#### **1.2.3.3.2 Branded Medication in Canada**

Branded medication price in Canada is almost six times higher than generic medication, with an average branded medicines price of CA\$ 110 compared to less than CA\$ 20 in 2019. This shows how profitable branded medication is for pharmaceutical companies compared to generic ones. Whereas the price for generic medicines was relatively stable around CA\$ 20 since 2004, the branded medication market has seen a substantial change with an average price increase of about CA\$ 50 per medication since 2004 (Mikulic 2020).

#### **1.2.3.3.3 Branded Medication in Switzerland**

Making researches for this topic turned out very difficult and no usable information could be found. However, when analyzing the document «Le marché du médicament en Suisse» published by the interpharma, a calculation was possible. The total amount of reimbursed medicine in 2018 was of CHF 5'037.3 million and the amount of generic medication being reimbursed in the same year was of CHF 720 million. By subtracting the generic amount to the total amount resulted in a total of CHF 4'317.7 million for branded medication (Flury, Geiger, Sandmeier, Wüthrich 2019, p. 25,28).

### **1.2.3.4 Generic Medication**

#### **1.2.3.4.1 Introduction**

Generics have become an integral part of today's society to a point where many people don't make a difference or notice when they take generic drugs. It is very common that when going to a pharmacy to retrieve some medication, the pharmacist informs the

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<sup>5</sup> According to IGE, a patent is an intellectual property for an invention. In order to obtain a patent, basic information have to be disclosed. Patent have to be applied in each country, where there is intention to sell the product. (Swiss Federal Institute of Intellectual Property [no date]).

patient that there is a generic available. The difference between the two offered medication is often the price, whereas generics are usually cheaper.

A generic drug has the same active substance as the original version; however, the inactive substances may vary. Their shape and color may vary as the pills may not be produced by the same company. Generic medication will be produced and introduced to the market only once the patent, explained in the previous section, has expired (HealthEngine 2009). Sometimes original medications have their patent expired, however, there is no generic available as the price is already considered to be low. Going through the whole process of developing an equivalent generic would not be profitable from an economic standpoint. (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 42).

Sandoz for example, a now leading generic medication company and part of Novartis, was initially founded back in the 1880s as a chemical laboratory. In 1997 the firm merged with CIBA and was renamed Novartis. Even after the merge, Sandoz kept its activities as a subsidiary of Novartis. Several years later, Novartis made the strategic decision to concentrate its generic medication production under Sandoz (Sandoz 2017). By doing so, the company not only ensures revenues from its patented medicines but also once the patent is expired.

#### **1.2.3.4.2 Generic Medication in Canada**

The medication market in Canada is mostly dominated by generics, accounting for more than 75 percent of medication sales in 2019. This high percentage ranks Canada third according to the Organization for Economic Co-operation and Development (OECD), right behind the US and Germany. Looking at an individual's spending on generic drugs, the average Canadian household spent CA\$ 164 in 2018 (PMPRB 2019, p. ii). There are almost 1'700 different generics available on the Canadian market accounting for CA\$ 1'225 million in sales (PMPRB 2019, p. 3). The overall generic retail spending, however, is a few billion CA\$ heavy, with about CA\$ 5.4 billion in 2018 (PMPRB 2019, p. 5). With generic retail spending of CA\$ 3 billion back in 2006, the generic market observed a huge increase of more than 80 percent. One of the reasons for this massive surge is the generic pricing policy<sup>6</sup> introduced in 2010, which led to a price drop for generic medication. This resulted in a price drop of almost 60 percent in the last decade (PMPRB 2019, p. i,11). Other reasons for such high generic use in Canada will be further discussed in the analysis part of this report.

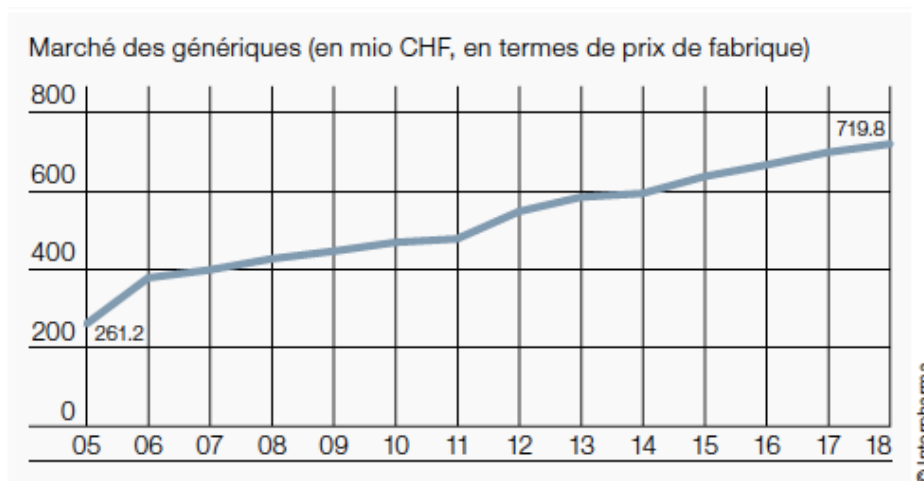
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<sup>6</sup> The generic pricing policy was set in place by the pan-Canadian Pharmaceutical Alliance (pCPA) and the Canadian Generic Pharmaceutical Association with the goal to reduce generic prices as low as ten percent of the price of the brand-equivalent (Patented Medicine Prices Review Board 2019).

#### 1.2.3.4.3 Generic Medication in Switzerland

The generic market in Switzerland has been flourishing since 2005 with twice as much sales in 2017. Back in 2005, the generic market only represented slightly more than CHF 260 million (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 42). The graph below shows the steady growth of the Swiss Generic market since 2005. It is interesting to see that the generic market more than tripled its size in 15 years. This can be explained by the fact that several patents expired in the last 15 years which resulted in 189 new active substances being accessible for the generic market (Flury, Geiger, Sandmeier, Wüthrich 2019, p. 30). This important increase in the generic market is also due to the introduction of a higher “quote-part” which will be addressed in the section about health insurance (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 42).

**Figure 2 – The Evolution of the Swiss Generic Market in CHF, 2005-2018**



Source: Interpharma sur la base des données d'IQVIA Suisse, 2019.

Source: (Flury, Geiger, Sandmeier, Wüthrich 2019, p. 29)

A recent article stated that overall medication in Switzerland is still very expensive, however the price gap with the compared countries<sup>7</sup> have slightly went down since the previous year, bringing the branded drug price gap down, from an average seven percent to less than five percent more expensive. A surprisingly high percentage was observed for the Swiss generic market compared to the other countries, where the price gap is more than 40 percent (Keystone-SDA/jdp 2020). This could be explained by the fact that pharmaceutical companies producing generic drugs might not be regulation in the price setting.

<sup>7</sup> The price gap observed was in comparison to data in Germany, Austria, Belgium, Denmark, Finland, France, Great Britain, the Netherlands and Sweden (Keystone-SDA/jdp 2020).

#### **1.2.3.4.4 A Comparison of the Two Markets**

Now that both markets have been introduced individually, it could be interesting to have them compared. It is safe to say that both countries observed a continuous growth in their generic market over the past few years. Since the Generics360 Report from the Patented Medicine Prices Review Board has used several graphs and figures, enabling a direct analogy based on OECD data, the following comparison will be based on them. While Canada ranks third when looking at the percentage of generic drugs in shares of units with 78 percent, Switzerland is way behind with only 48 percent, ranking on place 26 a few ranks behind the OECD median which is at 56 percent. However, if the share of sale is compared, Switzerland and Canada both have similar results, being 21 and 25 percent respectively (PMPRB 2019, p. 8). This interesting variation can be explained by the fact that Swiss generic medication prices are twice as high as the Canadian ones when taking Canadian prices as reference price (PMPRB 2019, p. 17).

### **1.2.4 Pharmacies**

#### **1.2.4.1.1 Definition**

According to the article written by Hartley and Krantz, Pharmacy can be defined as

*“the science and art concerned with the preparation and standardization of drugs. Its scope includes the cultivation of plants that are used as drugs, the synthesis of chemical compounds of medicinal value, and the analysis of medicinal agents. Pharmacists are responsible for the preparation of the dosage forms of drugs, such as tablets, capsules, and sterile solutions for injection.” (Hartley, Kratz 2017).*

#### **1.2.4.1.2 History**

The oldest records of basic pharmaceutical practices seems to date from the 28<sup>th</sup> century BC in China (Dailey 2018). Ancient Egyptian and ancient Greek doctors used to practice leaf juice extraction to apply to their patients' wounds. They also used to separate their “healers” in two groups, one group was visiting the patients and the healers who were not visiting, remained in the temple to prepare the medicine. The basic ingredients used for their medicine preparation were mostly plants and animals. Over the centuries, it evolved to some more sophisticated methods but still very basic, and many deaths had to be accounted for, due to the lack of knowledge at that time (Hartley, Kratz 2017).

It is only in the 19<sup>th</sup> century that the pharmaceutical industry underwent a major progress with several-life changing discoveries (Hartley, Kratz 2017). A significant achievement was the extraction and isolation of some components during the process, which allowed scientists and physicians to make considerable discoveries. For example, morphine was isolated from opium early 19<sup>th</sup> century; the same success was observed in 1860 where

cocaine was extracted from coca leaves. Firstly, this process enabled to control better the amount of drug administered to the patient. Secondly, it allowed to have a cleaner basis free of impurities and lastly, having pure drug isolation, enabled laboratories to find synthesis as a basis for other drugs (Dailey 2018).

Regarding pill administration, up to the 17<sup>th</sup> century, pills were only administered orally and its only mid 17<sup>th</sup> century that Richard Lower and Christopher Wren proved that drugs could also be administered through the veins directly into the bloodstream (Dailey 2018). It took a whole century until the hollow hypodermic needle was invented by the French surgeon Charles Gabriel Pravaz. Several other milestones were achieved throughout the 19<sup>th</sup> century, some of which were later replaced with less toxic alternatives (Dailey 2018). The pharmaceutical industry, with medicine manufacturing, only started in the late 19<sup>th</sup> and early 20<sup>th</sup> century. Universities encouraged their faculties to invest more time and resources in the pharmaceutical domain. A shift in the way pharmacists and physicians were trained was observed, as more and more opted for more academic education. However, the apprenticeship remained an important component in pharmaceutical education (Dailey 2018). Throughout the 20<sup>th</sup> century, governments and other public institutions started to provide their support to universities to encourage research (Dailey 2018).

#### **1.2.4.2 Pharmacies and Drugstores and their Revenues in Canada**

In Canada, pharmacies and drugstores do not have the same meaning as in Switzerland, for example. In Canada, prescription drugs are dispensed in drugstores in their dedicated pharmacy section (Andrews 2018). The remaining parts of the drugstore sell over the counter drugs (OTC) <sup>8</sup>, similar products to a convenience store, as well as beauty products and perfumes (*Health, Beauty, Pharmacy, and Convenience | Shoppers Drug Mart®* [no date]). In 2016, the largest Canadian retail pharmacy chain was Shoppers Drug Mart, with more than 1'300 stores throughout Canada (Bedford 2019). Based on that, it is difficult to individually analyze pharmacies and drugstores since they are nested into each other. This is why both have been regrouped and explained in the same section. In 2019, there were more than 8'000 pharmacies and drugstores recorded in Canada. The Province of Ontario alone accounted for more than 4'000 drugstores and pharmacies (Bedford 2019).

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<sup>8</sup> According to Disabled World, over the counter drugs are medication that do not need any prescription from a doctor (Disabled World 2017).

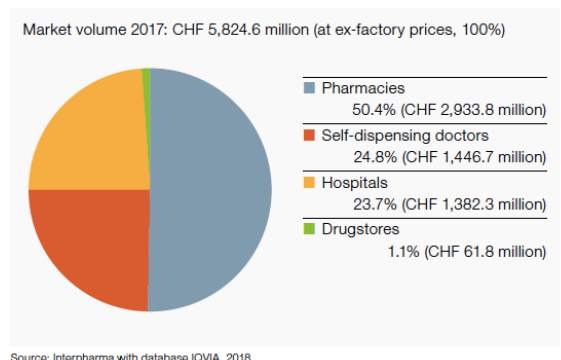
### 1.2.4.3 Pharmacies and their Revenues in Switzerland

Pharmacies in Switzerland have a high-frequency rate, with more than 94 million yearly visits by the Swiss population (pharmaSuisse 2019, p. 13). This is due to the fact that many insignificant illnesses are viral and do not need any prescribed medicine (Wechsler 2016). Since today's society is in a constant rush, quickly stopping at a pharmacy on the way home is much less time consuming and a less expensive detour than a visit to the doctor. However, if the illness or health problem appears to be more serious, and the pharmacist judges that a medical appointment is necessary, they will redirect the patient to its consulting doctor to have a correct and safe diagnosis with more accurate treatment.

There are several distribution channels in Switzerland when it comes to medication. Pharmacies, drugstores, hospitals and in some cantons, doctors dispense medicines from their inhouse pharmacy (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 38). There is a difference to be made between a pharmacy and a drugstore in Switzerland. Pharmacies are allowed to dispense, in addition to OTCs, prescription-only drugs, whereas drugstores are only allowed to sell so-called "over-the-counter drugs"(Enderli, Käch, Sandmeier, Wüthrich 2018, p. 38).

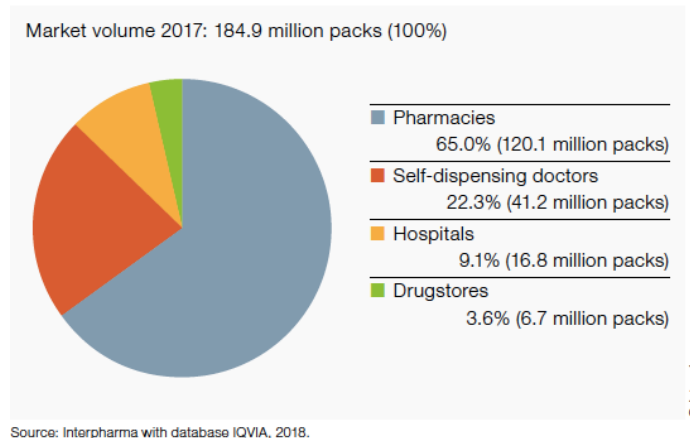
When comparing the market by its value or by its volume, it is interesting to observe that either way, pharmacies have the most important shares and accounting for more than 50 percent. The percentage for the self-dispensing doctors remains almost the same in both views with around slightly less than 25 percent. Self-dispensing doctors are not current throughout Switzerland but only in some cantons. This explains the variation in density of pharmacies in the different cantons of Switzerland. However, pharmacies do remain, with 1'800 active pharmacies Swiss-wide, the most important drug dispensers (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 44).

**Figure 3 – Switzerland's Market Volume in CHF – 2017**



Source: (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 39)

**Figure 4 – Switzerland’s Market Volume in Sold Packs – 2017**



Source: (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 39)

To ensure highest quality standards when dispensing medication, an ISO norm has been introduced which certifies that pharmacies work by following some health and safety standards. This ISO 9001QMS-Pharma will be further discussed in section 2.5.2, which addresses in more details the laws and regulations.

#### **1.2.4.4 Swiss Medication Dispensation Categorization**

Swissmedic and the Swiss Agency for Therapeutic Products<sup>9</sup> established five medication dispensation categories. Category A and B are for prescription-only medication, whereas category C and D are for behind the counter medication (BTC)<sup>10</sup> and E is for OTC medication. Category A medicine will be for single dispensation by a pharmacist, and category B will be for medication to be renewed, when needed. Category C medication can only be dispensed after consulting a pharmacist, whereas category D medication can also be dispensed by a drugstore employee. Finally, Category E medication does not need any medical advice and are most of the time publicly accessible on the shelves in the stores (*Abgabekategorien von Arzneimitteln* [no date]).

<sup>9</sup> Schweizerisches Heilmittelinstitut

<sup>10</sup> Behind the counter drugs do need approval from a pharmacist compared to OTC (Disabled World 2017)



## **1.2.5 Drugstores**

### **1.2.5.1 Introduction**

The definition of a drugstore will vary amongst countries. As already briefly explained in section 1.2.4.2, drugstores include a pharmacy section inside their stores in Canada (Andrews 2018). However, in Switzerland, pharmacies and drugstores do not have the same function. Pharmacies in Switzerland are allowed to hand out prescription-only drugs, BTCs, OTCs, and other health and nutrition products, whereas drugstores are only allowed to sell BTC's, OTC's as well as health and nutrition products (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 38). Based on this information and the grouping of pharmacies and drugstores for Canada in section 1.2.4.2, the further sections will only look at the Swiss Drugstore industry.

### **1.2.5.2 Revenues in Switzerland**

Switzerland has seen its number of drugstores significantly reduced over the past 15 years. In 2001, there were slightly less than 700 drugstores in Switzerland, whereas, in 2016, only half as many were still in business.

The drugstore market does not contribute very significantly to the Swiss prescription market revenue as drugstores don't sell prescription-only" drugs. In 2017, drugstores still represented about 1.1 percent of total market volume by value, whereas in 2018, their share fell down to 0.1 percent (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 39; Flury, Geiger, Sandmeier, Wüthrich 2019, p. 21). This is mainly due to the fact that drugstores are not allowed to sell prescription-only drugs, as mentioned in the previous paragraph. Their contribution to the drug market is therefore almost insignificant<sup>11</sup>. However, drugstores do sell a variety of other products and generated in 2016 a revenue of CHF 778.1 million (Statista 2019, p. 11).

It is interesting to observe that even if the number of drugstores was divided by two since the early 2000s, their revenue did not drop as significantly. Indeed, the income in the past years has been lower than in the early 2000s, however, the drop was only ten percent. The industry registered a peak year in 2003 with slightly more than CHF 900 million in revenue for Swiss drugstores, which has only been declining ever since (Statista 2019, p. 11).

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<sup>11</sup> Since drugstores are not allowed to sell any prescription drugs, their percentage can be explained by the selling of OTC drugs prescribed by doctors.

## 1.2.6 Doctors

### 1.2.6.1 Doctors in Canada

Primary care doctors have a key role in Canada's healthcare system; as most of the time, doctors are the first touchpoint for patients (IbisWorld [no date]). As it will be explained more in detail later in this report, primary healthcare is free in Canada. To receive prescription drugs, the patient will have to visit a doctor. It seems that depending on the province, some doctors are allowed to dispense prescription drugs themselves, as long as they follow the same regulations as a pharmacist. It is the case for British Columbia and Ontario for example (CPSO 2010; College of Pharmacists of British Columbia [no date]). In 2018, at least 75 percent of the Canadian population went to see a doctor, whereas slightly less than 50 percent had at least two visits (Elflein 2018).

### 1.2.6.2 Doctors in Switzerland

Swiss doctors do not all work in the same way; it depends in which canton there are practicing. Indeed, some cantons allow their doctors to have their little pharmacy from where they can dispense prescription-only medication directly to their patients. These practices are exclusively done in 15<sup>12</sup> German-speaking cantons. Dispensation solely through pharmacies is practiced in nine<sup>13</sup> cantons, mostly French speaking. Finally the last two<sup>14</sup> cantons on the list apply a so-called "mixed form" where they are allowed to "self-dispense" in certain conditions (pharmaSuisse 2019, p. 84). This mixed form is meant to enable "countryside doctors" to hand out prescription-only medicine directly to their patients, whereas "city doctors" will send their patients to retrieve their medication in pharmacies. This is to cope with the relatively important size of these two cantons and to ensure a balance of available doctors throughout the whole canton. This mixed form of dispensation, for such large cantons, is necessary in order to avoid having "countryside doctors" leaving the countryside for higher wages in the city, which would result in a doctor shortage in the countryside (Wechsler 2016).

Visiting a doctor can often be time-consuming, expensive and depending on the urgency of the problem, the waiting time until the appointment can be long. This can explain why Swiss citizens only visit their doctors in average about four times a year, but pharmacies do have a much higher visit rate with an yearly average of 12.2 visits per Swiss citizen (pharmaSuisse 2019, p. 13).

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<sup>12</sup> The 15 cantons are AI,AR,BL,GL,LU,NW,OW,SG,SH,SO,SZ,TG,UR,ZG,ZH

<sup>13</sup> The 9 cantons are AG,BS,FR,GE,JU,NE,TI,VD,VS

<sup>14</sup> The two cantons are BE,GR

Comparing both countries, Canada counted an average of 241 physicians per 100'000 population in 2018, whereas Switzerland only had 43 physicians per 100'000 population in 2016 (Statista 2020; pharmaSuisse 2019, p. 13). This significant difference could be explained by Canada's population being four times higher than the Swiss one (*Canada Population (2020) - Worldometer* [no date]; *Switzerland Population (2020) - Worldometer* [no date]).

### **1.2.6.3 Associated Challenges**

Doctors have a critical role in the healthcare industry, as they are at the intersection of such a complex environment between the patient, his health insurance and pharmacies. A doctor will have the role to diagnose the patient correctly and to prescribe the necessary treatment. Based on what a doctor decides and prescribes, a patient will be reimbursed or not. Most of the time, when someone is ill, they want to feel better as fast as possible. This can cause a lot of pressure and tension for the doctors, especially from the patient's side if they believe they need a specific treatment. Also, doctors might feel pressured into prescribing specific medication to satisfy a patient and avoid them changing their health practitioner because they did not receive the wanted treatment. This inappropriate drug prescription is often the case for antibiotics since patients are not well informed on when it is appropriate to use antibiotics and when it is not, which can result in antimicrobial resistance (AMR) in the long run. (Dall 2017; Gorman, Gorman 2018)

### **1.2.7 Hospitals**

Hospitals play an important role in the delivery of healthcare throughout the world. Their activities range from simple interventions to very complex and time-consuming surgeries. They also differentiate in- and outpatient care, meaning that inpatients are staying overnight when outpatients are not. As they never stop operating, they are essential in case of emergencies and disasters. Hospitals can be public or private, and some are called university hospitals, which includes medical student training. Hospitals are allowed to administer all kind of medication since the physician and nurses working in hospitals have to deal with more severe diseases, illnesses and accidents that require immediate care.

### **1.2.7.1 Hospitals in Canada**

A total of 962 hospitals were operating in 2019 in Canada, with roughly 73'000 beds in 2013<sup>15</sup> (Sutherland, Crump 2013). Health expenses for Canadian hospitals amounted to CA\$ 70'335 million in 2018 (Statista 2020, p. 18). It seems that only little research is done for the hospital sector in Canada, as only few information was found on this subject.

### **1.2.7.2 Hospitals in Switzerland**

Switzerland counted 281 hospitals with a total of 38'051 beds in 2018 (Girardin 2020, pp. 6–7). Outpatient treatment in 2017 accounted for 35 percent (CHF 29 billion). Swiss hospitals consumed for over CHF 1,382 million in medication in 2017 (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 39).

## **1.3 Health System Market and Health Insurance Systems**

### **1.3.1 Introduction**

Health system and health insurance systems are relatively new to the population as it was first introduced in Germany in the 19<sup>th</sup> century. When talking about health care, there are four basic models from which countries have derived their own system, if they have one. The first one is called the Beveridge model consisting of exclusive funding through taxes for the healthcare expenses, the second one, the Bismarck model, which uses an insurance system which is called “sickness funds”<sup>16</sup>. The next one is the national health insurance model, which is a mix of the two previous explained models where health providers are private but funded by the government. The last model is the out-of-pocket, which means no coverage for the population. The last model can be mostly found in developing and third world countries as the government does not have the necessary resources to implement a health care system. Having access to one of the three first health care models just explained, is a clear privilege in today's society, as health expenses can be costly (PNHP [no date]).

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<sup>15</sup> After visiting various sources; a more recent and accurate number could not be found.

<sup>16</sup> John E. Murray defines sickness funds as “[...] an early form of health insurance. They were financial institutions that extended cash payments and, in some cases, medical benefits to members who became unable to work due to sickness or injury.”

## 1.3.2 Canada

### 1.3.2.1 Medicare History

The universal health care plan was first introduced in Saskatchewan in the early 60s during the agrarian socialist<sup>17</sup> movement. They had already introduced the provincial universal public hospital insurance plan in 1947. This would be gradually accepted and introduced by other provinces in the following years. The new system (called Medicare) faced a high resistance from medical professionals, the insurance companies, as well as the population, who were afraid of being forced into socialized medicine<sup>18</sup>.

The Medical Care Act was passed on government level in 1966, which offered to: *“reimburse, or cost share, one-half of provincial and territorial costs for medical services provided by a doctor outside hospitals (Canada 2011).* Only six years later, all other provinces had adopted the new health care plan. The Canadian Health Act (federal legislation) was passed in 1984, and some reforms took place since.

Overview of the five principles the Canada Health Act is providing for

- a. Public administration
- b. Comprehensiveness
- c. Universality
- d. Accessibility
- e. Portability

### 1.3.2.2 Key Players

There are several key players contributing to the well-functioning of the Canadian health system. They consist of the federal government and the provincial and territorial governments. All three of them have their responsibility to ensure that the health of Canadians is ensured (Canada 2011).

#### 1.3.2.2.1 Role of the Federal Government

The federal government’s main goal with this new health care system was to provide *“universal coverage for medically necessary health care services provided on the basis of need, rather than the ability to pay” (Canada 2011)* to all Canadian citizens and

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<sup>17</sup> Agrarian socialism can be defined “[...] as an economic and political movement which seeks to combine an agrarian way of life with socialist economic policies. As opposed to standard socialist/communist doctrine, agrarian socialism is primarily a rural and local movement instead of an industrial and international one.” (Agrarian socialism [no date])

<sup>18</sup> Socialized medicine was defined by Shiel as *“A medical system like that of a socialist country, in which medical facilities and payments are under government, rather than private, control.” (Shiel 2018)*

Canadian permanent residents. Canada is divided between the provincial and territorial as well as federal government based on the Canadian Constitution, where the federal government is responsible for supporting financially provincial and territorial governments. Another of the federal government's duty is to deliver health and social services for specific people, such as First Nations, Innuits, veterans and other population groups with special needs. The role of the federal government here is to give medical care access to these specific groups of people where territorial and provincial infrastructures are missing.

Health care is funded publicly through private and corporate taxes throughout the provinces and territories. Several criteria are set in the Canada Health Act, which have to be met by the provinces and territories, in order to get the financial support from the government to cover their health costs. They also have to ensure the availability of doctors and hospitals throughout their provinces or territories.

#### **1.3.2.2.2 Role of the Provincial and Territorial Governments**

The provincial and territorial government are the bodies responsible for ensuring that medical care is available to its citizens. They are also in charge of verifying that the principles in the Canada Health Act are followed in order to receive the needed funds from the federal government. Since the medically necessary services are not explicitly written down in the Canadian Health Act, it is the role of the provinces and territories, in consultation with their medical corps, to define what their provincial citizens need. Supplementary health services such as dental care or prescription drugs, are not covered by the Canada Health Act and therefore are often complemented by private insurance companies.

#### **1.3.2.2.3 Beneficiaries**

Medicare<sup>19</sup> being based on a national health insurance model; every citizen is contributing indirectly to the system. This means that automatically, every Canadian citizen and resident has access to basic health care, without receiving medical bills home (PNHP [no date]).

#### **1.3.2.2.4 Structure**

Medicare is a combination of ten provincial as well as three territorial health systems which are all publicly funded. An extensive range of health services are delivered in different steps, which will be described right under (Canada 2011).

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<sup>19</sup> The term Medicare will be used when referring to the Canadian health care system

*Level 1:*

The first level has a double function: Directly providing first-contact health care services and to coordinating between institutions to ensure a continuous care service for patients dealing with doctors specialized in a specific field or function.

The first level health care includes:

- Prevention & treatment of common diseases & injuries
- Basic emergency services
- Referrals to coordinate with other level of care
- Primary mental health care
- Rehabilitation services
- Healthy child development
- Palliative & end-of-life care
- Health promotion
- Primary maternity care

(Canada 2011)

*Level 2:*

This level of care is mostly oriented into delivering special care and includes:

- Hospitals
- Long-term care facilities
- Community
- Home care
- institutions

(Canada 2011)

At this point, the aim is more focused on chronic or more specialized treatments which cannot always be found at the first level.

*Supplementary services:*

Since Medicare does not cover all health expenses, some supplementary services include:

- Prescription drugs outside hospitals
- Optical care
- Dental care
- Medical equipment like wheelchairs
- Other health professionals like physiotherapy

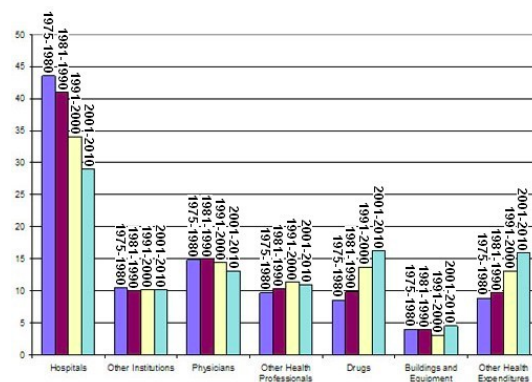
(Canada 2011)

Additional or supplementary services are either covered by the provinces and territories for seniors, children and low-income residents, or by private health insurance companies, that have to be taken out individually. Residents with neither of the two previous options, have to pay supplementary treatments and appliances out of their pocket (Canada 2011). Since almost all antibiotics are prescription-only, they fall under the supplementary services and therefore are not covered by the basic Canadian health plan but can be covered by additional private insurance coverage (Canada 2016).

### 1.3.2.2.5 Health Expenditures

Since every province and territory has a different size, population, demography, and Medicare services, they also receive different subsidy amounts from the government. The table below demonstrates the national health spending according to its sectors and shows the majority of expenses are for the hospital sector followed by medication and in third place by physicians. While hospital expenditures have drastically decreased over the last decades, it is the opposite for drug spending, which have steadily increased since 1975 (Canada 2011).

**Figure 5 – Total Health Expenditures by use of Funds, Annual Average, 1975-2010**



Source: Canadian Institute for Health Information. *National Health Expenditure Trends, 1975 - 2010*.

Source: (Canada 2011)

### 1.3.2.2.6 Economic Approach

In 2019, Canada's expenses for prescription drugs accounted for roughly CA\$ 34.3 billion compared to only CA\$ 5.9 billion for non-prescribed drugs (Mikulic 2019a). Canada's health expenditures have significantly grown over the past years, with drug expenses becoming the second-highest health care system expense, representing 14 percent of total healthcare spending (Health Canada 2004; Brandt, Shearer, Morgan 2018, p. 4).



This increase can be explained by two key drivers:

1. Increase in overall use of prescription drugs
2. Use of newer and more costly prescription drugs

On the OECD<sup>20</sup> scale, Canada's drug prices are ranked third, which equals to prices being one-fourth more expensive than the OECD median (Health Canada 2004). Canada's government and responsible agencies are actively working on reducing prescription drugs prices as well as lowering the generic drug prices. They also work on the patented drugs regulations prescriptions to protect their consumers from higher prices related to the patented drugs (Health Canada 2004). The Canadian Institute for Health Information states, in its 2019 published report, that "*Public drug program spending accounts for 41.8 percent of prescribed drug spending in Canada.*" (CIHI 2018, p. 5). This percentage, however, excludes drugs dispensed by hospitals or by cancer agencies and special programs (CIHI 2018, p. 5). 35 percent are taken over by private insurance plans, and the remaining 23 percent will be out-of-pocket<sup>21</sup> (Brandt, Shearer, Morgan 2018, p. 4). An increase of 4.6 percent was observed in 2017 for the public drug program spending, and every fourth Canadian citizen benefited from a public drug program (CIHI 2018, p. 5)

### **1.3.2.3 Strength and Pain Points**

The Canadian Medicare has proven to be effective as it is still in use today. One of its strength is to offer basic healthcare to all its citizens without addition costs, as long as it stays within basic healthcare services. Not including prescription drugs in its basic health care service could be seen as a pain point as it might keep Canadian citizens from taking prescribed medication as they might have to pay them.

### **1.3.3 Switzerland**

Switzerland enjoys positive and high reputation on many levels, including the excellent healthcare system in place. The living costs are amongst the highest worldwide, but this also comes with an above-average quality of life as well as a high ranking on the happiness index (Töre 2020).

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<sup>20</sup> Organization for Economic Co-operation and Development

<sup>21</sup> At the patient's own charge

### 1.3.3.1 History

Switzerland first started talking about a health system during the second half of the 19<sup>th</sup> century, which was also when the industrial revolution was happening. During this time, there were more than 600 health insurance companies active in Switzerland, with only counting a few hundred members each. According to the website “histoire de la sécurité social en suisse”, *“in 1880, [...] less than five percent of the total population was insured even though this proportion could go up to one quarter of the population in more industrialized regions like the cantons of Glarus, Zürich or Basel city.”* (OFAS 2013 Personal translation). In the beginning, the health insurance companies were insuring very specific groups of persons or specific regions and changing insurance company was very hard to almost impossible. The insured were mostly men, since most women were housewives at that time (OFAS 2013 Personal translation). Over the years, several insurance companies decided to regroup, in order to cover a higher number of people. This resulted in three bigger “alliances”, one for each linguistic region, and later, in 2002, they again merged to santésuisse (OFAS 2013 Personal translation).

In 1900, the Swiss government called for a popular vote on the law for the health and accident insurance (LAMA), which saw high opposition from many different sides. It was only in 1912 that a revised version of the first attempt of the LAMA was accepted during the popular vote. Not only were the insurance companies afraid to lose their autonomy, but the vote also saw a big resilience from federalists. Over the next few decades, there were several attempts to harmonize health insurance nationwide. However, it seems that a compromise could not be found. It is only in the late 60s that the subject of mandatory health insurance was brought back to the table, but again was voted against in the mid 70s by the Swiss population. Switzerland was facing by the time an increase in health costs and health expenditures. It is only in 1996 that the population voted in favor of the now called LAMal (loi sur l’assurance maladie et accident). With this, the Swiss government was able to set down the foundation for a mandatory Swiss-wide health insurance law, as well as uniform and clarify several aspects. Based on this uniformizations, the Swiss health insurance companies started offering more insurance options, as well as several different deductibles<sup>22</sup> linked to more or less flexibility in the benefits.

It is only in 2007 that the Swiss population got asked to vote again on the health insurance subject again and more specifically on the proposition of having only one centralized public health insurance for everyone. This, however, got rejected by the folk,

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<sup>22</sup> A deductible is the ensured persons out of the pocket contribution. It will be explained more into detail in section 1.3.3.4

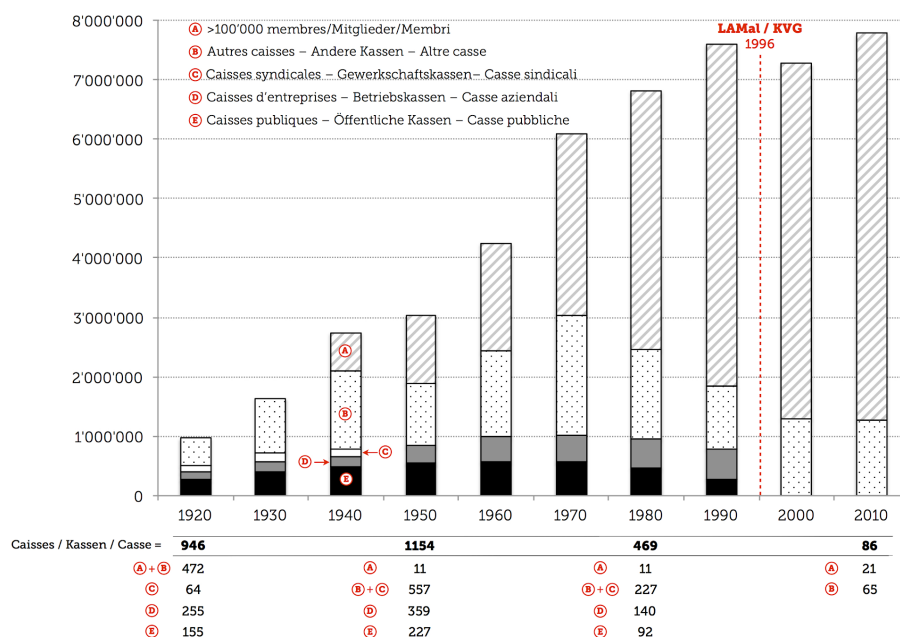
mostly because they feared a monopoly power followed by an increase in health expenditures for the population. This fear was expressed mainly by the health insurance companies and by the wealthier part of the population (OFAS 2013 Personal translation).

### 1.3.3.2 Switzerland's Health Insurance in Today's Society

Today, 86 private insurance companies are still active, compared to more than 1100 in 1950. Most of them decided to merge from the 60s on. It is to be noted that the five major insurance companies active today insure more than half of the Swiss population (OFAS 2013).

**Figure 6 – Number of Insured Citizens by Recognized Insurance Companies by the Confederation, 1920-2010**

**G14** Effectifs de divers types de caisses maladies reconnues par la Confédération, 1920-2010  
 Mitgliederbestände von verschiedenen Arten vom Bund anerkannten Krankenkassen, 1920-2010  
 Effetivo degli assicurati dei diversi tipi di casse malati riconosciute dalla Confederazione, 1920-2010



Sources/Quellen/Fonthe  
 Annuaire statistique de la Suisse / Statistisches Jahrbuch der Schweiz (1920-1980);  
 Statistique de l'assurance maladie / Statistik über die Krankenversicherung (1990-2010)

www.histoiredelasecuritesociale.ch/chiffres  
 www.geschichtedersozialensicherheit.ch/zahlen  
 www.storiadellasicurezzasociale.ch/cifre

Source: (OFAS 2015)

This graph clearly shows the evolution of the number of insured persons as well as the number of health insurance companies previously explained. Looking at the year 2010, a total of 86 insurance companies were active. The striped part of the bar represents the insurance companies accounting more than 100'000 members each, which only represented 21 insurance companies in 2010. The remaining 65 insurance companies insure less than 1.5 million Swiss citizens. The bar representing the year 2010 very much

looks like the Pareto rule<sup>23</sup> is applying, where 24 percent of the insurance companies account for 84 percent of the insured persons.

### **1.3.3.3 Key Players**

The Swiss health system structure is composed of several key stakeholders being cantons, municipalities, the government, the Federal Office of Public Health (FOPH), the Federal Department of Home Affairs (FDHA), and the Swiss Conference of cantonal Ministers of Public Health (GDK) and others. All play a crucial role when it comes to the Swiss public health system, and their collaboration is important and highly structured for a smooth running of operations. Each key player has its own set of responsibility and degree of power, and in some cases, the decision power is shared in order to provide a more adequate solution to the daily health system challenges (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 4).

#### **1.3.3.3.1 The Government**

The federal council (executive) and the parliament (legislative) draw up and enact new laws and ordinances for cantons to implement. In other words, the government gives the framework for the cantons to implement the laws and regulations to fit their cantonal structure best. Laws and regulation passed at the federal government level are the framework in which the cantons can adapt to the need of their population, if necessary (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 4).

#### **1.3.3.3.2 The FOPH, FDHA, and GDK**

The FDHA, which is part of the FOPH, is responsible for the national health policies in close collaboration with the Swiss government. Further responsibilities of the FOPH are representing the Swiss health policy interests at international gatherings. They also monitor and control epidemics and infectious diseases as well as prevent and address addictions. Some other domain of action is the supervision of mandatory health insurance as well as the decision-taking process regarding the reimbursement and price of medicines. The GDK regroups all health ministers of all cantons, and its duty is mainly to promote cooperation and common policies amongst cantons (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 5).

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<sup>23</sup> Carla Tardi defines the Pareto-Rule as “[...] 80% of outcomes (or outputs) result from 20% of all causes (or inputs) for any given event” (Tardi [no date])

#### **1.3.3.3.3 The Cantons**

The 26 cantons in Switzerland are mostly autonomous and are free to implement the legislation when it is not set on a government level. The cantons have various responsibilities, which are to maintain as well as co-finance and supervise hospitals and nursing homes, which is done with mandatory health insurance. Cantons are also in charge of the provision and funding of healthcare. The cantons secure healthcare by hospital planning and emergency as well as rescue services. Their role is also to monitor the licensing of the medical and paramedical professionals as well as finance doctors training through cantonal universities. Furthermore, the cantons assess and adjust premium reduction for economically vulnerable people. As already mentioned previously, the cantons have the responsibility to implement the laws and regulations passed at the government level; this is mostly supervised by the health minister. By letting the cantons adapt the laws and regulations set on a government level, this ensures that the laws are adapted to the local needs of the Swiss population (Enderli, Käch, Sandmeier, Wüthrich 2018, pp. 4–6).

#### **1.3.3.3.4 The Municipalities**

In collaboration with the cantons, municipalities own and control most hospitals. Similar to the duties of the cantons, the municipalities ensure provision of nursing and home care<sup>24</sup>. They also collaborate with the federal government and the cantons for some prevention campaigns (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 5).

#### **1.3.3.3.5 Swissmedic**

As Switzerland is not part of the European Union (EU), it is not affiliated to European Medicines Agency (EMA), but has its own drug regulatory authority known as Swissmedic which has two key activities, monitoring the Swiss pharmaceutical market and approving new medicine for the Swiss market (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 8).

#### **1.3.3.3.6 Beneficiaries**

Every Swiss citizen living in Switzerland or any Swiss resident is eligible. Foreigners have up to 90 days to affiliate themselves to an insurance company, if they fail in doing it on time, they will be attributed to one which could result in higher premiums (Buswell 2020). It is also to be noted that Swiss health insurance companies are legally obliged to accept any application without any age or health risk discrimination (Buswell 2020).

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<sup>24</sup> In Switzerland, Home care is taken care off by a firm called Spitex

#### 1.3.3.4 Structure

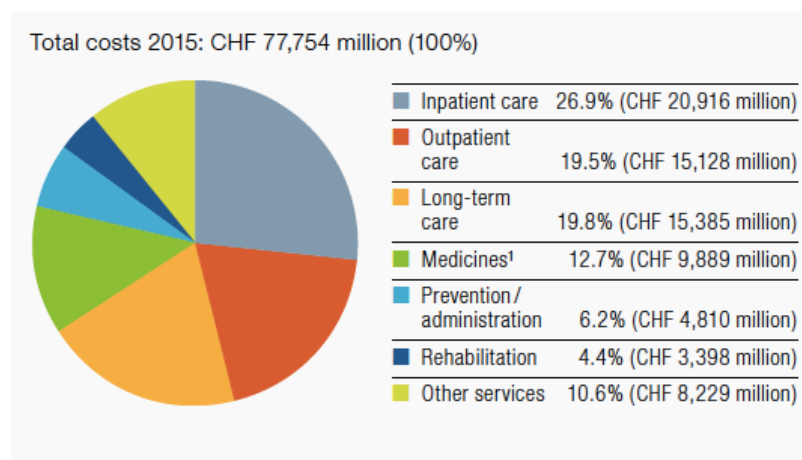
The current health insurance system is the same for all the insurance companies active in Switzerland. It is composed of three main parts, the premium, the deductible and the co-insurance. The premium varies amongst insurance companies, as well as the insured persons' residence, but does not depend on a person's income. The premium might change depending on the features or options chosen by the policyholder. For example, the insured person can choose to have no restriction in the choice of doctor or clinic, which will result in a higher monthly premium, same goes if private hospital cover is chosen, instead of general admission. Furthermore, the policyholders can change their insurance company every year before November. In addition to the mandatory basic insurance, Swiss residents have the possibility to add a complimentary insurance policy that covers alternative medicine, for example. Furthermore, this complimentary coverage does not have to be with the same health insurance company as the mandatory one. This gives a lot of freedom and the possibility to tailor each individual's needs at its best. A deductible can vary between CHF 300 and CHF 2'500 for adults (over 18 years) and between CHF 0 and CHF 600 for children (up to 18 years) (Assurance-info 2014). Furthermore, there is a ten percent co-insurance that every insured person has to pay on each bill. This means that every 1st January, the insurance year starts again, and the insured person will have to pay all their health costs out of the pocket until they reach their deductible. After that, depending on the health insurance company, some will first have to pay the bills and then ask for a refund where ten percent will be deducted, or the health insurance company pays the bill directly to the 3rd party and sends an invoice to the insured person for the remaining ten percent. As long as the insurance companies stays within the frame of the LAMal regulations, they are free to decide how they want to operate for the process explained above. The basic health insurance covers the following:

- Accidents
- Alternative therapy
- Cancer screening
- Dental care
- Doctors and medical specialists
- Eye care
- Hospital visits
- Maternity care
- Medical devices
- Medical transport
- Medication
- Mental healthcare
- Rehabilitation
- Sexual health
- Treatment abroad
- Vaccination

(Buswell 2020)

Accident cover is the only one without a deductible. Some of the above listed covered treatment can come with higher deductibles. Maternity care might be covered up to a maximum amount, and dental care is only covered if it is repair work after an accident, for example (Buswell 2020). Switzerland healthcare is the second most expensive in the world, with more than 12 percent of its gross domestic product (GDP) spent on health care, after the US (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 24). Healthcare costs increase by a few percent every year, which comes with an increase in premiums for the Swiss population. In 2015, total healthcare costs were about slightly less than CHF 78 billion (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 21). It can be seen in Figure 7 below, how healthcare costs were divided in 2015. The most important expenses were inpatient (26.9 percent) and outpatient care (19.5 percent) as well as long-term care (19.8 percent) representing about two-third of total expenses for the year 2015. Medicines costs on the other hand, represented roughly 13 percent which includes hospitals and accounts for almost CHF 10 billion, which seems to stay relatively stable over the years (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 20).

**Figure 7 – Switzerland’s Total Health Cost by Category in 2015**



Source: Costs and funding of healthcare, Federal Statistical Office, 2017.

Source: (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 21)

#### **1.3.3.4.1 Reimbursement Process for Health Expenses**

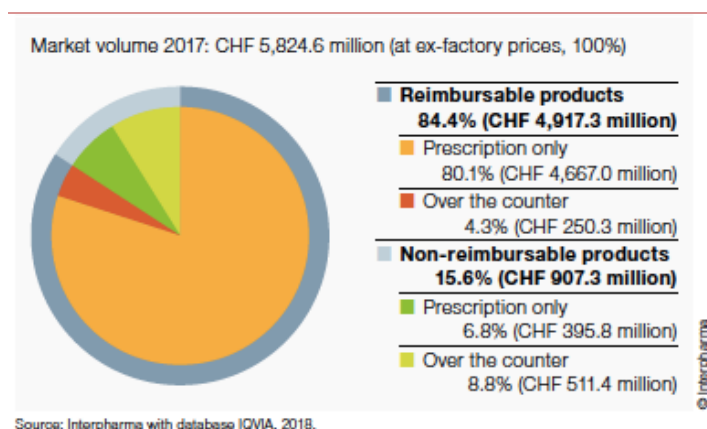
In order to enjoy the benefits of health insurance in Switzerland, the insured person has to follow the guidelines of the chosen insurance plan. Indeed, some health insurance plans have a lower premium but come with the obligation first to visit their home practitioner or to select a doctor from a specific list, elsewhere the costs of treatment will not be reimbursed.

According to Enderli, in 2017, around 67 percent of sold medicine in Switzerland have been reimbursed through mandatory health insurance (Enderli, Käch, Sandmeier,

Wüthrich 2018, p. 42). In 2018, for example, a total of almost CHF 5'038 million were covered by the Swiss health insurance companies in Switzerland (Flury, Geiger, Sandmeier, Wüthrich 2019, p. 20). To split down this amount, almost half accounts to pharmacies (48.2 percent). The remaining percentages are split almost equally between dispensing doctors, and hospitals and only 0.1 percent go to drugstores (Flury, Geiger, Sandmeier, Wüthrich 2019, p. 21).

The majority of the sold medicines being prescription-only drugs, which means that in order to receive these medications, the patient has to go through a doctor who will prescribe the medication. It can then be retrieved at a pharmacy and to a later point be claimed back at the health insurance company for the usual 80 to 90 percent once the deductible is fully paid (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 40). It is to be noted that prescriptions can be needed for two specific cases. The first case is when a prescription is needed to receive the specific medication due to its risk of use without doctor's approval, and the other case is the prescription is needed to confirm that a certain treatment is really needed by the patient. The second case is mostly for non-prescription drugs which are reimbursed by the mandatory health insurance only if they are prescribed by a doctor. These medications are over-the-counter drugs that would be entirely at the patient's expense without prescription. The last case figure are drugs that need prescription but are not reimbursed by the mandatory health insurance such as contraception (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 40). In 2005 a so-called "differentiated quote-part" was introduced in Switzerland, where original or branded medication now sometimes have a 20 percent quote-part whereas generic medication stays with the ten percent quote-part. The goal of this new regulation was to induce patients to favor generic medication when available (Flury, Geiger, Sandmeier, Wüthrich 2019, p. 28).

**Figure 8 – Pharmaceutical Market by Reimbursability, According to Value**



Source: (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 41)



### 1.3.3.4.2 Cost of Healthcare according to Services

Switzerland's healthcare expenses are divided in three main sections, as displayed in Figure 9 below, which are outpatient treatment, inpatient treatment and medicines. It is clear to see that all three sectors saw their expenses grow between the years 2011 and 2015. Outpatient treatment represents the highest expenses with over CHF 20 billion in 2015, compared to slightly less than half the amount for medicines. Analyzing the medicines section, it is evident to see that two lines stand out, one regrouping pharmacies and drugstores, and the other self-dispensing doctors. These two entities account for about 85.5 percent<sup>25</sup> of total medicine expenses in 2015. (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 23).

**Figure 9 – Switzerland's Different Types of Services and their Expense Evolution, 2011 - 2015**

Type of service (in CHF millions)	2011	2012	2013	2014	2015
<b>Outpatient treatment</b>	<b>17,372</b>	<b>18,202</b>	<b>19,036</b>	<b>20,095</b>	<b>20,916</b>
– Doctors	7,592	7,808	8,300	8,702	9,312
– Hospitals	4,744	5,246	5,483	6,047	6,284
– Dentists	3,895	3,978	4,061	4,156	4,068
– Others	948	976	1,002	1,035	1,096
<b>Inpatient treatment</b>	<b>13,584</b>	<b>14,138</b>	<b>14,796</b>	<b>14,947</b>	<b>15,385</b>
<b>Long-time care</b>	<b>13,257</b>	<b>13,832</b>	<b>14,255</b>	<b>14,627</b>	<b>15,128</b>
– Social medical institutions	11,301	11,747	12,040	12,324	12,640
– Spitex	933	1,015	1,096	1,155	1,251
– Others	1,023	1,069	1,118	1,149	1,237
<b>Medicines</b>	<b>8,811</b>	<b>9,025</b>	<b>9,266</b>	<b>9,407</b>	<b>9,889</b>
– Hospitals inpatient	556	519	518	478	503
– Hospitals outpatient	683	724	739	790	802
– Pharmacies and drugstores	4,396	4,462	4,477	4,475	4,679
– Self-dispensing doctors	3,085	3,227	3,428	3,561	3,794
– Import	91	93	104	102	111

Source: (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 23)

The graph below shows the evolution of the different health services, and it can be observed that the medicine services has had a serious drop over the past 20 years compared to the others, who remained relatively stable. According to the OECD, medication costs represented 13 percent<sup>26</sup> of 2016s total health expenses in

<sup>25</sup>  $(100/9889)*8473=85,68 \%$

<sup>26</sup> Including medication dispensed in hospitals (Flury, Geiger, Sandmeier, Wüthrich 2019, p. 6)

Switzerland. The remaining percentage, namely 41 percent, were attributed to hospital and 29 percent to outpatient care (Flury, Geiger, Sandmeier, Wüthrich 2019, p. 6). Looking at medication expenses for Swiss households, on average 3.2 percent, including the expenses covered by the health insurance coverage, was spent on medication in 2019 (Flury, Geiger, Sandmeier, Wüthrich 2019, p. 10).

### **1.3.3.5 Strength and Pain Points**

The Swiss health insurance system is composed of various parties all with their own set of responsibilities and power. The national framework is set at government level and cantons, and communes or municipalities have, to a certain extent, the freedom to shape the laws and regulations to the needs of the local citizens. Having health insurance mandatory for each citizen enables all Swiss residents to enjoy high quality health care throughout Switzerland. Health insurance companies are private and can therefore make profit out of their activities. Each of the 86 Swiss health insurance company being private enables them to shape their insurance policy as they wish, within the regulations set out at government level. Knowing this, could give the health insurance companies to have the wrong incentives and be more profit driven than what is best for the consumer.

## **1.4 Research Question**

### **1.4.1 Purpose of the Study**

The topic for this research paper came to the author while on exchange in Canada, having herself experienced the Canadian antibiotic distribution system. The purpose of this report is to understand the key players in the antibiotic industry as well as the implications linked to the antibiotic market. Furthermore, this report focuses mainly on two countries namely Canada and Switzerland, which are compared throughout the report. The aim of this paper is to understand the complexity of the pharmaceutical world as well as the legal implications and barriers for this industry, and more specifically for the antibiotic distribution. This, to understand the current setting, the distribution system is operating and what possible obstacles could arise. Finally, the author also intends to understand the implications, a change in the Swiss distribution of antibiotics, would bring and how another distribution system could help reduce health expenses as well as medication waste with the following research question:

*“Is there an economic benefit in changing the Swiss antibiotic distribution system, by taking the Canadian system as an example?”*

## 2 Literature Review

### 2.1 Antibiotics

#### 2.1.1 Antibiotics Discovery and Evolution

The word “antibiotic” comes from Latin and means “against life”(What Are Antibiotics? 2019). According to various sources, the benefits of nature-based antibiotics were used since ancient times (Society [no date])(Gould 2016, p. 1). However, their benefits and use were more a folkloric belief, since they did not know the origin of the infection by that time nor what agent exactly healed it. One famous “antibiotic” from the ancient time was moldy bread, which people used to cover an infected wound (Gould 2016, p. 1).

It was only from the 17<sup>th</sup> century and onwards that scientists such as John Parkinson, Antonie van Leeuwenhoek, Louis Pasteur, Robert Koch and others started experimenting with “living creatures”. Alexander Fleming must be the most famous scientist in antibiotic discovery, with his “accidental” penicillin revelation in 1928.

However, it seems that several other scientists made similar findings before Flemings but were unable to extract and use it as Flemings did. At first, they had difficulties in extracting higher quantities of the so-called “mold juice”, and only after collaborating with Ernst Chain and Howard Florey in 1940, were they able to achieve mass production, right on time for WWII. Discovering penicillin and other antibiotics, revolutionized the medical world and helped save thousands of lives since (Gould 2016, p. 1). The first wave of antibiotic resistance was observed shortly after WWII and threatened the recent progress from the past decades. Scientists were able to counter this threat by discovering new beta-lactam antibiotics which countered the resistance (Ventola 2015). Nonetheless, resistance has been observed for nearly every type of antibiotic on the market. A lot of effort has been put into introducing new antibiotics between the 60s and 80s but has drastically decreased since then, and only a very small number of new antibiotics have been introduced to the market since (Ventola 2015).

#### 2.1.2 Definition

Dr Mary Harding gives the following definition for antibiotics:

*“Antibiotics are a group of medicines that are used to treat infections caused by some germs (bacteria and certain parasites). They do not work against infections that are caused by viruses - for example, the common cold or flu.” (Dr. Harding 2018).*

Antibiotics are generally plant-based, and bacteria or fungi are added in the process (Cheesman, Ilanko, Blonk, Cock 2017). They have two processing modes; they either destroy (bactericidal) or slow down (bacteriostatic) the growth of the bacteria (Kohanski, Dwyer, Collins 2010).

Antibiotics do come in various forms depending on who will use it or for what the antibiotic will be used. Antibiotics can come in the form of tablets, capsules, liquids, creams, and ointments<sup>27</sup>. Most of them can only be retrieved with a prescription, but others in forms of cream or ointment can be available over the counter (Healthline's Medical Network 2018). However, every country has its own laws and regulations regarding antibiotics and; some do not require a prescription (Auta, Hadi, Oga, Adewuyi, Abdu-Aguye, Adeloye, Strickland-Hodge, Morgan 2019).

### **2.1.3 Evolution**

There are now over 100 antibiotics available worldwide. Yet, most of them are derived from less than ten classes of antibiotics (Everett 2019). The few decades after the discovery of penicillin were considered the "golden age" of antibiotics. But this golden age is coming to an end, with fading interest in researching new antibiotics since the early 2000s (Kollewe 2018). The faded interest is also linked to the low economic benefits for the pharmaceutical companies (Ventola 2015) (Boseley 2020). Moreover, in recent years, an increase in antibiotic resistance has been observed, which is becoming a major preoccupation for scientists as well as health experts (Gould 2016, p. 2).

The misuse or overuse of antibiotics are responsible for this improved in resistance, but also, the lacking introduction of new antibiotics on the market (Ventola 2015). Some volume-bonus incentives also drive resistance, as health practitioners will tend to prescribe more than needed, to receive a higher margin. However, according to the Antimicrobial Resistance Benchmark report, several research-based companies have taken measures to address the overselling of antibiotic medication driven by the volume-bonus (Massey, Cogan, Jones, Ross 2020, p. 7). Pfizer, who is one of the market leaders in the pharmaceutical industry has decided to publicly publish its raw data on AMR surveillance (Massey, Cogan, Jones, Ross 2020, p. 12).

Looking at antibiotics use, penicillin has become a very popular antibiotic and is the most used one, at least in Switzerland and Canada, accounting for 34 percent and 28.6 percent respectively of total antibiotic consumption in each country (Federal Office of Public Health and Federal Food Safety and Veterinary Office. 2018) (Mikulic 2019b).

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<sup>27</sup> Ointments are an oily or greasy form of cream containing drugs and destined for external use (Merriam-Webster [no date])

Antibiotics have played a crucial role in domains like oncology, immunology and surgery. Patients enduring treatment or surgery, that are certainly effective and of high quality, are however often highly vulnerable to infections. Thanks to the use of antibiotics during their treatment, they have seen their chances of survival rise drastically (Praz, Trolliet 2016, p. 1). Since patients undergoing chemotherapy for example, are highly subject to infections due to their weakened immune system, taking antibiotics avoids them catching infections that could be deadly in their vulnerable state (Praz, Trolliet 2016, p. 1).

It is also to be noted that antibiotics as well as antibiotic resistance are a very serious problem for livestock and pets, however, since it is not relevant to the current discussed topic, it will not be explored or analyzed any further.

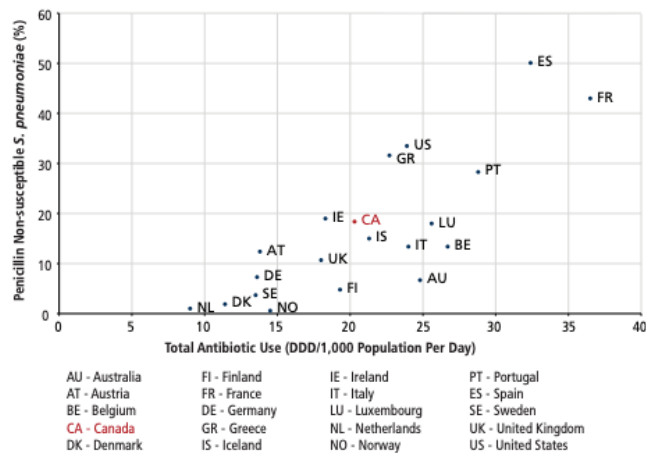
#### **2.1.4 Antibiotics in Today's Society**

The antibiotic industry is not as attractive as it once was. Indeed, more and more pharmaceutical companies decide to focus on more profitable illnesses where the treatment period is much longer than just a few days or weeks. Oncology or diabetes treatment can be for life, and pharmaceutical companies make a much higher profit by focusing on developing medication treating cancer or diabetes rather than the good old antibiotic (Stone 2018). Several scientists and experts warn about an antibiotic shortage as their supply chain is getting more and more fragile. As previously mentioned, antibiotic research is not a very lucrative commercial activity; consequently pharmaceutical companies are pulling out of business resulting in antibiotic shortages as well as leaving only few suppliers left (White 2018, p. 1; Stone 2018). This has for consequence that some antibiotics, such as penicillin are since 2015, unavailable in several countries, including Canada (White 2018, p. 1).

##### **2.1.4.1 The Situation in Canada**

The Canadian antibiotics consumption for humans in 2016, was only 20 percent, whereas the majority is consumed by livestock (Council of Canadian Academies 2019, p. 6). The most used antibiotic in Canada was beta-lactam antibacterial and penicillin; accounting for 28.6 percent in 2015 (Mikulic 2019b). The Canadian Antimicrobial Resistance Surveillance System (CARSS) updated report states that in 2017, 92 percent of antibiotics in Canada were dispensed by pharmacies, and the remaining eight percent accounts for hospitals. The Defined Daily Doses (DDD) for the same year was 19.5 per 1'000 inhabitants, and consumption varied amongst provinces In contrast, the provinces of Newfoundland and Labrador have twice as high DDD compared to Quebec and the territories (Public Health Agency of Canada 2018, p. 50). On an international scale, Canada's DDD is in the average zone (Council of Canadian Academies 2019, p. 45).

**Figure 10 – Total Antibiotic use in DDD**



Adapted with permission from Albrich et al. (2004)

Source: (*When-Antibiotics-Fail* 2019, p. 45)

Regarding the most treated diseases, respiratory and urinary tract infections were on top of the ranking (Public Health Agency of Canada 2018, pp. 13–14). According to the “*When antibiotics fail*” report, at least 980’000 bacterial infections were recorded in Canada in 2018 from which about 25 percent were resistant bacteria. Out of these 25.5 percent, representing 250’000 individuals, 14’000 people died. For the remaining 730’000 individuals, a total of 30’000 deaths were recorded (Council of Canadian Academies 2019, p. 19). The same report estimates that one in 19 deaths can be attributed to resistant bacterial infections in Canada (Council of Canadian Academies 2019, p. 2).

The report further

*“recogniz[ed] how little is known about potential AMR impacts on the Canadian public and healthcare system, the Minister of Science, on behalf of the Public Health Agency of Canada (PHAC, the Sponsor), asked the Council of Canadian Academies (CCA) to convene an expert panel to provide an evidence-informed, authoritative assessment.”* (Council of Canadian Academies 2019, p. 3).

This panel decided to concentrate on the ten most common resisting bacteria:

1. Bacterial gastro-intestinal infection
2. Bloodstream infection
3. Clostridioides difficile infection
4. Intra-abdominal infection
5. Musculoskeletal infection
6. Pneumonia
7. Sexually transmitted infection
8. Skin and soft tissue infection
9. Tuberculosis
10. Urinary tract infection

This list is not exhaustive and does not include all resistant infections in their entirety and therefore, undervalues the extent of Canada's resistant infections. The panel went further in its analysis and made an interesting framework comparing the economic and social impact for Canada.

**Table 2 - The Economic and Social Impact in Canada Regarding AMR**

<b>ECONOMIC IMPACTS</b>	<b>SOCIAL IMPACTS</b>
<b>Healthcare System</b> <ul style="list-style-type: none"> <li>• Increase in Resistant Infections in Humans</li> <li>• Additional Treatment Costs</li> </ul>	<b>Individual</b> <ul style="list-style-type: none"> <li>• Increased Morbidity, Mortality, and Inequality</li> <li>• Decreased Quality of Life</li> </ul>
<b>Canadian Economy</b> <ul style="list-style-type: none"> <li>• Reduction in Workforce</li> <li>• Reduction in GDP</li> </ul>	<b>Community</b> <ul style="list-style-type: none"> <li>• Reduced Social Cohesiveness</li> <li>• Lower Trust and Social Capital</li> </ul>
<b>Agricultural System</b> <ul style="list-style-type: none"> <li>• Decrease in Animal Farming Industry Productivity</li> <li>• Decrease in Animal Exports</li> </ul>	<b>Policy and Legislation</b> <ul style="list-style-type: none"> <li>• Changes in Healthcare Delivery</li> <li>• Travel Restrictions</li> </ul>

Source: (*When-Antibiotics-Fail* 2019, p. 37)

This framework lists some relevant points related to resistance in Canada and underlines how both aspects are seriously threatened by AMR. It also shows the importance for the Canadian government to tackle this issue without further waiting, as it is a major threat for its society and economy in the future.

#### **2.1.4.2 The Situation in Switzerland**

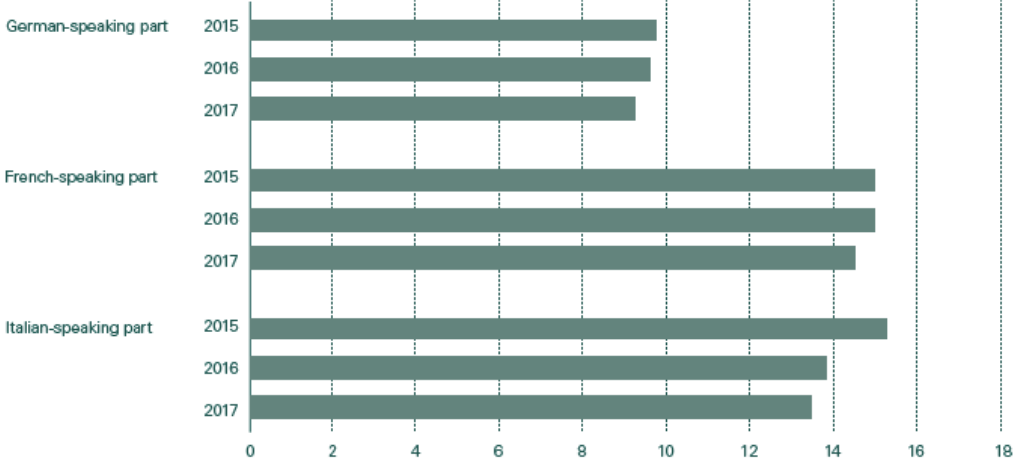
For this research paper, the focus will be mainly on outpatient care and not on inpatient, as it is not relevant for the targeted outcome since the focus is primarily on antibiotic consumption outside hospitals and in pill form.

Based on the results from the Swiss Antibiotic Resistance Report from 2018, which used IQVIA<sup>28</sup> datasets, the total antibiotic consumption in 2017 in Switzerland was 10.7 DDDs per 1000 inhabitants per day. This average is relatively low compared to some other European countries like Greece with 36.3 DDD's, and with a European average of 21.9 DDDs (Federal Office of Public Health and Federal Food Safety and Veterinary Office. 2018, p. 40). The most used antibiotic in Switzerland is penicillin, representing 48 percent of total consumption. In Switzerland, penicillin is often combined with beta-lactamase inhibitors which represent 34 percent of systemic antibiotic groups (Federal Office of Public Health and Federal Food Safety and Veterinary Office. 2018, p. 41). It is also

<sup>28</sup> A private drug market investigation company

interesting to observe that the three linguistic regions in Switzerland, namely French-, German-, and Italian-speaking do not have the same antibiotic consumption for the observed year 2017 (Federal Office of Public Health and Federal Food Safety and Veterinary Office. 2018, p. 42).

**Figure 11 – Total Antibiotic Consumption in DDD per 1'000 Inhabitant per Day by Linguistic Region in the Outpatient Setting in Switzerland, 2015-2017**

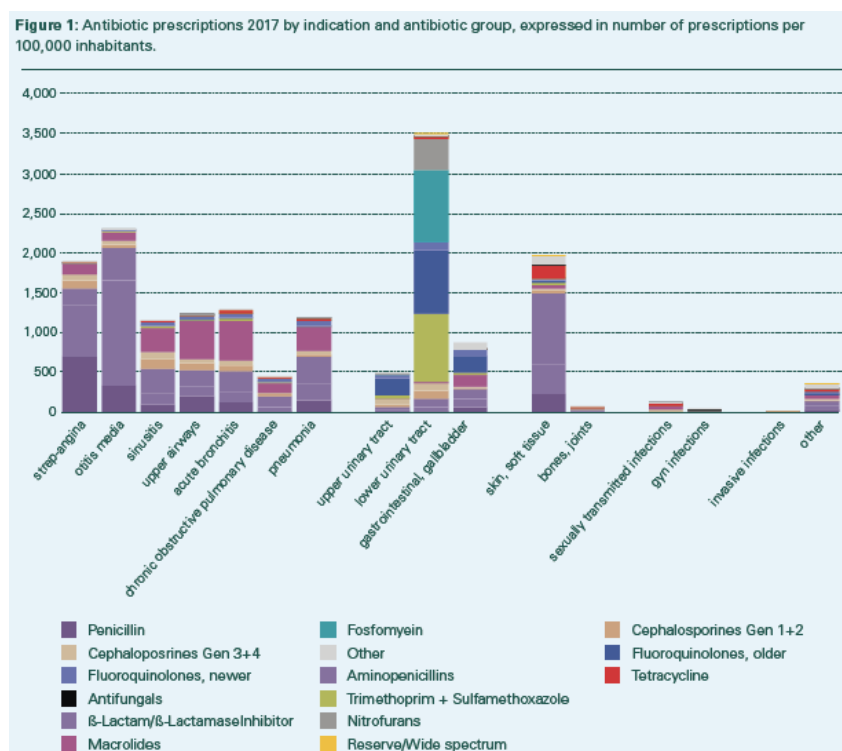


Source: (Federal Office of Public Health and Federal Food Safety and Veterinary Office. 2018, p. 43)

The graph above shows how antibiotic consumption has slightly decreased in all three regions between 2015 and 2017. It also reveals the significant lower consumption in the German-speaking part, with less than 10 DDD per 1000 inhabitants compared to the two others both having a DDD higher than 12 per 1000 inhabitants.



**Figure 12 – Antibiotic Prescriptions in 2017 by Indication and Antibiotic Group per 100'000 Inhabitants**



Source : (Federal Office of Public Health and Federal Food Safety and Veterinary Office. 2018, p. 46)

The graph above shows the different antibiotics prescribed according to the infection. It is clear to see that the most common infection treated with antibiotics is for lower urinary tract. Followed by otitis media in second place and skin and/or soft tissues in third place. The graph also shows that penicillin and beta-lactam are the most common except for the most common infection, urinary tract infection.

In terms of market shares, antibiotics land in third position in the category for infectious illnesses, which regroups antibiotics, Hepatitis C, and HIV as well as vaccines representing roughly 10.6 percent market shares (Flury, Geiger, Sandmeier, Wüthrich 2019, p. 36).

### 2.1.5 Current Challenges

As already mentioned in the previous part, antibiotics come with a great risk when not used correctly. Misuse or overuse could lead to developing resistance to that bacteria which can be fatal for the individual, later in his or her life. It is, therefore, crucial to follow the prescribed treatment period to ensure that the harmful bacteria are killed. Once antibiotics are taken, symptoms often drastically diminish in the first 24-48h, giving the impression that there is no need to continue with the treatment (Healthline's Medical

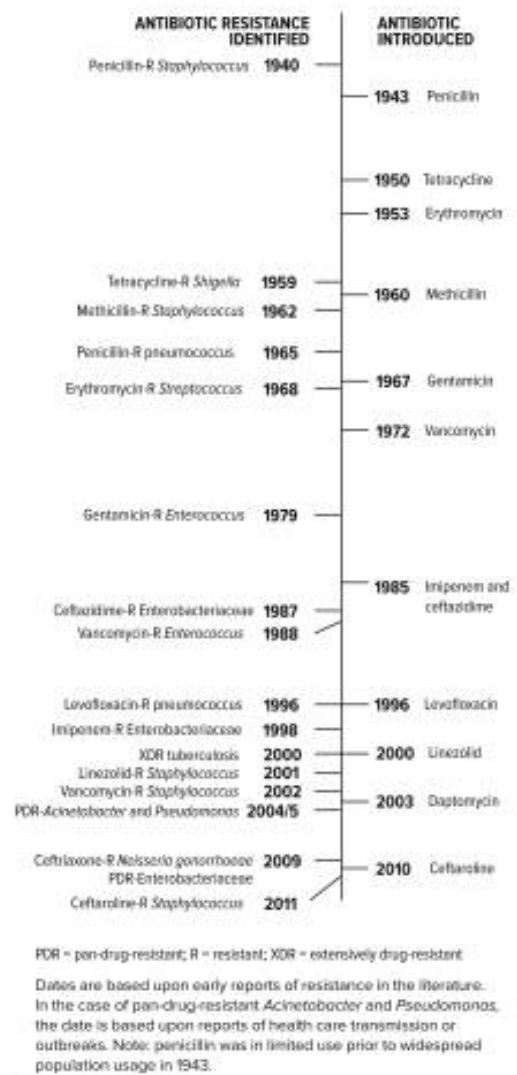
Network 2018). If a treatment is interrupted, and the bacteria is not completely killed, it could develop sort of immunity to the antibiotics, making the bacteria resistant. Treatment varies depending on the infection whereas some treatments have a duration of several days (seven or 14 days is the most common) however some antibiotics can be taken in single doses, such as for urinal infection or some have to be taken over several weeks for more severe infections (Wilson, Daveson, Del Mar 2019).

### 2.1.5.1 Resistance

Antimicrobial resistance (AMR) happens when an antibiotic is no longer effective in killing or slowing down an infection and has evolved in being resistant to the antibiotic administered (*When-Antibiotics-Fail* 2019, p. 35). This phenomenon appeared at the same time as when antibiotics started to be used. Resistance happens when the treatment is not taken correctly, meaning when a treatment is interrupted or taken without any infection. AMR has become more and more frequent since antibiotic treatment became so popular, and an increase in misuse or overuse has been observed (*When-Antibiotics-Fail* 2019, p. 35). The figure hereby shows the evolution of AMR since the first introduction of antibiotics in 1940. It is clear to see that AMR significantly increased in the late 80s compared to only a few antimicrobials showing resistance.

**Figure 13 – AMR Timeline**

Figure 1 Developing Antibiotic Resistance: A Timeline of Key Events<sup>a</sup>



Source: (Ventola 2015)

### **2.1.5.1.1 The World Health Organization (WHO) AWaRe Classification Antibiotics Database**

In 2019, the WHO expert Committee developed this database classifying medicine, amongst others, 180 antibiotics in three categories being:

1. Access
2. Watch
3. Reserve

(WHO 2019)

This database was created to help countries better monitor and optimize their antibiotic use. Another reason for the creation of this database is to monitor AMR as well as adequate treatment. This list also clearly mentions which antibiotics are not recommended to use by WHO (WHO 2019).

#### Access Group

There are 48 antibiotics in this group which are active against a widespread of pathogens and which should be widely available in healthcare systems. These 48 antibiotics also have a lower risk of AMR and are therefore considered as first-choice antibiotics. (WHO 2019; Ivanovska, Muller, Schweikert, Sharma, Tao 2018, p. 21).

#### Watch Group

This group includes 110 antibiotics which have a higher resistance potential than the Access group. Antibiotics in this group should be considered as key targets to be monitored (WHO 2019).

#### Reserve Group

This group includes all the remaining 22 antibiotics, which should be considered as the last resort when all other treatments have failed. It is important to keep these antibiotics as last options to keep their effectiveness at the highest level (WHO 2019)

### **2.1.5.2 Waste**

Waste, in any kind of form, is a serious problem nowadays. A lot of products are bought in excess that cannot be consumed and hence are thrown away. This happens at the restaurants when plates come with too much food, or at the supermarket when people buy more than their needs and end up wasting the leftovers. The same occurs in the medical world for medication. Yearly, tons of medicines are disposed, which results in huge sums of money, not only for the consumer, but also for other paying entities, such as health care insurances or governments. Furthermore, dumping chemical pollutants, such as unused medication, which if not properly disposed of, can cause undesired effects on the environment (Canada 2011).

Christian Rappaz's states in his article for the "l'illustré" magazin, that the western countries medication waste represent not less than 20 percent of their total health spending (Rappaz 2019). CHF 13 billion worth of medication is wasted on a yearly basis in Switzerland based on the OECD data (Rappaz 2019). He furthermore states that there is a 20 percent overconsumption of medication for the Swiss population (Rappaz 2019). Various reasons are given to explain this important amount of waste. Some can be attributed to a failed attempt in healthcare delivery, and 30 percent is attributed to a problem of overmedication.

In Canada, the estimated waste for prescription medicine amounts for a bit more than CA\$ 5.1 billion for 2013<sup>29</sup> (Express Script Canada [no date]).

### **2.1.6 Switzerland's Attempt to fight Medication Waste**

Swiss politicians have addressed medication waste in the past years by submitting parliamentary motions, where the politicians explained the current situation and the reasons for the motion deposition, including several facts and data supporting their argumentation. However, none of them was approved by the parliament, until September 2017, when Geneva-based politician Manuel Tornare, submitted the motion 17.3942. In this motion, the Swiss politician stated a total waste of around 30 percent of medication yearly. His three main arguments to change the medication distribution method are the cost savings, the reduced self-medication<sup>30</sup>, and the reduced waste of pills. Mr. Tornare further states that by better monitoring the medication dispensation, this would help reduce AMR as well as enabling considerable economies (Tornare 2017, p. Personal translation).

The Swiss national council accepted the motion in December 2017 and the Swiss state council accepted it in September 2018. One of the reasons to accept the motion 17.3942 was due to a recent study made in France regarding a different distribution system for antibiotics. The study results stated that in more than 50 percent of the time, the antibiotic packages available was not corresponding to the prescribed treatment. Furthermore, the study also showed that dispensing the exact number of antibiotics helped reduce by ten percent the number of pills handed out to the patient. Regarding the duration of treatment, the exact number of antibiotics had showed that up to 90 percent of the patients followed their treatment to the end, compared to only 60 percent with the current system in place (Tornare 2017, p. Personal Translation).

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<sup>29</sup> It seems that more recent numbers for Canada are not available even after extensive research.

<sup>30</sup> Self-medication is when a person does not visit a health practitioner before taking medication (Merriam-Webster [no date]).

After both councils accepted this motion, a pilot project was designed to test if a different distribution system would be viable in Switzerland. The project is still running to this date, and the outcome should be published by the end of 2020.

## **2.2 Packaging and forms**

### **2.2.1 Different Antibiotic Dosage and Packaging**

Antibiotics come in various kinds of shapes and forms. Depending on what or who they are supposed to treat, they will be more or less strong. A toddler or a child will not be able to swallow a pill like an adult and therefore, pharmaceutical companies had to come up with another shape for children or for a patient unable to take pills. Moreover, when it comes to antibiotic dosage, several parameters have to be considered which will depend on the illness intended to cure, but also the patient's weight, and sometimes age for example. If the prescribed dosage is too light, it might not cure the bacteria and result in AMR (Grigorovsky 2018). If the dosage is too heavy, it might cause unwanted side effects (HSE 2011).

To be suitable for the different treatments they are intended for, as well as for whom they are intended, antibiotics are found in various shapes as already previously mentioned in section 2.2.1. Their most common forms on the market are tablets, capsules, liquids, creams, ointments, and suspension (NHS 2017). Hospitals most often use the intravenous option, as it is much more efficient and rapid, especially in an urgent situation, they are confronted on a daily. All of them could be discussed and analyzed individually, however, this report will only look at the pill shape to keep the scope clear.

#### **2.2.1.1 Packaging in Canada (Available packaging options)**

Canada uses various of the in section 2.2.1 mentioned packaging possibilities for its overall medication. To ensure health and safety in the use of medication, Health Canada published a 90-pages-long document with all the requirements for proper medication packaging (Canada 2013). The report is divided into several subsections addressing all the important requirements that have to be met. It contains instructions about general labelling requirements, but also what information have to be available on the label (Canada 2013).

A pharmaceutical company intending to produce medication for the Canadian market will have to make sure to follow all the described guidelines and regulations published by Health Canada, which are derived from the Food and Drugs Act (Canada 2013). This guidance document will be further discussed in section 2.5.1. After extensive research,

the only available packaging form found for antibiotic packaging was creams and ointments, that are available as OTC's (Shoppers Drug Mart [no date]; Jean Coutu [no date]). After individually searching through product lists available on Canadian based pharmaceutical companies, bulk-like formats were found. The pills usually come in bulk of 100, 500, or 1000 pills (Apotex [no date]; AA Pharma [no date]). Kim Overstreet mentioned in her 2019 published online article for Healthcare packaging that

*“Canadian pharma packaging is more functional than marketing driven, with the exception of OTC. Rigid plastic containers are most common, both for pills and liquids.”* (Overstreet 2019).

### **2.2.1.2 Packaging in Switzerland (Available packaging options)**

The Swiss website compendium.ch, regroups all medication available on the Swiss market. This website further indicates in which category the medication is listed, for what illness the medicine is usually taken, and further information to the use and precautions. Furthermore, it also indicates the name of each product and the producing pharmaceutical company. With the help of specific filters and keywords, the different packaging options in Switzerland were identified. Since this report mainly focuses on solid pills, only these will be listed hereunder.

By using the keyword “antibiotic” and the filter “solid”, a total of 172 results came up. Their dosage varied between 100mg and 1g. It is interesting to observe, that all solid antibiotics come in blisters<sup>31</sup>, with a few exceptions coming in doses or bottles. The search results also showed that the smallest available number of pills in a blister was three, and the highest available blister format was 56 units. This brings us to the conclusion that solid format antibiotics distributed in Switzerland exclusively come in individually prepacked format.

## **2.3 Antibiotic Producers**

The antibiotic market has a relatively small number of producers. Most of them are big international pharmaceutical companies, generic companies and a few are categorized in the small and medium enterprises (SME's), summing up to a total of 22 companies. These 22 companies are producing about 1'520 antibacterial or antifungal medicine. Out of the 1'520, more than 1'270 are antibacterial medicines, representing more than 80 percent (Antimicrobial resistance benchmark 2020).

The eight pharmaceutical companies producing antibiotics, led by Pfizer, Novartis, Sanofi, and GlaxoSmithKline (GSK), have more than 590 antibacterial products

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<sup>31</sup> In the pharmaceutical industry, a blister is a packaging form of medication, where each pill is packed individually and sealed with an aluminum cap (Cambridge Dictionary [no date]).

marketed. Unfortunately for them, only six percent of these products are still under patent. The generic companies, on the other hand, have more than 850 antimicrobial products on the market. This relatively important difference is because most of the antibiotics patent are expired. The last 68 antibiotics marketed are produced by only 5 SME's with a clear leader being Wockhardt, with 59 products (Antimicrobial resistance benchmark 2020).

According to the online article written by Alan Cassels, most of Canada's medication is produced abroad, in countries including China, India or Puerto Rico (Cassels 2012). According to "le Monde" article published late 2018, about 90 percent of the world's antibiotics are produced in India and China. Furthermore, the article states that 150 pharmaceutical companies are based in the south of India, where they produce their antibiotics, having devastating consequences for the surrounding villages and the environment (Barnéoud, Bomboy 2018). This was not the case back in the 80s when still 80 percent of raw material for medication was produced in Europe (Hubacher 2020).

This section intended to state the major antibiotic suppliers for Canada and Switzerland; however, it came out that even after extensive research, there could not be found any precise information about the exact antibiotic producers and suppliers for both countries.

### **2.3.1 Antibiotic Brands available in Switzerland**

The same filters mentioned in section 2.2.1.2 were used to identify the primary producers of antibiotics in Switzerland. Twenty-nine different companies produced the 172 antibiotic products from the search results. Amongst them were: Pfizer, Sanofi, Mylan, Teva etc. (*compendium.ch* [no date]).

## **2.4 Distribution System**

### **2.4.1 Antibiotic Distribution in Canada**

Based on the findings in section 1.3.2.2.4, stating that antibiotics are prescription-only drugs, they will exclusively be dispensed through a drugstore with the approval of a pharmacist.

### **2.4.2 Antibiotic Distribution in Switzerland**

Based on the findings in section 1.2.4.4, antibiotics in Switzerland are in category A which means that a doctor will have to prescribe them. It was also stated earlier in this report, in section 1.2.6.2, that depending on the canton, antibiotics could be dispensed

directly by the doctor himself or exclusively through pharmacies, with two exceptions having the mixed format.

## **2.5 Laws and Regulations**

### **2.5.1 Laws and Regulations in Canada**

#### **2.5.1.1 Labelling of Pharmaceutical Drugs for Human Use Guidance Document**

This guidance document was published by the authority of the Minister of Health for the health products and food branch and is in force since 2015. This document is supposed to help professionals comply with governing statutes and regulations, but they do not have force of law, and therefore, have some flexibility in their application (Health Canada 2013, pp. 1–3). The document is based on the requirements in several sections of the *Food and Drug Act* and also on the *Food and Drug regulations*. Section 2.2 of the regulation mentions that prescription drugs do not fall under the Canadian bilingual law, and the required information can be printed in one language only. The next section advises on how the information shall be printed and displayed. This is mainly to ensure that the text is readable and does not cause confusion for the end-user (Health Canada 2013, p. 5).

#### **2.5.1.2 Medication Approval Process**

For prescription, non-prescription, and over-the-counter drugs to be approved for the Canadian market, a specific process has to be followed. It starts with the manufacturer submitting a New Drug Submission (NDS) to receive a Notice of Compliance (NOC). It is important that the NDS contains as many details as possible, for the Minister of Health to assess if the drug is indeed safe and effective. The NDS is composed of several test-phases to ensure the safety of the drug.

There is a total of four phases that a drug will go through. The first one, also called the pre-clinical phase, will be to examine the drug to make sure it is safe to administer to patients. The two next phases will consist of administering the drug to different type of patients. The first type being healthy volunteers, the second to “ill” patients which the drug is supposed to treat. The last phase is considered as a follow-up phase once the drug has been introduced on the market. The last phase is mainly to see if the use of the drug could be optimized (Graham, Swanson 2018).

To obtain the NOC, a drug has to pass a considerable number of tests. Once the NOC is obtained, the drug will receive a Drug Identification Number (DIN). If the manufacturer applies for a generic, the NDS is replaced with the ANDS, short for Abbreviated New



Drug Submission. This is a shorter process since the drug is already marketed under its patent (Graham, Swanson 2018).

This process is regulated by Health Canada. All medication produced in Canada or imported are regulated by the Food and Drug Act (FDA) to ensure safety for the Canadian population. Health Canada is also responsible for determining if a drug needs a prescription or if it can be available OTC. However, provinces are free to impose stricter distribution standards if they believe it is necessary (Graham, Swanson 2018). This whole process comes with costs starting at around CA\$ 350'000 and can go up to CA\$ 600'000 depending on the complexity of the drug (Graham, Swanson 2018).

The National Association of Pharmacy Regulatory Authorities (NAPRA) defined three schedules where drugs are categorized.

- Schedule I is for prescription-only drugs
- Schedule II will contain drugs with the status “behind the counter”
- Schedule III is for drugs that have to be sold in pharmacies exclusively and must be approved by a pharmacist

All other drugs that do not fall in the three schedules are categorized as unscheduled and do not have any sales restrictions (Graham, Swanson 2018).

In order to sell prescription drugs, a provincial license must be obtained by the health care professionals. The distribution is mostly regulated by the provincial Colleges of Pharmacy or Pharmacy Boards, while the scheduling and classification are done at the federal level (Graham, Swanson 2018).

## **2.5.2 Laws and Regulations in Switzerland**

### **2.5.2.1 Federal Law 812.21**

Switzerland highly regulates its medication market with strict laws and regulations to ensure its population and animals safety and health. The federal law 812.21 on medicinal products and medical devices was last revised and approved on the 15<sup>th</sup> December 2000 and is still in force today.

This set of laws is composed of 9 chapters, some with subsections, and includes a total of 96 articles. The articles cover the legal framework for manufacturers, what guidelines and procedures have to be followed when marketing a new drug into the Swiss drug market. This set of law also includes information about the import and export regulation, and several articles encompass in detail the most important points to be followed regarding the prescription, distribution and dispensing of drugs on the Swiss market. Several terms are also defined, to avoid any misunderstanding for the reader. Furthermore, it also very specifically prescribes what a drug manufacturer has to print on

the products and how to formulate the sentences to avoid any confusion (The Federal Assembly of the Swiss Confederation [no date]).

### **2.5.2.2 Federal Ordinance 812.212.22**

This federal ordinance was decided in December 2001, entered into force in January 2002 and is still valid up to today. This law regroups the most important guidelines regarding the requirements for marketing authorization. It regulates the marketing process of ready-to-use medication, how the drug should be labeled and what information it should include. This federal ordinance also mentions the legal obligation to join a leaflet for each individual drug pack. Reading through this legislation, the following articles proved to be the most relevant to the topic of this research paper.

**Article 12** is about the information, which has to figure on the packaging container (Le Conseil de l'Institut Suisse des produits thérapeutiques (Conseil de l'institut) 2001, p. 7). It redirects to its first appendix, where a more detailed list of mandatory information is available.

**Article 14** focuses on the mandatory packing slip that has to be added to every single medication box, cream or bottle. Detailed guidelines are available in its fifth appendix, which gives an extensive guideline regarding font size and other formatting conditions (Le Conseil de l'Institut Suisse des produits thérapeutiques (Conseil de l'institut) 2001, p. 8). Furthermore, it also states that the packing slip has to be available in the three national languages namely French, German, and Italian (Le Conseil de l'Institut Suisse des produits thérapeutiques (Conseil de l'institut) 2001, p. 31). The ordinance further gives exact wordings to be used for specific sentences that have to be available in the packaging slip (Le Conseil de l'Institut Suisse des produits thérapeutiques (Conseil de l'institut) 2001, pp. 32–35).

### **2.5.2.3 Distribution Regulations**

To ensure the highest quality standards when dispensing medication, an ISO norm<sup>32</sup> has been introduced in line with Article 30 from the revised federal law about the dispensing license of medication in which it ensures that pharmacies work by following some health and safety standards, which includes process optimization and shortens them. The ISO norm also promotes a positive error culture<sup>33</sup>. The ISO 9001 QMS Pharma norm is not

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<sup>32</sup> ISO is an international organization for standardization bringing together an international expert panel. (ISO [no date])

<sup>33</sup> Wilson defines a positive error culture as “[...] a mistake, or a bad result, is viewed as an opportunity to improve your way of doing things. An individual error is actually good thing in that it brings a deficiency in your procedures to light. Now you have an opportunity to improve

yet mandatory throughout Switzerland, but only in some cantons. In 2019, there were around one-third of all Swiss Pharmacies that were ISO 9001 QMS Pharma certified (pharmaSuisse 2019, p. 34).

#### **2.5.2.4 Medication Approval Process in Switzerland**

Each medicine approved for the local market or intended for export has to follow a strict process to ensure the health and safety of its users. In 2018, more than 7'540 new medicines were approved on the Swiss market (Flury, Geiger, Sandmeier, Wüthrich 2019, p. 80). After marketing authorization has been granted, the pharmaceutical company has to apply to the FOPH to have their medicine added to the specialties list<sup>34</sup>. They also have to prove that the medicine is effective and efficient as well as suitable to the swiss market. For a medicine to be approved on the Swiss market, it has to go through four testing phases. The first one will be done on healthy volunteers; the second phase is conducted on a small number of patients. The next phase is conducted on a larger number of patients. The last phase is mainly to monitor the new medicine in practice (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 84).

The process usually takes about 330, or 140 days for the fast-track procedure (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 52). The SL counted roughly 2'903 products in 2017, whereas more than 40 percent of them were generics (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 52). For reimbursed medicine, prices are set by considering their therapeutic referencing and their price abroad. Once these steps are completed, the medicine is added to the SL, and the price is reconsidered every three years. During this period of time, prices can be lowered but not increased (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 58). If however, the medicine in question is not eligible to be reimbursed by the Swiss health insurance, the price can be set at the pharmaceuticals own convenience (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 8).

##### **2.5.2.4.1 Medication Development and Testing**

On average, it takes between eight and 12 years for a new medication to be developed. This comes with extremely high costs due to more severe legislations to ensure the safety and health for the target population. Also, the clinical trial participants requirement has significantly increased in the past years, going from a few hundred to a few thousand participants. They estimate the total cost per successfully marketed medication to around CHF 2.3 billion (Flury, Geiger, Sandmeier, Wüthrich 2019, p. 60). More than 36 percent

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*them so the problem will not recur. Errors are part of the process of improving your body of practices.” (Wilson 2015)*

<sup>34</sup> The specialty list is published by the OFSP and contains all medication that is eligible for reimbursement by the health insurance (Flury, Geiger, Sandmeier, Wüthrich 2019, p. 82).

of this amount was allocated to R&D, which in turn, also represented almost 50 percent of staff expenses. Some 20 percent were dedicated to taxes and other expenses (Flury, Geiger, Sandmeier, Wüthrich 2019, p. 60)

#### **2.5.2.5 Price Setting**

Pharmaceutical companies are free to set their price for their drugs if they do not intend to have them included in the SL. However, if they want to have their drug included in the SL, to be reimbursed by the Swiss health insurance, the maximum price will be set by the OFSP (Paris, Docteur 2007, p. 10). Regarding the generic pricing, the law imposes at least a 30 percent lower price than the original price (Paris, Docteur 2007, p. 18). The price for drugs available in the SL is calculated by considering various factors like the marketing portion of the overall costs, the ex-factory price<sup>35</sup>, and various taxes (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 54). This ex-factory price is based on two pricing systems: the basic of a therapeutic reference system and the international reference pricing system. The first system is employed in order to compare the cost of production of other medication already approved for the same treatment of disease, and the other method is to compare with other European countries with a similar economic situation. These countries include mostly wealthy northern countries like Sweden, Belgium, Germany, the UK (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 54). It is only since beginning 2017 that both systems are accounted equally, whereas it used to be solely based on the international reference pricing system.

One of the sales taxes mentioned earlier in the paragraph is levied by Swissmedics<sup>36</sup>. This tax is based on the ex-factory price and is due for every pack sold but does not exceed CHF 5.-. This tax is crucial from an economic aspect for Swissmedics as it represents 50 percent of their income (Enderli, Käch, Sandmeier, Wüthrich 2018). The sales and marketing tax, on the other hand, is prescribed by law and varies in percentage, going from seven percent to up to 12 percent, adding to that a price-related surcharge is levied by pack sold. The state does not regulate the non-refundable medicine market and pricing is set in accordance with the prices practiced by the competition (Enderli, Käch, Sandmeier, Wüthrich 2018, p. 54).

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<sup>35</sup> “Ex-factory price is defined as the price at which Licensed Products are sold by the Licensee to Distributors (net of any sales taxes only) in the currency in which the Licensee invoices Distributors” (*Ex-factory price | legal definition of Ex-factory price by Law Insider* [no date])

<sup>36</sup> The Swiss Agency for Therapeutic Products

On an international scale, Swiss drug prices are part of the reference consumer basket used by many industrialized countries. This has for consequence that any price variation of even “only” 10 percent would massively impact the industry’s revenues (Flury, Geiger, Sandmeier, Wüthrich 2019, p. 90).

## **2.6 Findings and Gaps in the Literature Review**

The findings in the literature review enabled to understand better the history and evolution of antibiotics, how the antibiotic industry works, as well as the laws and regulations for both countries, Canada and Switzerland. This chapter further helped to understand what challenges are linked to the antibiotic industry, the most concerning one being antibiotic resistance. Furthermore, it was interesting to learn about the discovery and evolution of antibiotics and how they impacted the population. The second section helped to get a clearer overview of the shape of antibiotics and how they were packaged according to their shape. The third section, about the producers of antibiotic, underlined how fragile the antibiotic industry was due to its low profit, few producers as well as few production sites. The fourth section disclosed only little about the distribution of antibiotics, data was found about the distribution for the medication category including antibiotics, but no information was found on the way and packaging format the antibiotics were supposed to be dispensed. The last section highlighted various laws and regulations for the manufacturing, marketing and distribution of medication, including antibiotics. Interesting findings included that both countries have very similar guidelines regarding the safety and health regulations for the approval of new medication as well as the printed information that must be available on the medication package, called leaflet. One interesting point was that Switzerland legally requires a leaflet for every medication pack that is handed out to the consumer, which is not the case in Canada.

The literature review research also raised some questions and gaps to be filled. Extensive research only resulted in insufficient data and information about the packaging regulations of antibiotics and under what form they are dispensed in Canada. However, two pharmaceutical companies active in the Canadian drug market had their product lists public and offered a slight insight into the batch-size antibiotics were packaged. The intention is to try to fill this gap by conducting interviews with professionals. The literature review also disclosed that Switzerland is operating in a dual distribution system depending on the canton, which partially explains why medication is all prepacked. The literature found about Switzerland’s attempt to reduce waste by conducting a pilot project was not sufficient, and it would be interesting to know in what phase this pilot project

currently is and how is it been conducted. Literature about the pharmaceutical industry in Switzerland gave an interesting overview of the industry; however, it would be interesting to go deeper and grasp the point of view of a pharmaceutical company from the inside.

## **3 Methodology**

### **3.1.1 Research Methodology**

The main intention of this report is to understand how both systems, the Canadian and the Swiss, work. Its purpose is further, to understand all the stakeholders involved as well as what makes the pharmaceutical industry such a sophisticated environment. Moreover, this research paper intends to explore the possibilities as well as burdens of introducing a different antibiotic distribution system in Switzerland. All possible bias was neutralized as this research was essentially based on observations and existing literature.

Three research methods were used to gather primary data, observations, a survey, and interviews. The observations happened mostly before the research paper was written. Some observation occurred in Canada, but most observations were done in Switzerland. For the survey, a total of 14 questions were written, especially focusing on Swiss citizens antibiotics habits. The questionnaire was sent out to various demographic groups. Finally, interviews with professionals were conducted to obtain qualitative data about the industry and its complex functioning. These interviews aimed to understand better the “hidden” side of the industry that antibiotic consumers are not aware. Since part of this research paper is about Canada, having an interview with a Canadian professional added value to the Canadian part.

### **3.1.2 Primary Data Collection**

#### **3.1.2.1 Observation**

The first research method for this paper happened by observations, which started in Canada when antibiotics were handed out in a small refillable plastic container. This resulted in some curiosity since the Canadian antibiotic distribution is not the same in Switzerland. Based on this discovery, further researches were made and led to the base for this research paper. Observations in Switzerland were made on several occasions before this research paper was in writing.

#### **3.1.2.2 Survey Design**

As already mentioned in the first paragraph, the survey had the goal to gather consumer insight and habits. It also intended to understand how brand sensitive Swiss citizens were for their medication, and how often they favored generic medication over branded medication when available. Furthermore, it was to find out if there was any correlation with the mandatory health insurance and the antibiotic consumption of Swiss citizens.

The survey was written in French, English and German to get a higher response rate within Switzerland. The first part consisted in understanding the demographic setting to see if it had any impact on the outcome and if a trend could be observed. This was mainly to confirm the results found in the literature review. The second part was to gather information about the health insurance company as well as their monthly premium and deductible. The last part was mainly about antibiotic consumption habits and what happened with an antibiotic surplus.

### 3.1.2.3 Qualitative Data through Interviews

The interviews, on the other hand, had the goal to obtain an overview of various professionals in the field. By collecting qualitative data through these interviews made it possible to understand the implications and the complexity of the pharmaceutical industry as well as the distribution system for antibiotics that is not always accessible. The interviewees were carefully selected to get various point of views. The selection of suitable candidates was mainly made in Switzerland and one person from Canada. A total of five professionals were interviewed for this research paper.

A template was created to ensure that the structure was consistent as well as to provide a structure and continuity for the interviews. To write pertinent questions, each interviewee was individually looked up on the internet better to understand his or her role and professional experience to design relevant and individual questions.

Following persons were interviewed:

**Table 3 – Interviewed Professionals**

Name	Company	Role in the Company	Industry
Ernst Niemack	VIPS <sup>37</sup>	Director	Pharmaceutical
Laurie Doyle	Shoppers Drug Mart	Pharmacist	Pharmacy
Virginie Di Biase	Canton of Neuchâtel	Cantonal Pharmacist	Cantonal Government
Doris Corda Penna	Eli Lilly	Regulatory Affairs Manager	Pharmaceutical
Sébastien Marti	PharmaciePlus Marti	Pharmacist	Pharmacy

### 3.1.3 Secondary Data Collection

Secondary data was mainly used for the first part of this paper. Using secondary data is crucial to understand how the industry functions, as well as consumer and production

<sup>37</sup> Swiss pharmaceutical trade organization



data that could not be collected otherwise. It also helped to put the theoretical framework and scope for this research paper mainly through online articles, statistics and reports as well as legislations and guidelines. Each source was carefully selected, and the authenticity, as well as accurateness of the information was weighted out to avoid false information. Most sources were double-checked and confirmed by at least another source to ensure the data used was indeed accurate.

#### **3.1.4 Data Collection Limitation**

Several observation phases in Canada and Switzerland were planned early in the research phase, however, due to the current COVID-19 pandemic and its associated health risks, it was decided not to conduct these extensive observations for health reasons. However, some observations were possible before the validation of this research subject.

## 4 Results

### 4.1 Interview Summary

Due to the COVID-19 situation, all interviews were conducted over the phone or skype. The interview questions were all tailored based on the interviewee's position, industry and country. The interviews were conducted to fill the gaps and questions raised in the literature review conclusion. It was decided to display each interview individually since the interviewed parties represented different stakeholder, and it was important to separate each point of view individually. The order of the interviews below is not linked to the order in which they were conducted. Furthermore, the key findings of each interview will be highlighted and further discussed in the discussion and recommendation part.

#### 4.1.1 Interview 1 – Ernst Niemack

This interview was conducted over the phone, with Mr. Ernst Niemack from Switzerland, current director at the VIPS. Mr. Niemack has over 30 years' experience in the pharmaceutical industry occupying different roles in Switzerland and abroad. He has worked for major pharmaceutical companies like Abbott and Mylan and as an independent consultant after creating his own company with his principal mandate being the VIPS. The transcribed interview is available in Appendix 1.

The aim of this interview was to better understand how pharmaceutical companies operated on the Swiss market and understand what was keeping Switzerland to change their distribution system.

Mr. Niemack confirmed several statements made earlier in this paper which were:

- The antibiotic is not a very profitable business for pharmaceutical companies, the profit margin is too small, as prices are low.
- There are little incentives for pharmaceuticals to invest in R&D in the antibiotic category, but rather specialize in more profitable businesses like oncology.
- Switzerland's antibiotic prescription behavior varies amongst linguistic region.
- The distribution of antibiotics varies amongst cantons.

During Mr. Niemack's interview, valuable knowledge was added to the findings in the previous parts of this research paper. He explains the efficiency and necessity of the current distribution system by the dual dispensing method described in section 1.2.6.2 and by the fact that antibiotics packs are done by taking the average and most commonly prescribed treatment as a base reference. In his opinion, the current distribution system

is a high-quality system that is working very well and has a well-working distribution chain behind.

When asking about what he would improve in the current distribution system, Mr. Niemack mentioned sometimes wrong margin incentives by pharmacists where more expensive products are sold to the patient to receive a higher margin. Same for the self-dispensing doctors whose margin is price related.

Regarding the motion 17.3942 mention in section 2.1.6, and the pilot project currently being conducted, Mr. Niemack believes it would be interesting to see the results once the test is over. However, he raises concerns about new regulations following resulting in a complicated restructuring of the production. Mr. Niemack also raised the question of cost benefits behind it, knowing that Switzerland is a relatively small market.

Mr. Niemack made an interesting comment about the fact that about 25 to 30 years ago, patients used to receive the exact number of pills for their treatment.

#### **4.1.2 Interview 2 – Laurie Doyle**

This interview was conducted over skype, with Mrs. Laurie Doyle, a former pharmacist and Shoppers Drug Mart franchise owner from Canada. With over 30 years' experience as a pharmacist in Canada, Mrs. Doyle was a strategic candidate to be interviewed for this paper. The transcribed interview is available in Appendix 2.

This interview aimed to fill in the gaps from the literature review mainly regarding how antibiotics were dispensed in Canada. Another point that need to be filled was about the leaflets for the patients as well as the safe storage and manipulation of the drugs.

Following points confirmed the findings from chapter one and two in this research paper:

- Antibiotics are not covered by the basic health insurance in Canada, and most of the Canadian citizens have private insurance coverage for their medication.
- Confirmed Medicare coverage is only for medical visits, hospital stays.

This interview further clarified several gaps from the literature review. Mrs. Doyle explained that pharmacies receive their antibiotic in bulk format. Depending on the antibiotic, they can come in 100- or 1000-piece containers and only very few antibiotics come individually packed. Regarding the expiry date, Mrs. Doyle explained that there is an expiry date on each bulk container, and it is assumed that if a seven days' supply of antibiotics is handed out to the patient, it will be consumed in seven days after reception of the antibiotics. Mrs. Doyle further went on, explaining the individual packaging process according to the patient's prescription. Pharmacists use spatulas and counting trays when preparing a prescription. The whole process is done manually, and errors cannot

be avoided, but due to a time constraint, double check is not possible unless its tightly controlled or for narcotics.

A further gap was filled regarding the mandatory leaflet for Switzerland, which is not the case in Canada. Mrs. Doyle explained that every patient retrieving prescription medicine would already have had several questions asked by its health physician, and similar questions will again be asked by the pharmacist regarding possible allergies or counter-indications. Some pharmacies use a software that prints out so-called “monographs” which seems to be the equivalent to leaflets, but they are not mandatory, and each pharmacy can decide if they want to hand one out or not. Regarding the allergy check, Mrs. Doyle explained that the system will automatically show a pop-up every six months to ask for any allergies.

An interesting point was raised regarding the follow up of handed out medication. As antibiotics come in batches, not every pill can be recorded and traced individually. Mrs. Doyle explains that even if there is a batch series number, it is not recorded in the patients file therefore, if a medication has to be recalled, every single patient will have to be individually called. Regarding the ratio for the dispensing drugs, Mrs. Doyle estimated it to be around 60 to 40, 60 percent accounting for government coverage for senior citizen and the remaining 40 percent accounting for half out of pocket and half covered by private insurance plans. Mrs. Doyle also underlines that the current system is very time consuming and could certainly some sort of efficiency update. Regarding AMR, Mrs. Doyle is not convinced the Canadian distribution system is helping to reduce AMR, but believes it is mainly in the patient’s hands to take his medication properly. The current system might help in assisting patients to take the prescribed treatment until the end but does not believe it’s the unique solution to AMR.

Further, when addressing the topic of generic medication, it became clear why Canada’s generic consumption was 70 percent. The legislation provides that the lowest cost alternative drug must be dispensed. However, Mrs. Doyle did state that there is a strong belief in the Canadian population that branded medication is better than generic. She did mention a higher frequency in the use of branded antibiotics for children, for antibiotic destined for an adult to use, it will depend on the availability in the pharmacy and the delay if it has to be ordered.

Interesting information came up during the interview, talking about the private insurance companies in Canada, covering prescription drugs. It came out, that both countries had a similar coverage system regarding prescription drugs. Insurances companies covering antibiotics, in both countries, are privately owned and have a deductible between ten and 20 percent.

Mrs. Doyle further talked about the medication pricing and the different prices depending on the country the medication is sold. Canada is suffering from recurrent drug shortage for several drugs, and Mrs. Doyle raised the question if it was linked to the prices each country was willing to pay if countries paying more for a drug would more likely get it than countries willing to pay less.

Mrs. Doyle also addressed an interesting aspect of the prescribing habits of doctors. A tendency was observed, to have longer treatment periods than necessary. She assumed that doctors might prescribe a ten days treatment when seven days would be sufficient by hoping the patient will follow through at least for the seven days. She further explained that pharmacists, at least in Ontario, had the right to adapt prescription, with the patients' consent, if they felt the dosage was not right. Any change in the prescription treatment will need the head pharmacist's approval and will have to be notified to the doctor.

(Doyle 2020)

#### **4.1.3 Interview 3 – Virginie de Biase**

This interview was conducted over skype, with Mrs. Virginie de Biase who is the cantonal pharmacist for the canton of Neuchâtel since the beginning of 2020. Before that she was a pharmacist for the past 20 years. The interview was conducted over skype on the 14.08.2020. Mrs. De Biase was selected for an interview since the pilot project from the Swiss confederation is currently being conducted in the canton of Neuchâtel. The aim of this interview was to understand how the pilot project was being run, what are the challenges linked to it and if there was any feedback from the field already available. A more detailed summary of this interview is available in Appendix 3.

Unfortunately, the pilot project had to be interrupted for eight weeks between mid-April to mid-June 2020 due to the COVID-19 events. By the time of the interview, there was no available feedback from the field regarding the pilot project progress. Several points already discussed earlier were confirmed by Mrs. De Biase amongst others:

- The antibiotic market was not an interesting market due to low margins and short treatment periods.
- Most of the antibiotic production is being outsourced to China and India
- Drug shortage is an essential problem for Switzerland
- Returned medication is destroyed, and none of it is sent to third world countries anymore

The main focus of this interview was on the pilot project to understand what the intention of the Swiss government was, and how it was conducted. It came out that the main focus for the Swiss government was to fight AMR and not an economic interest. As already

mentioned, the antibiotic industry is not profitable. Regarding the project itself, it is in the phase of feasibility, if after this first phase of testing, the answer is positive, the second phase will be to find solutions to implement it on a national scale. Indeed, since Switzerland has different ways of dispensing medication, it would have to review the whole distribution in place, especially for the cantons where doctors hand out the medication directly to the patients. Mrs. De Biase underlines that this will be a major challenge and feels that there might be some opposition if the pilot project goes into the next phases.

Regarding the pilot project, and how it was conducted in selected pharmacies is still from an economic point of view not beneficial at all, since pharmacies still receive the antibiotics within their blisters and will dispense them within their original cardboard box without any price difference. In other words, if the blister has some sort of perforation, which enables a safe removal of the excess pills, the exact amount of antibiotics will be handed out to the patient. However, if the blister has no perforation, no pills will be removed, and the box will be handed out with all the antibiotics. Mrs. De Biase explained this practice with safety and health issues, to avoid confusing the patient regarding the number of antibiotics already consumed and also to prevent raising scepticism about the medication itself.

(De Biase 2020)

#### **4.1.4 Interview 4 – Doris Corda Penna**

This interview was conducted over the phone with Doris Corda Penna, Regulatory Manager at Eli Lilly Switzerland, on the 20<sup>th</sup> March 2020. Mrs. Corda Penna has a PhD in biochemistry and has been working in the pharmaceutical industry since 2001 in several departments such as governance, quality. Since 2006 she is responsible for the regulatory affairs department where she mainly concentrates on oncology. This interview was conducted with the aim to grasp the implications and challenges from a pharmaceutical point of view. Further, it was to understand how the antibiotic packaging process functions. The interview addressed several topics going from the packaging used in Switzerland, what regulations the pharmaceutical companies had to follow and the logistical aspect behind the distribution process. A more detailed summary of this interview is available in Appendix 4.

Mrs. Corda Penna first started by explaining how the approval process worked, and that every change had to be communicated to Swissmedics. Regarding the change in distribution system it would mean that the pharmaceutical company would have to send a report about the stability of the drug in the new packaging form, which means that six to 12 month tests would have to be done to ensure that the medication does not change

in the container stored. This would result in a very time consuming and a complex administrative process.

Linked to that, she explained that the Swiss market was very regulated compared to other countries. She also stated that the main constraint was the mandatory leaflet for every sold medication on the Swiss market.

Regarding the dosage of antibiotics, she affirms that most of the packages are corresponding to an average treatment period. She further explained that the prescribed dosage would depend on a patient's weight, his age, and the severity of the illness, which can cause variations in the prescribed dosage. Mrs. Corda Penna used the antibiotic co-amoxicillin, which is the most common and used antibiotic on the Swiss market. Some interesting points were also raised regarding the distribution to hospitals where the hospitals receive so called "uni-dosage" prepacked blisters, meaning that each pill from the blister will have the drug name, dosage and other important information to help the hospital staff gain time and avoid any confusion when dispensing drugs to the patients. Mrs. Corda Penna also underlined that compared to Switzerland, Canada, and the US had a specific infrastructure in place in the pharmacies to enable such distribution system to work efficiently.

The interview was concluded by the fact that changing the distribution system would mean massive changes, especially for the pharmacies and pharmaceutical companies.

(Corda Penna 2020)

#### **4.1.5 Interview 5 – Sebastien Marti**

This interview was conducted with Mr. Sebastien Marti, owner of the pharmacieplus in Cernier, the Canton of Neuchâtel. It was conducted over the phone on the 15<sup>th</sup> August 2020. Mr. Marti has a PhD in pharmacy and also worked in R&D. After several years in R&D, Mr. Marti obtained his MBA in the USA, and is now the owner of the pharmacieplus in Cernier, in the canton of Neuchâtel (pharmacieplus Marti 2019). This interview was conducted to get a feedback on the pilot project conducted in the canton of Neuchâtel. Furthermore, interviewing a pharmacist helped to understand better the day to day constraints and challenges linked to the distribution of antibiotics. The interview was composed of two parts, one about the pilot project and the other about the antibiotic distribution in pharmacies. A summary of the interview can be found in Appendix 5.

The pilot project was conducted in 13 different pharmacies throughout the canton of Neuchâtel, where each pharmacy was asked to record around 50 cases. To dispense antibiotic by its exact amount of pill, the client has to sign a form, which brought to light that many times a friend or relative was retrieving the prescription and the procedure could not be conducted. Mr. Marti also noted that many times the treatment prescribed

by the doctor was corresponding to the available packaging size, and no manipulation was needed. Mr. Marti further explained that this pilot project, at least for his pharmacy, was time-consuming for him and his three other pharmacists. He mentioned the fact that only pharmacists were allowed to manipulate antibiotic packages, which brought additional work to their already busy schedule. When asked about the overall conclusion after this pilot project, Mr. Marti underlines that for the moment, with the current setting, the tested distribution system was resulting in more constraints than actual benefits, and several changes would have to be made, but process himself was not complicated, just time consuming. Mr. Marti roughly estimated that only around 20 percent of prescription were adapted but underlining that he works with three other pharmacists and did not have a global overview at this point of the project.

Regarding the second part of the interview, Mr. Marti explained that the antibiotic treatments that need the most modification are the ones for children, as the dosage has to be adapted to the child's age and weight. Other than that, Mr. Marti observes a relative exact fit between what the doctor prescribes and what package size are available. For the question regarding what doctors prescribe and what the pharmacies hand out, Mr. Marti explained that some doctors prescribe the branded medication but the pharmacies will discuss with the patient for better alternatives and also inform the patient that branded medication might have a higher "quote-part" when reimbursed by the health insurance company compared to generic medication. He further stated that, doctors who were practicing only since a few years tend to write the active substance and the pharmacist can hand out the correspondent antibiotic.

Finally, the most common and sold antibiotic active substance is co-amoxicillin and Mr. Marti compared the several brands available for a 625mg dosage and a 20-pill pack. Out of the six results, Zentiva, Helvepharm, and Axapharm were all three priced at CHF 28.35. Sandoz priced for the same package CHF 29.-. Mepha, which is not sold by Mr. Marti's pharmacie has its price at CHF 37.10, almost as expensive as the original called Augmentin<sup>38</sup> with a price of CHF 39.70.

(Marti 2020)

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<sup>38</sup> Augmentin is currently sold by GlaxoSmithKline (*compendium.ch* [no date])

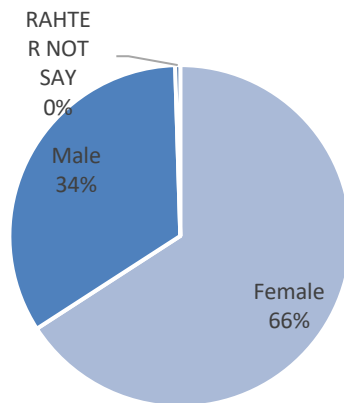


## 4.2 Survey Analysis

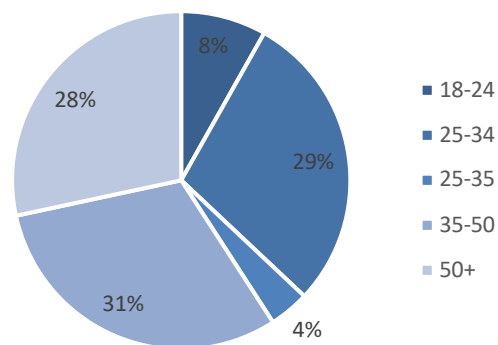
### 4.2.1 Demographic Survey Analysis

The survey resulted in a total of 208 answers throughout Switzerland. The survey results show that the majority of responses were by Women, accounting for 66 percent of the answers. Furthermore, regarding the age of the responders, three age classes are standing out. This can be explained by the distribution channels chosen for the survey. Facebook, Instagram, and targeted emails were the main channels used to collect survey responses. Relatives and friends further shared the survey with their entourage to gather a maximum of answers. This is clearly reflected in the age range results, accounting for almost one third for each of these channels. A total of 300 responses was targeted, resulting in a 69 percent answer rate with 208 responses.

**Figure 14 – Gender**

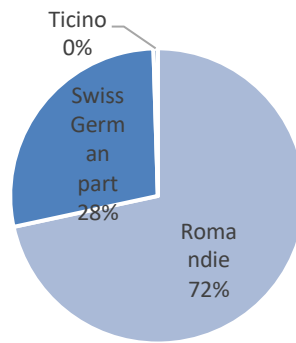


**Figure 15 – Age**



Similar explanation goes for the respondent's region of residence with two third of the answers coming from the French-speaking part of Switzerland and the remaining answers from the Swiss German part, leaving the Italian speaking region without answers.

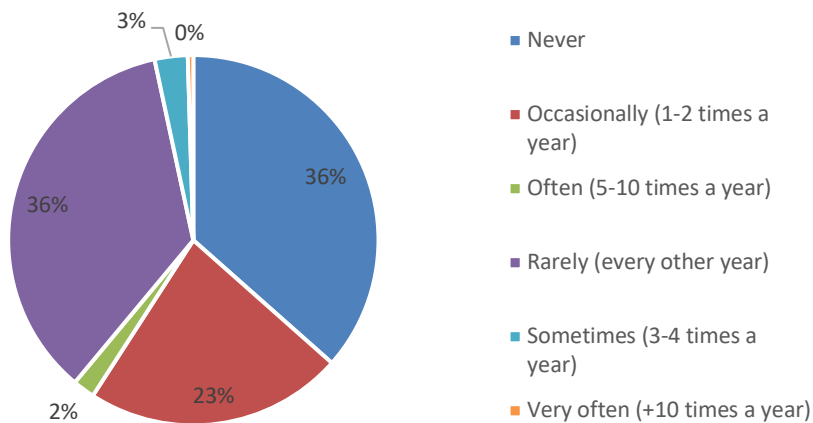
**Figure 16 – Regions in Switzerland**



#### 4.2.2 Antibiotic Consumption Analysis

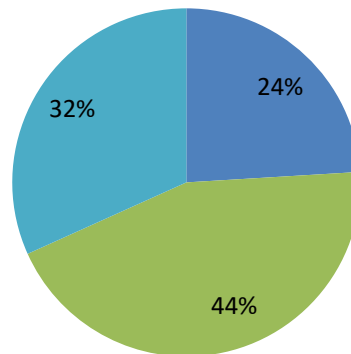
Regarding the question about the average use of antibiotics over a year, a total of 76 person answered with “never”, representing more than a third of the answers. This graph also highlights that antibiotics consumption is relatively low, with 95 percent consuming antibiotic less than three times a year, and only one answered with “more than ten times a year”.

**Figure 17 – Yearly Antibiotic Consumption**



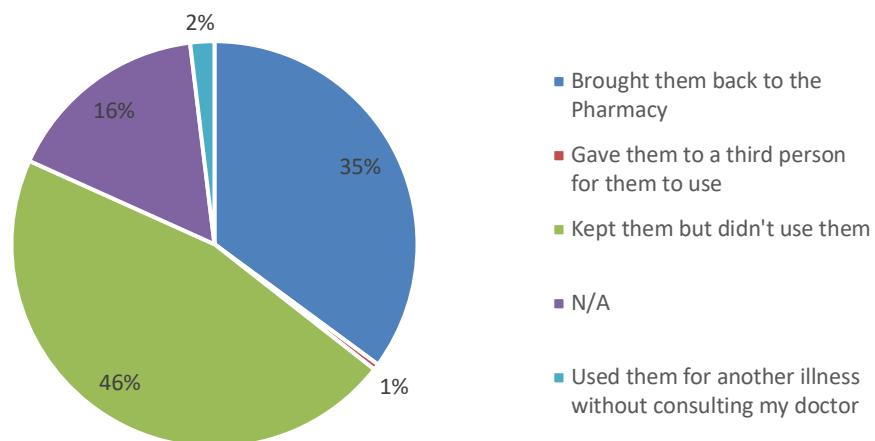
**Figure 18 – Tendency to receive more Antibiotics**

■ Don't remember or didn't pay attention ■ No ■ Yes



The result above shows that slightly less than one fourth of the surveyed do not remember if their received antibiotics was corresponding to the prescribed treatment, narrowing down to 158 the ones who remember. By taking the 158 answers as the new 100 percent, almost 60 percent received the exact number of pills for their treatment, compared to one third not obtaining the right number of pills for their treatment.

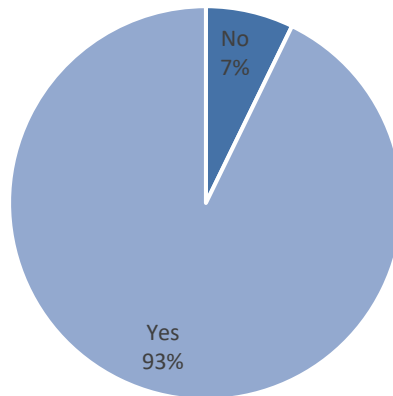
**Figure 19 – Behavior with unused Antibiotics**



Out of the 66 people receiving too many antibiotics, 46 percent kept their antibiotics without using them. It was reassuring to see that only two percent used their unfinished antibiotics for another purpose than the prescribed treatment. Finally, more than one third of the surveyed brought their unused antibiotic back to the pharmacy for a safe disposal.

Nevertheless, the graph from Figure 18 shows that no matter the previous given answer, more than 90 percent of the surveyed are favorable in receiving the exact number of pills.

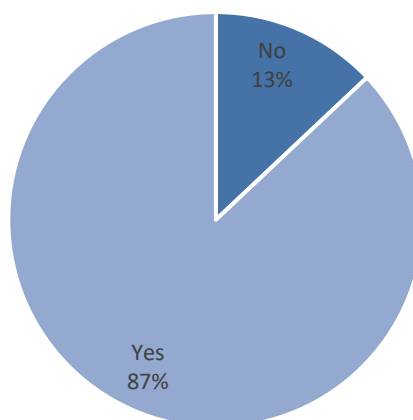
**Figure 20 – Exact Number of Pill Favorable**



### 4.2.3 Generic Acceptation Analysis

This graph shows the general acceptance of generics in the Swiss market, which also confirms the steady increase of generic consumption in Switzerland for the past years, previously explained. This graph shows that nearly nine persons out of ten in Switzerland favor generic medication over branded, when available. This might also tightly be linked with the fact that branded medication can have a higher “quote-part” than the generic alternative.

**Figure 21 – Generic over Branded Medication**



## 5 Analysis

After the introduction of the health industry with its key stakeholder being the pharmaceutical companies, the role of the government and different authorities, the pharmacies and drugstores, the health insurance companies, the hospitals, and the doctors, it is clear that this industry is very complex. All these stakeholders play a crucial role in the current health system, both in Canada and Switzerland. Each one of them has its responsibilities and duties and only if all collaborate on a daily basis, can such a complex system function. Specific setting, regulations and constraints are part of the daily duties that each of the above-mentioned stakeholder tries to satisfy. The different stakeholders do have different interest as a driving force, pharmaceutical companies will have new drug discoveries and ensuring that their drugs are available where needed, governments will have their citizens interest as their driving force and will make sure there is a win-win situation. The government probably has the most complex role in this setting, as it has to deal with the other stakeholders by trying to find the best possible solution for all the stakeholder and make sure none of them is left out. Health insurance companies are facing increasing health costs and have to adapt to the steady change.

A global overview of the pharmaceutical market enabled to understand the importance of this industry, not only from an economic point of view but also from a scientific aspect regarding R&D in the medical world. The second part of this paper highlighted the antibiotic industry as well as its challenges and regulations. This research process also raised some questions that were tried to be answered in the primary data collection part through several interviews and a survey. The most important and relevant points were highlighted throughout that fourth section and will be further discussed in this section. This last section also intends to discuss the feasibility and economic gain a change in the Swiss antibiotic distribution system would bring.

### **5.1 Interview Key Findings**

The outcome of the different interviews and their key findings will be further discussed in this section as well as the gaps they filled. The table below is an overview of the different parties interviewed and will be referred to as “Interview” and the corresponding number.

**Table 4 – Interview Overview**

Interview	Name	Industry	Appendix
1	Ernst Niemack	Pharmaceutical	Appendix 1
2	Laurie Doyle	Pharmacy	Appendix 2
3	Virginie de Biase	Government / State	Appendix 3
4	Doris Corda Penna	Pharmaceutical	Appendix 4
5	Sebastien Marti	Pharmacy	Appendix 5

### 5.1.1 Change the Distribution System

The complexity of the Swiss dispensing system with its dual dispensing form through doctors or pharmacies according to the canton seems to be a major barrier to consider a change in the distribution system according to interview 1, 3, 4, and 5. They also raised concern about the actual benefit a such important change would bring, considering the small market Switzerland represents. Interview 3 underlines the challenge it would be to change the distribution system as well as the high resistance it could encounter from the cantons with dispensing doctors. Interview 4 stressed how regulated the pharmaceutical industry was and how every, even slightest change, had to be communicated to the corresponding authority. Main concern here was raised regarding the unsafe storage of antibiotics in bulk format.

### 5.1.2 Pilot Project

Interview 3 was mostly focusing on the pilot project to understand how it was conducted. It resulted in, as what seems as the main barrier, the dual dispensing mode in Switzerland being a problem for the pilot project. Indeed, the canton of Zug was not selected for the pilot project due to its dispensing mode through its doctors directly. Interview 3 confirmed that the aim of it was not to reduce waste but to reduce AMR. Interview 5 was very insightful regarding the actual implementation of the pilot project. Which turned out to be a laborious process. A strict process was put in place for the pilot project and it turned out to be time consuming especially for pharmacists. Another concern was raised regarding this pilot project with the fact that only pharmacists were allowed to manipulate the antibiotic packs which resulted in additional workload in the already busy schedule of a pharmacist. As mentioned earlier, antibiotic packs seem to most of the time correspond to the prescribed treatment period and therefore the adaptation of the antibiotic packs was not necessary.

### **5.1.3 Accuracy of the Treatment Prescribed versus Available Packaging**

Interview 1, 3, 4, and 5 highlighted the fact that antibiotic packages are done on the most common and average prescription treatment time, which seems to be accurate in most of the cases. Dosage variation most of the time varies depending on the severity of the illness. Most of the time, variation is done for children's antibiotic as the dosage will depend on their age and weight. Interview 5 also confirmed that in many cases, the prepacked boxes did not have to be adapted for the pilot project as it corresponded to the prescribed treatment length. Out of the interview also came, that the most frequent treatment was three pills a day over seven days.

### **5.1.4 Canadian Insight**

Interview 2 explained that pharmacies received antibiotics in bulk format of several hundred pills. Furthermore, the pills are counted manually and is very time consuming, but no double counting is performed. Furthermore, it came to light that even with such distribution method, AMR was very present in Canada. Interview 2 further stated that patients did not receive leaflets with their antibiotics but had a chat with the pharmacist and beforehand with the doctor to make sure the prescribed antibiotic was adequate for their treatment. Regarding the traceability in case of recall, interview 2 brought to light that if a recall happened, every patient that received antibiotic from the same bulk container had to be called individually, a very time-consuming process.

At this point of the research, it is to be questioned if a change in the Swiss antibiotic system would make sense from an economic point of view. Throughout the introduction and the literature review it came to light that the antibiotic industry is not very profitable. The interviews also confirmed that the antibiotic packaging was based on an average treatment and that the majority of prescribed treatment was matching a prepacked antibiotic blister. The outcome during interview 5 confirmed that antibiotics only rarely had to be adapted and if the number of pills had to be adapted it was only for a very little number of pills.

The pilot project seems not to be very conclusive. It seems that the feasibility was compromised by the current system in place as well as the laws and regulations around the distribution of antibiotics. It is to be questioned how the feasibility of a not yet in place system can be successful when no derogation to the current system is allowed.

### 5.1.5 Economic Analysis

Interview 5 confirmed that the most frequent treatment length was seven days and with three pills a day. A simple calculation enabled conclude that 21 pills were needed for the most common prescribed treatment, knowing that boxes are coming in ten or 20-pill packages. This resulted in curiosity of the author to conduct other mini interviews with local pharmacies. One employee in each visited pharmacy was asked, if they estimated that the treatment prescribed was corresponding to the available packages. Both responded negatively to this question and affirmed that the packages were most of the time not corresponding to the needed treatment. At this point, an economic analysis was necessary.

In order to have an idea of the financial impact such distribution system change could have; it would make sense to have a financial calculation done. From the interview came out that the most commonly used antibiotic in Switzerland was the co-amoxilin. During the interview 5, the dosage of 625mg and a 20-pill pack was used as reference to compare the different prices, which will also be used as a reference for the following calculation. The aim of this economic analysis was to estimate how much could be saved by dispensing exact number of antibiotics.

The table below shows a possible cost saving calculation based on the average yearly DDD per 1000 inhabitants in Switzerland. Most of the reference numbers and amounts were taken from the Swiss Federal Antimicrobial Resistance Report 2017(Federal Office of Public Health and Federal Food Safety and Veterinary Office. 2018). Throughout this calculation became clear, that the excess in pills was relatively significant and that for a 21-pill treatment to be done entirely, almost a whole 10-pack pill had to be wasted. Indeed, treatment length vary depending on the severity of the illness, however, it is surprising to see that such an important number of pills is being wasted per treatment only because one pill is missing in the prepacked boxes. From what came out of the calculation in the table above, Switzerland could save up to CHF 67 million only with the co-amoxilin antibiotic prescriptions. This calculation shows that there is an inefficiency in the Swiss antibiotic distribution system. It also opens new research topics to estimate how much could be saved if the exact treatment was dispensed also for other drugs such as OTCs.



**Table 5 – Possible Cost Savings Calculation for Co-Amoxilin**

		Calculation	Result
Total consumption	10.7 DDD per 1000 inhabitant	$10.7 \times 365$	3'905.5
Total Swiss population 2017	8'420'000	$8420000/1000$	8'420
Annual total consumption in pills		$8420 \times 3905.5$	32'884'310
Annual consumption in Penicilin in pills	48 %	$32884310 \times 48 \%$	15'784'469
Annual Aomixilin consumption in pills	27 %	$15784469 \times 27 \%$	4'261'807
Available packs on the market	10-pill pack 20-pill pack		
Co-Amoxilin 625mg availability (Helvepharm)	10-pill pack 20-pill pack	CHF 16.60 CHF 28.35	
Number of 10-packs per year		$4261807/10$	426'180.66
Number of 20-packs per year		$4261807/20$	213'090.33
Average price per pill	10-pack	$CHF\ 16.60/10$	CHF 1.66
Average price per pill	20-pack	$CHF\ 28.35/20$	CHF 1.42
Average treatment length	7 days		
Co-Amoxilin average treatment if 3 pills a day		$7 \times 3$	21
Needed packs	3 pills a day treatment	10,20	30 pills, 2 boxes
Excess pills		30-21	9
7 day, 3 pills per day treatment cost		$16.60+28.35$	CHF 44.95
Possible savings	9 pills excess	$1.66 \times 9$	CHF 14.94
Annual Penicilin prescription 2017	1975 per 1000 inhabitant*	$8420 \times 1975$	16'629'500
Percentage Co-Amoxilin	27 %	$16629500 \times 27\%$	4'489'965
Possible savings on a 7 days treatment	9 pills total 14.95	$14.95 \times 4489965$	CHF 67'080'077.10

\* Approximate number read from the graph from Appendix 6

## Conclusion

To conclude, this research paper has answered to some of the questions and gaps raised earlier, however some new interrogations have emerged and could be used for future researches. This research has shown how complex the health care sector is and displayed its most important stakeholders being; pharmaceutical companies, pharmacies, hospitals, health insurance companies, doctors and the government. Changing such a complex and complicated system is not an easy task and requires a thorough analysis including all the parties at stake just cited.

This research enabled to better understand the Canadian and Swiss Healthcare system as well as get a better grasp of each of their main stakeholders mentioned in the previous paragraph. It came to light how well organized both systems are, even if they might not be the most optimal systems. A very interesting finding was made for the Swiss dual distribution system, which is relatively unique. Knowing how immense Canada's territory is, it could have made sense to have such a dual distribution system for Canada rather than for Switzerland. This research paper further pointed out that the DDD per 1000 inhabitants in Switzerland varies amongst regions, which could be linked to the dual distribution system currently in place. The research also showed two clear sides in Switzerland. One side being the patients, the health insurance companies and the government, that are financially drained by this current distribution system. And on the other hand, the pharmaceutical companies, doctors and pharmacies that enjoy high profits from this standardized distribution system and would not benefit from a change in the distribution system.

This literature review showed how AMR and drug shortage are a worldwide problem that is not linked to the distribution method of antibiotics and are subject to a lot of discussion on government level for both countries, Canada and Switzerland. The research made clear that AMR is more linked to the little education patients have about how to properly take antibiotics than receiving the exact number of pills. Drug shortage on the other hand is mostly linked to the fact that antibiotics are all produced in very few places, namely India and China which results in a very fragile supply chain. If one factory has to shut down or encounters any problem, it can have dramatic repercussions on drug supply for a whole country. Switzerland is trying to address both these subjects by currently conducting a pilot project in Neuchâtel to test the feasibility of dispensing the exact number of pills to patients following the parliamentary motion passed back in 2018. The

aim of this parliamentary motion and pilot project was in a first phase to see the implications of such change.

The gaps that appeared in the introduction and the literature review tried to be answered by interviewing health professionals and through a survey. The interviews disclosed sort of a reluctance to change the current distribution system by those who would the least benefit from it. The interviews also helped understand how the pilot project was conducted and made it clear that the current setting was not in favor of successfully proving the feasibility of the project. The Interviews in Switzerland revealed a very important aspect by explaining that medication manipulation and repacking was exclusively allowed on manufacturing level and doctors did not have that competency, which is one of the reasons why the Canadian distribution system could not be applied as such.

On the Canadian side, the interview helped to better understand the Canadian distribution system and confirmed that antibiotics treatments were prepared individually for each patient directly at the pharmacy. The Canadian interview further confirmed that AMR and drug shortage were very present in Canada and that patient's awareness has to be increased to fight AMR.

The economic analysis done in this paper gave a clear idea of the amount of money that is potentially wasted on a yearly basis just with one antibiotic. Knowing that there are over 100 antibiotics available, by changing the distribution system could help the health insurance companies as well as the consumer save millions of CHF a year, this not to mention if the same would be done with non-prescription medicine.

### Recommendations

Based on what was stated in the literature review, the distribution systems of both countries have their strength and weaknesses. If Switzerland seriously considers changing its distribution system several points should be considered. If Switzerland wants to keep their blister for health and safety reasons, using the same blister packaging such as hospitals do would be an option. Indeed, in one interview it came to light that hospitals received their blister already pre-cut and with individual medical information printed on each blister to ensure a safe and correct use of the medication. This would not only ensure the stability of the pill, but it would also allow a quicker process for the dispensing pharmacies and doctors. Several interviewees claimed that the current blisters were adapted to the most common prescribed treatment, however, this paper showed that the currently available blister packages were not adapted to the most currently prescribed treatment. Therefore, rethinking the number of pills as well as the pill alignments inside the blister could be considered to reduce pill waste.

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If Switzerland decides to consider a dispensing method without blisters, an automated process could be designed to ensure a lower error rate as well as a hermetic preparation, once again to ensure the stability of the pill. This automated process could be done in partner with engineering schools based on a competition to promote innovation. In both cases, it would make sense to review the current laws in place, not only to enable doctors and pharmacy staff to be able to repack antibiotics, but also regarding the mandatory leaflet. Another interesting law revision would make sense for the generic pricing in order to make it financially more accessible, but also in order to set a ceiling price for generic products to see a concrete price difference with branded medication.

#### Further research

This paper has mostly focused on the savings that could be done from a pill perspective. Further research could be conducted on a more sustainable aspect regarding the packaging of medication. It would be interesting to further research the packaging direct and indirect costs as well as how the packaging process could be done with more environmentally friendly materials or how to reduce packaging waste.

Furthermore, the economic analysis made for co-amoxicillin could be extended to all available antibiotics on the Swiss market to have a more accurate amount of possible savings. Additional research could be conducted for the number of wasted pills for non-prescription drugs as they also come prepacked and their treatment might also not be adapted to the number of pills available in the prepacked box. This additional research could be done by starting to analyze the most common prescription duration compared to the available packaging formats available on the market.

The literature review and the interview have shown that the pilot project might not have been successful in its feasibility test and further research would be make sense to better understand the reason for its low success as well as how to make it successful in order to be continued.

Findings about AMR showed that AMR is not specifically linked to a particular distribution system but more a global problem and pursuing supplementary research on how consumers can be better educated about antibiotic consumption would make sense to better understand how AMR can be fought efficiently.

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# **Appendix 1: Qualitative Interview with Ernst Niemack, Director of the Swiss Pharmaceutical Trade Organization (VIPS), 15.04.2020**

E.N: Ernst Niemack

S.J: Sophie Janett

S.J: So, maybe first about myself. So I'm last year student at the HEG in Geneva, in International Business Management bachelor. And so I did my previous year in Canada where I did one year as an exchange students. And when I was there, I had to take antibiotics. And I discovered a whole new way of distributing antibiotics. And when I got back to Switzerland, I was like, but why don't we do the same here? Like, why are we wasting so many pills?

E.N: How do they do that?

S.J: I was pretty surprised when it happened the first time because I didn't understand but you basically go to the pharmacy or the drug store, you give your prescription and they tell you to come back in half an hour. And when I heard that I was like, but why can't you just give the pack right now. So then when I got back half an hour later, I received a little plastic box with the exact amount of antibiotics that I had to take. And I had a short discussion with the pharmacist to explain how I was supposed to take them. And so, I had the exact number of pills I actually needed for the treatment, which really helped me because I'm kind of sometimes forgetful, and I never really, sometimes I'm, I'm afraid I will forget one pill or something. So yeah, I found that really a great way to distribute antibiotics. And I thought why not? Maybe try to explore it a little bit more for my final paper for my bachelor.

E.N: Okay, interesting. Yes. So you get no leaflet, about side effects nothing,

S.J: Actually, they just assume that you discussed that with your doctor beforehand and that he prescribed the antibiotics knowing your allergies and knowing the patient. So, I actually without really thinking about that on the moment I brought back one of these little boxes and it literally just says, Who prescribed it and how to take it. So, I have just taken one tablet four times a day and if there are any refills necessary or not, and the name of the antibiotics. And its a reusable little box that was made out of recycled material I think so. Yeah, I found that really interesting.

E.N: Interesting. Yes.

S.J: So yes, that's how I came to my subject. And now about you. Could you maybe introduce yourself, maybe talk how you started in the pharma industry? I saw you did most of your career in different pharma companies.

E.N: Exactly. Yes. Yes, I started in the pharmaceutical industries for more than 30 years. I started as a sales rep. And then after, after a couple of years of sale, I changed to the diagnostic industry. There I worked for eight, nine years. And then I wanted to come back to the pharma. I continued as national sales manager and then I already had all commercial positions in the pharmaceutical industries. And at the end I was General Manager for Abbott and Mylan, responsible for Switzerland and Austria. And two years ago, a little bit more I decided to found my own company. And now I'm self-employed as

a as an independent consultant. But my main mandate is the director of the pharmaceutical trade organization. So this islet's say 95% of my time is spent with leading pharmaceutical trade organization.

S.J: okay. And during all these years in pharma were you mainly focusing on the Swiss pharmaceutical market?

E.N: So most of the time I was here in Switzerland, but the last four and a half years, I was working for Abbott and for Mylan, I also was responsible for Austria. I had a team here in Switzerland, of about 35-40 people and the same size of team, I also have in Austria. So, and I travel back and forward. So, I'll say interesting experience. Yes.

S.J: Okay. And during all these years, did you have any direct? Not contact, but were you at one point responsible for, for example, an antibiotic distribution or in direct link with antibiotics?

E.N: Yes, of course it was one of our main products in the beginning when I started with Abbott, but it was one of our main products, Clarithromycin.

S.J: Okay. And knowing that these companies are mostly international companies who also do sell in the US and in Canada, is it I mean, because I'm trying to understand what makes it so difficult to implement a new distribution system in Switzerland knowing that most of the big pharmas they are actually in other countries where this kind of distribution system already exists, and so I'm trying to understand like, since they already have the know-how and they actually do it. What keeps them from also doing it in Switzerland, if it's only legal basis? Or if there's something behind that. Is it more I guess it's more profitable to do it actually this way in Switzerland.

E.N: Yeah, pain for whom it is, is profitable. So to be honest, the antibiotic market now is from the financial point of view, it's a niche market. So it's not, that there is not a big margin. So the prices are so low, so deep, and the Big Pharma are not interested in doing antibiotics anymore. Because there is almost no research and development on this. You don't get any fair price, fair reimbursement for all these products. And if you have a new product, the it's a research product, nobody wants to use it. So everybody wants to keep it in backhand if the common antibiotics are not effective anymore, so everybody wants to keep it in backhand, let's say. So this is not a let's say a financial driven market and most of, or the main reason is that you do have legal restrictions, so so you have regulations you need a pack you need a leaflet you need primary package secondary package for the product in three languages and you also have GDP guidelines, good distribution practice guidelines and here in Switzerland and also in Europe, so all these all these points makes it easier to handle it like it is. also, for pharmacists and for doctors so you have a self-dispensing system in the eastern part of Switzerland for example, when doctors If the antibiotics or the pill directly to the patient, and in the French part, you mainly have a prescription market and to handle all these different systems, it's easier to a half a pack. And mostly you have the right size for the therapy.

S.J: Okay, yeah, that's true. I also had an interview with a person who works for Eli Lilly. And she told me a similar answer about the fact that these packs are pre packs for a specific therapy, and it does fit a certain therapy but again, as the antibiotics are used for several ones, sometimes it's not the case, and that one pack is not enough.

E.N: Yeah. But not enough or too many pills in it. That's right. It's possible Yes, it's possible. So, so, sometimes you have for class E (11:10), clarithromycin, you have different indications for a one indication you need seven pills and for the other one you

need 14. So, though if you if you get packed with 14 pills in it for the wrong indication, then of course you have too many pills. the main reason is practicability and not financial aspects behind

S.J: yeah to fit both markets and how they actually dispense the antibiotics.

E.N: Yeah, margin is too low. The market is too small. Switzerland is too small for doing an own system. So, it's not interesting from the financial point of view.

S.J: Okay. And since you started in the pharma industry, have you seen any major changes? in general?

E.N: Yes, of course, now the pharmaceutical industry is totally different. Or had a huge change over the last, let's say 10-15 years, so tons of new regulations. The pharmaceutical industry has a totally different image compared to 15 years ago. There is a globalization behind due to decreasing prices decreasing margin, the pharmaceutical industry had to adapt and to overcome, they had to cluster the production sites to bring the production sites to Far East for API's or for the product. Then there is there is a move from primary care health care to highly specialized medicine, personalized medicine, for example, in rare in a rare disease area, the older healthcare systems are under high cost pressure. So, this is a huge change and for the healthcare systems, it's easy to bring down the pharma prices compared to closed hospitals. So it's easy, it's much easier to implement and this has a huge impact to the pharmaceutical industries. So margin are decreasing and this leads into mergers of different companies. For example, we had over the last years but also specialization of the companies. So, as you may know that you mentioned Big Pharma that sort of the big pharmaceutical companies, they are very specialized. For example, Roche is specialized in oncology. They sale all the arrays for example, OTC products they sold the old established products for the whole primary care sector they don't have anymore, they focus on rare disease or oncology and same thing with AbbVie and Abbot, I was responsible for the split between Abbott and AbbVie. AbbVie is only specialized some rheumatology oncology, HIV and these products and all these big pharma really big pharma they are they are more or less specialized.

S.J: Okay, And I also saw that some of these big pharmas groups they also own some generic companies like Sandoz, so in the end the day the generic industry is I mean is mostly owned by some big pharma company. So, they kind of like work still together. It's not against.

E.N: Yeah. So you're right. Sandoz is owned by Novartis. But, but for example, the second big player here in Switzerland or also in the United States is Teva or Mepha. And this is an independent generic company so far. Then the third one also a big player is Mylan. They build now a new company together with the Pfizer portfolio and this is a totally new company named Viatris. Just founded right now in these days and there and you had a generic part from Sanofi I think but, but they want to split it from their core business and also Novartis, Sandoz is owned by Novartis, that's correct. But about Sandoz is working totally independent from Novartis. And it looks like that the Big Pharma is not very interested in the establishing because you have decreasing prices everywhere and the margin is not that good.

S.J: And how do you see the current Swiss distribution system of antibiotics or medication in general?

E.N: So in general, it's a fantastic system. So it's a high quality distribution system. You have almost no counter fights through the official channels. You have some dominating wholesalers. So, a little bit a disadvantage, there is a limited market, let's say yeah, two,

three, maybe four important wholesalers dominated by one, but the quality is very good, you have a fantastic distribution chain behind, it's very professional. The products are available, more or less on the market. And if not, they are able to bring the product into the market. So the quality is high, but you're right, the costs are also higher compared to other countries. That's correct.

S.J: And do you see any improvements that could be done or any suggestion?

E.N: Improvement maybe, maybe there is in distribution margin a wrong incentives in it, let me give you an example if the pharmacist is selling a product for 100 francs it's distribution margin is higher compared to a product if he gives the product for 50 francs. So, there is a price related margin behind. So, the interest for pharmacies is higher to give them more expensive products to the patient. There is not a fixed margin.

S.J: okay. So that could actually push the pharmacist to prefer more expensive products just to have a higher margin.

E.N: Exactly.

S.J: And is that also the case for doctors?

E.N: for self-dispensing doctors of course, yes. They are more and more on pressure from the healthcare system and from the healthcare insurance companies, and there are many discussions to change this distribution margin and take out this wrong incentive behind it. because for pharmacies, it doesn't matter if he gives, for example, an expensive antibiotic or a low price antibiotic as long as the quality is the same.

S.J: And I don't know if you have the time to look, or probably you're aware of the motion that was accepted last year, about selling the medication in single dosis? I think it was accepted. Yeah. Last year in September. I don't know if you if you heard about it.

E.N: Yeah, of course, yes. Or no, this was in 2018

S.J: they actually are testing it right now in in Neuchâtel. Yeah. I don't know. How do you see this pilot project? Do you think it's going to work?

E.N: possible, Yes, why not? So it's interesting therefore they run the pilot right now and afterwards we can see if it's worth doing it but I'm not sure that the impact is that high that you have a real benefit behind. My theory is a little bit that there is a new regulation afterwards, that makes it much more complicated and it makes it much more difficult to handle it. So now it's easy to handle and i'm not sure that there is that there really is a huge benefit for Switzerland because, as I already mentioned before, it's a small market, it's not that much money behind, the cost saving effect is not that high and for sure, we don't need further regulation. And now there are some legal restrictions behind, of course you can change it if the pilot is successful, we are the last who are against a new approach. But yes, there must be a benefit behind. And I'm not sure that the cost benefit ratio is good enough. And of course, you have to take the safety aspects into account the GDP regulations you have to respect so you can't exclude only antibiotics from total system. And when I started in the pharmaceutical industries, let's say 25 years or 30 years ago, doctors already had the single dose system so if you had headache, you got five pills. painkiller from the doctor. Yeah, glasses with 3000 tablets in it. And then you got the envelope with five pills in it. This, we already had 25 years ago.

S.J: Yeah, I experienced that in Bolivia last summer where I had the flu and I went to the pharmacy and I was expecting to buy a whole box and she just asked me how many pills

do I want? So I said, oh, maybe three or four. And she just cuts them out of this aluminum plastic. And I just received the exact amount I asked for.

E.N: At least you had a blister. Only the pills, the quality is not good. So, here you also have safety aspects behind.

S.J: because from what I understood in this motion is that they mainly want to go against antibiotic resistance. And I think you also talked about it earlier about the fact that more and more people do get resistant to antibiotics because they might also take the treatment not as they should. So do you think that by having a new distribution system where you have the exact amount could help on this point?

E.N: So, as we already mentioned, many antibiotics already have the exact number of pills in the pack for therapy. The problem is that the briefing from the doctor or the pharmacy is not good enough. Or if the patient takes, let's say, three pills and he to take seven or 10 pills, and after three days or after four days, he is becoming better and better, and then he thinks, okay, therapy is over, I stop with the antibiotics. And then he has the disease coming back. So, I'm not sure that this is really the right solution for decreasing the resistance.

S.J: So the main problem is mainly the patient who don't take their treatment as they should?

E.N: Yes, so you just have another form, you get the pills. So either in blisters or in an envelope. So what's the different? Maybe after the right number of pills, maybe? Yes. Maybe you know that you already have taken the pill today, or that you forgot the pill. Maybe this is easier, but I'm not sure that this is the right solution for reducing the resistance but maybe maybe there are data from other countries that shows us a different picture and then we have to try Why not?

S.J: That is very interesting to maybe see with the countries like the US or Canada who have this exact pill system to maybe check how their resistance report looks like? I didn't think about that.

E.N: So for example in Switzerland we see huge differences in the prescription behaviors of antibiotics. We see that in the southern part or in the French part, the doctors are much more willing to prescribe antibiotics compared to German part. We also see in countries like Italy or Spain, they prescribe antibiotics without any thinking about if it's necessary or not.

S.J: I had that with a Brazilian friend. I had a flu one day one or two give me some random antibiotics they had from Brazil and I was like, No, no, no, no. I'm like, Yeah, I totally understand. Yeah.

E.N: So, the behavior here is important and not the distribution.

S.J: So maybe there would be more like them. The government should put more effort into better educating the population?

E.N: They tried over years and the numbers of prescriptions, they are decreasing every year. Depends a little bit if you have a seasonality are not in it, but the use of antibiotics is decreasing. The problem is that you already have a certain resistance here in Switzerland, and there are no new antibiotics. Who are coming on the market anymore.



S.J: Yeah, I read something about that when I was researching more about the antibiotics themselves. And if I remember, right, all the antibiotics that are currently produced and sold are only from 10 parents of antibiotics. So I believe that by not putting more effort in researching for new antibiotics, at one point, if we don't do it, we'll end up all resistance to these 10 root antibiotics. Can we say it like that?

E.N: Yes. Yes, you can say it like that. And if there is a new antibiotic, nobody wants to use it because everybody wants to keep it in reserve.

S.J: In case there would be this huge resistance and then they could come up with the new ones?

E.N: exactly. And therefore it's not the interesting thing. So if you email a pharmaceutical company investing in a new product it costs from finding the substance to the market authorization it costs on average 1.2 billion and takes 12 years. And then you bring it on the market, you don't get a fair price from the health care authorities, you don't get good patent protection on it. Then the market says, OK, we are happy to have this product, but we don't use it. We only use it if the other antibiotics are not effective anymore. So it's not an interesting business model.

S.J: So that means that they could already be some new antibiotics discovered but they are kept in the shadow and will be only introduced if we should face a major resistance in a few years. So we're waiting for a catastrophic event.

E.N: Hopefully not, but this is the case. So therefore, the pharmaceutical industry is not interested in researching.

S.J: So, it's kind of the same like we have right now with the COVID-19. They haven't really made any effort to maybe research for some vaccinations.

E.N: that's a little bit different because a virus is changing his form every, not every day but every, every couple of months. So, you cannot develop a vaccine in advance, you need the virus and then you can researching a vaccine, therefore it takes time now, they talk about 12 to 18 months this is fantastic. But, but you have to know the virus you can't develop a vaccine. If you don't know what kind of virus you want to vaccinate.

S.J: Okay, makes sense. Okay, so just to have a quick summary of what we discussed. So basically, the antibiotic market is a niche market that has not a big margin. And it's not really interesting anymore for big pharma's, as we just discussed, because they're not gonna sell anything new right now because nobody's gonna buy it. And the problem too, in Switzerland is that we do have two different ways of distribution, the French and the German parts and the current system is kind of working for both right now. And it also fits to all the regulations, actually about the regulation. I was trying to find where I could find all these packaging regulation and I am not sure if I actually got them right. I don't know if you have them in mind more or less.

E.N: You can find it on the Swissmedic homepage.

S.J: Swiss medic. Okay. And just one question about this good distribution practice guideline. Is that available online?

E.N: Yes, also on the Swissmedic homepage.

S.J: Okay, great. I think I got all my questions answered. Thank you very much.



## **Appendix 2 : Qualitative Interview with Laurie Doyle, Former Pharmacist and Shoppers Drug Mart Franchise Owner, 16.04.2020**

L.D: Laurie Doyle

S.J: Sophie Janett

S.J: So if you could maybe introduce yourself and your professional career.

L.D: Exactly, yeah. So how we how we connected First off is my daughter Christine is a student of Dr. Hallett. She's in her fourth year business. She's over at Brescia. So that's how she knows Dr. Hallett and I guess because Professor Hallett because she connects with her students so closely. She learns all their background and all their connections. And so she reached out to Christine when she heard that you were looking for pharmacists. So I've been a retail pharmacist in Canada for 30 years. I have just recently retired, so I'm not currently working full time. I'm just doing relief work at the moment. So right now it's if somebody's sick, I'll get a call to go in and cover their shift. So fortunately, I haven't had to work in the past few weeks because everybody has stayed well, and hopefully that continues, but I'm kind of on backup call right now. So my career in retail pharmacy Most of it was spent on the ownership side, I owned a franchise pharmacy with Shoppers Drug Mart. I'm not sure if you're familiar with Shoppers Drug Mart, so major Canadian retailer. So I had business ownership as well as practical dispensing. I mean, the majority of your time is spent working one on one with your patients and your clients as a pharmacist and I'm currently licensed in Ontario as well.

S.J: Okay. So that means being licensed, that means that you still own like, do you still own the shoppers drug mart,

L.D: So, I don't have any ownership in the pharmacy. I sold out a year and a half ago. But I'm still licensed, which means that I can still practice pharmacy, I maintain all my current designations, all my current education and practice requirements.

S.J: So that's why you're still kind of a backup in case they need. That's, that's what makes it possible to be okay.

L.D : Yeah, yep.

S.J: Okay, great. And I have some pretty like they're more technical questions because I wasn't able to really get the background like I know how it works in Switzerland because I grew up there and I see how it works. And I have more kind of technical questions regarding the Canadian distribution. So is that really a fact that all antibiotics are distributed the exact amount of pills?

L.D: So yes, pretty much so. Most of my supplies for antibiotics will come in depends on the volume of the drug bottles of 1000 bottles of 100. There are a few that are in the packaging that you'd be familiar with the exact quantity that a patient would need. So that would either be six, seven or 10 depending on the type of antibiotic that it is.

S.J: And is that like these exact packages are there for a very specific treatments.

L.D: Most of them are. So they're very rarely that the quantities very rarely deviate so that you can use them. Again it because we're so used to dispensing exact quantities for everybody because everything else is also in bulk supplies. Even when we do get those packages, we tend to split them up to give you exactly what we what you need, because that's what we're used to doing.

S.J: Okay. And and how Do you like because then Switzerland, I think in 2018 they voted on Parliament level that they were kind of looking into a new distribution system that seems to be similar to the one in Canada, where they were trying to dispense the exact amounts. And there's a pilot project running right now when one of our cantons were actually trying this distribution mode in I think 13 pharmacies and their main concern in Switzerland is mostly because they already tried to pass it on Parliament level, I think in 2012 or 13. And they got rejected, because they kept saying that the like, on a safety and health issue that they could not ensure that the medication was stored properly and how, how can you ensure it because For me, I feel like I mean, the US and Canada are both developed countries and I mean, if it works in Canada, it should also be possible to work in Switzerland. So I'm trying to understand like, what what in the process helps you to ensure that the medication is stored properly that there are no in between or like how does it work.

L.D: So, with the, the manufacturing process, that's there, the products are all dispensed in specific packaging or bottles with desiccants or whatever the product needs to ensure stability of a closed container to a certain expiry date. So even though we're opening and closing that container a few times it's it's assured I guess that the product will have stability to a certain expiry date they could be shorter than what a prepackaged one would be because obviously light and moisture does get into those packages each time they're opened. And it's assumed that once the product is dispensed then it is consumed by the consumer at that time. So if if I dispense the seven day supply, it's assumed that it would only be in my consumers hands for seven days as opposed to being stored for months and years. You know, as a matter of practice, we we tell our patients you know, if you've got something at home that's been previously dispensed depends on where you've stored it, that medication may not be suitable after we typically get patients about a year. But again, it's an assumed expiry on the products

S.J: and so how does the actual distribution work because you said you were opening the containers. So, does that mean like you go in with like the spoon and like

L.D: So, we use we use counting trays and counting scales to prepare the medications. So it will be one of two things, I mean the most manual ways to pour it onto a tray. Use the spatula to count off the number of tablets or capsules that you need. And then the trays are designed so that you can pour the excess back into the stock bottle and then the the patient's requirements are put into their vials so there's no touching involved other than with your tray and your spatula, which we would clean in between uses.

S.J: Since it's let's say a human process going on? How do you make sure that there is no miscounting? Or is there like, Are there several people involved to double check everything?

L.D: there would not be just due to time restraints. Counting is a very manual process which takes a lot of time. So no there wouldn't be any recounting. Basically, the only things that we would recount on a practical basis would be anything that's narcotic or tightly controlled. So that's where staff training comes in. Yes, miscounts happen. That's a fact of life. At the end of the day, you just do what's right for your, your patient or your customer and make it right at the end.

S.J: Okay, so there's basically just one counting that happens. And then, because I remember, I took my medication at the western pharmacy, and I remember having one person who took the doctor's note. And who told me then to go to an like, I think the actual pharmacist who would then explain me how to actually take it. So does that also happen in like regular pharmacy?

L.D: Yeah, so the typical typically what would happen is we would get the prescription prescription order in and it would either be you presenting a physical piece of paper or the doctor's office sometimes communicate directly with the pharmacy to give that order. You would have technical staff that would enter it the information into a computer system. They would then retrieve and prepare the medication and then present everything to the pharmacist, who would then double check everything. So I mean, we as a pharmacist, I will do a visual check on it does it look like it's the right quantity? I'm not going to necessarily recount everything, but I've had a look at it and you could sometimes pick up on some very obvious errors. And then, you know, we'll do our therapeutic check, as well. And then at the end, you you are presented with your medication and a physical chat with the pharmacist to make sure that you know, what you're getting and why you're getting it and how you're going to take it.

S.J: Okay. Yeah, because that's another issue we have right now. I mean issue. Another thing in Switzerland is we have a legislation saying that every every medication needs like how is it called in English, the instructions how it should be used and and it has to be in our three official languages. So French, German and Italian. And that's also one of the reasons it got rejected in 2013 is because with these customized medications boxes they could not have like, apparently our Yeah, legislation is pretty strict on that point. If How is it in Canada or do you also have these, these medication? How are they called?

L.D: Yeah, we call it a monograph. I don't know if that word translates my Well, well to you. So yes, we do provide our patients with a written write up of their medication. It's software driven at the pharmacy level. So each farmer See would have their own software to develop a monograph for each specific drug.

S.J: So then you just kind of up and down medication and then it prints out on the moment.

L.D: Yeah, so as it's as it's processed through through our system, the system will automatically generate that paper when that prescription prints. So in my my particular pharmacy, when I check or sign off on a prescription, that's when any any monographs that would be required would print, I have to retrieve it from the printer and match it up with the physical bottle. So as I say, it's software driven at the pharmacy level, so it's not manufacturer driven.

S.J: Yeah, because I remember when I had to take my medication, I was surprised because I realized I had no idea when I was taking I just got the little box. And I was like, wait, but how like, Okay, I guess I'm just take it.

L.D: yeah. So that's, that's, that's up to the pharmacy that dispenses it, there isn't an actual requirement that we give you that piece of paper or that information, but I think it's probably 99.9% will do for every drug and, and there are certain drugs where I don't have an official monograph where the system will generate something very generic and plain that could apply to anything. Just so that we provide you with something that at the end will say you know, if you have any questions, make sure you ask and we're here to help.

S.J: And another question is for the medication because from what I understood in Switzerland, every kind of batch of medication needs us kind of a serial number or just to follow up and kind of have a better overview does that also exist in Canada?

L.D: So, I'm not sure are you talking like from a manufacturer's batch level?

S.J: I think I should go and have a look at our boxes but from what I understood and read; every pre-pack box has its own kind of batch number. So there is a tracing possible and they can better trace it.

L.D: Yeah, okay. So yes, each each drug has its own batch and an expiry, unfortunately in the Canadian system that isn't always recorded at the specific patient level. So when I just spent something I don't necessarily record, the batch, the exact batch that it's come from. We have gone to the level of we record the expiry of the medication, but we don't necessarily record the batch. So if there is a recall or a problem with a specific batch, I basically have to contact any patient that was dispense that medication within a certain time window that that batch was on the market. So it means over contacting patients with recalls, because we don't have any better system to do. I would see going forward because it's becoming more and more commonplace through these recalls that there will be systems to develop to make it easier for pharmacy staff to to record this information, because it's just so time intensive. That your 30 minute wait would have turned into an hour wait just because of recording that extra data. But I'm sure that manufacturers are probably looking at probably barcoding that information so it could be scanned into a system, but that's a future enhancement.

S.J: And for you to like the current distribution system that you have right now in Canada, for you what are the positive or negative points that you see in that system after maybe like your 30 years in business.

L.D: So, certainly from an efficiency or time standpoint, it's much more labor intensive and takes a lot more time to count and prepackage medications. As opposed to something that comes pre counted. As you're used to getting it we call it unit dose or dose packs. The other thing that of course, is coming up right now because of all of the infection control procedures that are in there is I think people are recognizing how much that medication is handled, and at risk of becoming contaminated due to human error. So that's obviously, changing a lot of practices is opening up a lot of a lot of eyes for people to make sure that we aren't contributing to any infection.

S.J: And so the most, I guess, it's, as you already said, it's pretty much a time consuming process. Do you do you actually have some staff that is always at the counter and interacting with the customer and then you have some other staff who are in the background? I mean, I guess it's not every single person goes and does exactly her batch for her patient. I guess it's does that work?

L.D: Yes, we tend to we tend to work on roles or stations, and it depends on the volume of the pharmacy how much movement you will get between those those roles. But you will certainly have somebody who's just greeting you as you come up to the counter, letting us know of what your needs are. You'll have somebody, sometimes somebody else entering that data into the computer. Certainly there's another person who would just be counting and packaging, the, the product, and then the pharmacist does two two slots in there, they do their their therapeutic check. Usually we do the therapeutic check before the product is actually counted and filled. And then we also do a final product, check at the end before it reaches the client.

S.J: And do you also as a pharmacist, ask for any allergies and stuff or do you mostly rely on what the doctors did beforehand?

L.D: No, we always ask because it's such a stuff that's easily missed and forgotten. So we do an allergy check when when the patient presents, our computer software's is generated so that it will ask that question every six months, I think it is on a patient so if you forget to ask it's going to pop up to confirm the allergies. So we do ask for allergies each and every time basically.

S.J: And antibiotics are covered under Medicare right there.

L.D: So in in Canada, government coverage is not automatic. Most people have private coverage for their medications. Government coverage is only for senior citizens. So those 65 and over or those with financial need, then there will be some government coverage and each province will have kind of different levels of coverage. So the majority of your population is covered under private plans provided either by their school as you were students, your schools all have drug plans or their employer.

S.J: So that means that as a Canadian citizen or resident, Medicare mostly covers the like the visit you have at doctors and you need a separate one that covers actually drugs and medication.

L.D: Yes

S.J: Oh okay, that's why I ever got reimbursed. No, it makes sense. Yeah.

L.D: Yeah, the government health coverage only covers your medical visits, your hospital stays, any lab work or scans that you would need. But anything else is all private insurance. So, all your drugs, your physiotherapy, your alternate healthcare so your optometrist for your eyes, chiropractor, all that stuff is all out of your own pocket or your private insurance.

S.J: Okay, yeah. So, I missed that point about medication when I read on Canada Health, I think but good we cleared that. So, from your experience with your clients to what percentage which you see have private insurance for their medication

L.D: in the in the dispensing that we did at my particular pharmacy, probably about 60% of the prescriptions that we dispense was government coverage. So that would be your, mostly your senior citizens have the balance of the 40% it was probably about half and half about 20% had your private insurance and 20% paid out of pocket as some of those people that paid out of pocket could then submit manually to an insurance company.

S.J: And I don't know if you actually also have that issue in Canada, but I know that those last few months we had a lot of kind of prevention campaign going on in Switzerland about the antibiotics resistance and how the population was getting more and more resistant. And we were asked to bring back our not used pills back to the pharmacy. I don't know, how present is that topic in Canada? Is that like, also a very current and actual problem or?

L.D: Yeah, yeah. So antibiotic resistance has been a topic for many, many years. And there's lots of education programs, both on the professional level and on the patient level to kind of rationalize the prudent use of antibiotics. You know, at the public level is not every infection needs an antibiotic, right? In terms of unused medication, in Ontario pharmacies do have a take back program where we do accept unused medication is

primarily from an environmental standpoint. You know, if you've got it in your home and you're not taking it, please bring it back to the pharmacy for proper disposal.

S.J: And do you feel that having this unit I mean exact distribution of the needed antibiotics kind of reduces the probability of having a resistance to develop resistance or

L.D: I would assume that it probably encourages people to take it until the right time because they've got that visual reminder. I've got so many tablets left that's what I need to finish. How much deviation from that at the patient level there is? There's probably a lot I don't know this statistic, but I know that there have been studies done on unused antibiotics and how much people don't take up their proper.

S.J: So even with your distribution system, there is still a high amount of people who don't take their antibiotics properly until the end of the treatments.

L.D: I would assume so. Yeah. Yeah, I think that's a fair assumption.

S.J: Because that was another point they were partially also why they accept that this Parliament motion is to fight resistance. And that was also my thoughts about if people have the exact amount it will motivate them to take up to the end, but it's true that with antibiotics after a second or third day you'll feel much better. And then you forget taking it and you think it's fine. So, I think yeah. So, for you, if we look more into the resistance problem, do you see any improvements that could be done to fight this resistance for what actually is happening?

L.D: Well, I think it's tough to fight resistance. It's basically an education program. And it's, it's constant education at the consumer level. It's constant education at the professional level, to warrant the appropriate use of antibiotics and, you know, at a professional level, you've got the doctors who are prescribing it and then the pharmacists who are dispensing it and we each play a role in that the doctor's obviously have to make a correct diagnosis and then choose that antibiotic. at the pharmacy level, we try to the best that we can to confirm that diagnosis with you as a patient coming in, what are you taking this for? Then we can kind of do that double check, is this an appropriate antibiotic or that type of infection? And is it an appropriate dose for that type of infection, so that we make sure that you're getting the right drug for the right thing at the right dose at the right time. You know, we do we do that as a matter of, of standards. And each of those touch points is another opportunity to educate the consumer on the appropriate use of antibiotics. So, it's education all the way through. That's the only way that we're going to going to drive this. at the pharmacy level we're, of course limited by we don't have access to all of the tests that a patient may have gone through to achieve that, that diagnosis. And you're also limited by the patient's knowledge of what they're actually being treated for, because not every patient will present with the same knowledge.

S.J: And another question that just actually popped up because since in Switzerland, we have these pre-packed boxes, we have a lot of times we have some branded medication that is still under patent and then we have the generic options. And that is also a big subject that I figured out was still kind of funny when I did my survey is that a lot of people feel that generic is not as efficient as the actual branded medication. And I feel like this might also be a problem in Switzerland about these generic and branded. How does that happen in Canada since the customer actually don't really see that point like about branded or generic? So does that mean that for the products that are still branded, you will just dispense the original version and for the others do you prefer the generic ones or as a pharmacy in general, you always go with one or the other.



L.D: So as a pharmacy and in general, we tend to dispense the generic version, if that's available, and that's part and partially of Ontario legislation that unless there is a discussion with the patient, you have to dispense the lowest cost alternative to your patient. So, as a matter of course, we tend to just dispense the generic branded one. Antibiotics it's not as much of an issue because the reality is there is very few branded antibiotics left most of the antibiotics on the market long enough that the brand is either very cost prohibitive or even not available any longer. It's just the generic ones on there. But certainly, it is a discussion and that that brand is better than generic kind of philosophy is very prevalent in your in your patient population. I know with certain children's antibiotics where it's in a liquid form taste issues tend to crop up a lot. So, there's a lot more branded use on that side. Because they feel that the taste is better with the branded product, whether that's true or not, I don't know. But that's, that's more where we see it.

S.J: Okay. And so that means that in general, so if I understand, right you, as soon as you have the generic version, you go for it a generic. So, if one patient comes up and says, oh, for that treatment, I want the original. Does that mean you would have to then order it?

L.D: Yeah, I mean, it would it would depend some things that if there's common requests for that branch, then we would have that on hand and you would have both other times Yes, it would mean you'd have to order it, which for an antibiotic usually isn't suitable because that's another couple of days delay in their treatment.

S.J: Yeah, these are very interesting points to actually compare also, because in Switzerland, it's also on insurance points. That is, again, pretty different. Like we don't have this nationwide coverage. It's mandatory, but we can choose with which private insurance we want to go. And we still have a certain premium to pay and we have deductibles and for every, as soon as we get over the deductible, we still have a 10% of the total charge that we have to pay out of pocket. So that is not the case in Canada, from what I understood. Is that the health system is for everybody. And you have deductibles too or not.

L.D: So, I think we're probably close on the drug side, we're probably closer to what you personally have there in Switzerland because we're on a private insurance. So, every private insurance plan is different in how they pay, but quite often there are deductibles either a threshold that you have to achieve before your insurance kicks in or it's a percentage of your total cost. Some are set dollar amount per prescription, but those plans are becoming less and less most have gone to a percentage of the of the total prescription cost either 10% or 20% is probably the most common.

S.J: Do you have any of these insurances, the name of them, like the most common ones.

L.D: Uh, so Manulife would be a common one, Blue Cross. But there's literally probably hundreds of these companies and plans.

S.J: No, but that's good that at least I have like two that I could maybe compare. It makes more sense to compare with our actual program. Because Yeah, it's a fact that in Switzerland every year we have higher premiums and it's a big issue every year and they, it's been years that they're trying to make a one and only insurance for everybody, but then there's the fear that it's gonna get to controlled and that will Yeah, that everything's going to increase. So, it's Yeah, it's interesting situation,

L.D: pretty much pretty much the same here. You know, and again, the Canadian government, I mean, that there are certain political parties that are trying to get a, what they call a national pharmacare plan, so a national plan that would pay for prescriptions. But it's, it's so cost prohibitive that the taxpayers will feel the burden of that and probably will not be accepted.

S.J: Yeah, I can imagine that. I'm really curious to see how this is gonna end with our Yeah, that pilot project that is running right now, I didn't hear about it until I submitted my subject. And I heard about it and I was like, Oh, no, then my project is actually obsolete, so I have to find something else. And so I tried to contact them to at least maybe be part of the project since I'm free work, but they refused, but they ensured they would not disclose any results or by the end of 2020. So I'm good on that. And maybe now with the Coronavirus, they might even push it even further. Yeah. So, yeah, I'll hope I'll be fine on that point. But it's Yeah, I'm figured out it's a really complex process, and especially with all the legislations we have in Switzerland and all the Yeah, the kind of the, we have a several big pharma's in Switzerland that actually. And I think compared to other countries in the European Union, they make a lot of money with Switzerland. Like just for some Ibuprofen like the Advil. In Switzerland, there's a small box that have maybe 20 pills is around 15 Swiss francs. So that's like 20 Canadian dollars. And you could get a box of 40 in Spain for literally three euros. So that's double for, five times less. And it's, yeah, as a Swiss citizen, it's really frustrating to see how this system keeps working, knowing that everywhere else, it's different and it's also working.

L.D: yeah, pricing is a huge, huge issue. I mean, it's a pharmacy sees it, you know, as governments are trying to drive pricing down on medications, right. That's kind of their In the interest of their people, however, because these are all worldwide suppliers, does driving pricing down limit your supply of medication. Because if they can make more money in Switzerland, are they going to just supply more to Switzerland where they can make money and less to a country that isn't willing to pay for it? Because we've had, you know, lots of drug shortages in Canada, that's a huge issue in pharmacies is drug shortages, we can't get the medications that we need. And this has been ongoing for at least the last five to 10 years, but certainly very prevalent in the last five years, and becoming increasingly so. And to the point where, right now with this pandemic going on, we've had to limit supplies to patients because we can't guarantee that we'll have enough medication So nobody is getting more than a 30 day supply right now when they're used to getting a 90 day supply of their maintenance medications just due to supply concerns with medications.

S.J: So, is that drug shortage really linked to the actual as you just mentioned that some countries who are more like willing to pay more have

L.D: nobody's proven that fact. Right? That's just a speculation. But nobody's proven that fact. Certainly, there there are increasing manufacturer controls, which lead to shortages. You've got border controls, because nothing is manufactured and produced in one location anymore. Everything is they source different products and different parts from different countries all around the world. And as borders Get tightened. I mean, your supplies get slower and slower to reach you. It's a very complex issue.

S.J : Yeah, that's true. But I feel like I had an interview with one employee of Eli Lilly. And it was interesting to see their point of view about this new way of distribution. And again, if obviously, if we ask the person who made the more money out of it, for sure, they will say that this is the best way of distribution because it works like this and it always has and it shouldn't be changed. But they, even yesterday, I had an interview with the director of, of the trade association of pharmacists in Switzerland then he also kept saying that the current system was working and that the pharma industries were not

making that much money out of antibiotics and that their margin was pretty small. And it's actually really interesting to have all these different points of view. Especially. Yeah, I mean, I guess, because for me having these international, I mean globalization, the, like Novartis and Johnson Johnson, all of these companies they have, they do supply the whole world. So they do have the know how the knowledge, they have everything. So it's just about implementing it also for Switzerland in the end. So that's, yeah, I found it really interesting.

L.D: Oh, yeah. I think that that packaging concept that you have there in Switzerland, I think that's a kind of a European Standard, because we get many pharmacists that either come from Europe or the Middle East a lot to the Middle East is all standard packaging as well, where it's more of a North American distribution system to use the bulk.

S.J: But during my survey, I actually asked, one question was, do you often get more medication that you know? Yeah. Do you get more medication that you actually have to take? And I think I haven't analyzed the outcome yet, but from what I've seen a lot, like probably more than half say yes. And then I talked to these two persons from the pharma industry and they were telling the opposite that most of the time, the packs were indeed pre-packed for a certain treatment and that most of the time they the package does this was correct. So, yeah, since you don't really have that problem because you have mostly bulk you probably don't really see but do you maybe remember the most for how could I say that? Do you feel that the treatments that doctor prescribe for a specific illness are most of the time the same number of pills? Or do you feel there's a lot of variation depending on the I don't know if my question is clear, but yeah,

L.D: there's there tends to be a lot of variation. A lot of physicians will deviate from the Recommended or the normal quantity, I mean, a lot of them will do 10 days when seven days is enough as a matter of a course. And then they'll do that with the philosophy that, well, if my patient is going to stop early, then maybe if I give them 10 days, by the stopping early, they'll actually take the seven days that they need. So, they do sometimes from a psychology basis, try and do it that way. So, there does tend to be a lot of a lot of variation when there should not be right it should be if you've got this diagnosis, this is what you should be prescribing, but there is a lot of variation.

S.J: So you as a pharmacist, when you see that kind of examples happening where you clearly know that seven days will be enough, but it's 10 days written on the on the doctor's note, how do you do you have the freedom to actually decide or are you bounded to really give the 10 out without discussion?

L.D: No, we're not bounded to get the 10 out. So, if we truly know into our professional knowledge, know that that is the wrong duration. We do have the right to modify the prescription. So, what we would do in that case is I would say, Sophie, you know, you've been, you're telling me, you're diagnosed with this, the guidelines are that we use this dose for this for seven days and not 10 days. Are you comfortable with me modifying your prescription for you, and if we get your consent, then I can change the prescription. So, in Ontario, we do have the right to modify a prescription

S.J: and does that happen often?

L.D: Probably not as often as it should, and then you have to also, you know, kind of make that judgment call. How much harm would it be to my patient? How much harm would it be to society as a whole when it comes to antibiotic resistance? So, we do modify a certain number of prescriptions,

S.J: and the patients who actually are in this case where apparently, they were prescribed more than they should take, how do they react? When you tell them that they could actually take less are they often very okay with that and fine with the five to have less or are they more susceptible and preferred to use?

L.D: It's becoming, it's becoming more and more that they're, they're very appreciative of the pharmacist's advice, because they feel that it's another kind of independent check on their own. Health. So by and large, most of them would be agreeable to the pharmacist changing it. I don't get much pushback on changing anything. There will be a few that says no, that's what my doctor wants so, we'll stick with what my doctor wants. And that's fine. Right? That's, that's fine unless I see a big danger that I'm not going to push for anything different.

S.J: And just for that, those modification. So, when your pharmacy when one of your staff members feels like it should, it could be changed? Yeah, I guess they have to come see you for validation for that.

L.D: Yeah. Yeah. So, would it be a concern that's brought up front or most often it comes from the pharmacist looking at the prescription and going, something's not right here. And then with discussion on the patient, you decide to modify or modify?

S.J: And does that sometimes happen that you actually call the doctor?

L.D : So any modification that we do, We do have to notify the doctor that we have done so and that so that the doctor's records are corrected for what the patient is actually going to take. So that is part of our requirement is that we notify the doctor, sometimes. I mean, in the past, before we had this ability, we would contact the Doctor, do you want to change your prescription and then have to wait for a response we now no longer have to wait for a response. We can just change it, let them know. This is what I've done. Okay. Great. That actually probably helps you to be more efficient. Yeah.

## **Appendix 3: Qualitative Interview Summary with Virginie de Biase, Cantonal Pharmacist for the Canton of Neuchâtel, 14.08.2020**

Questions asked during the interview:

- Pouvez-vous rapidement vous présenter et parler de votre parcours professionnel ?
- Quand est-ce que le projet pilote a-t-il commencé ?
- Avez-vous déjà reçu un retour des pharmacies participantes au projet pilote ?
- Quels ont été les critères de sélections pour participer au projet pilote ?
- Est-ce que vous pensez qu'un nouveau système de distribution pourrait être implémenté en Suisse ?
- Comment est-ce que le projet pilote est-il conduit ?
- Le prix des antibiotiques facturé est-il adapté si certains comprimés sont enlevés ?
- Voyez-vous des inconvénients dans ce genre de système de distribution à l'unité ?
- Est-ce que vous pensez que ce genre de système de distribution pourrait être intéressant pour un autre type de traitement ?
- Avez-vous observé une certaine tendance entre les produits de marque et les génériques ces 20 dernières années ?
- Que pouvez-vous dire du marché des génériques ?
- J'ai récemment lu un article parlant d'une rupture de stock de certains médicaments et antibiotiques à l'échelle internationale, et que la majorité des antibiotiques étaient produits au même endroit, qu'en pensez-vous ?
- Il y a une croyance populaire que les médicaments retournés sont envoyés dans divers pays du tiers monde, est-ce correct ?

### **Translated summary of the interview conducted in French**

SJ: Sophie Janett

VdB: Virginie de Biase

SJ: Could you quickly introduce yourself?

VdB: I started working as a pharmacist 20 years ago and is now the cantonal pharmacist for the canton of Neuchâtel.

SJ: When did the pilot project start?

VdB: The project started mid- March but got interrupted from mid- April to mid-June due to COVID-19.

SJ: Have you already gotten a feedback about how the pilot project went?

VdB: A check-in with the participating pharmacies will be done end of August.

SJ: What made the canton of Neuchâtel to be selected for the pilot project?

VdB: After the parliamentary motion passed, Zug and Neuchatel were candidates for the pilot project, Zug got rejected as they dispense antibiotics through doctors and the unpacking and preparing of an antibiotic prescription was considered to be done at manufacturing level which doctors are not.

SJ: do you think a new distribution system for antibiotics could be implemented in Switzerland?

VdB: A change in the distribution system would result in massive changes for the cantons, especially for the 15 cantons dispensing through doctors.

SJ: How is the pilot project carried out?

VdB: To comply with the leaflet obligation, the pharmacies hand out the antibiotics in their original packaging. They (the pharmacists) remove the excess antibiotics only if the blister has perforations, if not the excess antibiotics are not removed. Mainly to avoid confusing the patient during his treatment.

SJ: is there any price adaptation made if pills are removed?

VdB: The price stays the same even if less pills are handed out as the current pilot project is only to test feasibility. The goal of this motion is mainly to combat AMR not to reduce waste from an economic point of view. A study in France showed that dispensing antibiotics differently than in blisters was feasible but not interesting from a cost and time point of view for pharmacists.

SJ: do you see any weak points for this pilot project, or for this type of distribution system?

VdB: Individually preparing each prescription is very time consuming for the pharmacies and the waiting time for the patient is high

SJ: would you see this distribution system currently tested to be economically interesting for another kind of drugs?

VdB: This distribution system could be financially interesting for expensive treatments like oncology. Antibiotics do not represent a high cost for insurance companies compared to oncological treatment.

SJ: have you seen any tendency change between branded and generic drugs during the past 20 years working as a pharmacist?

VdB: A reversed tendency was observed regarding the branded and generic preferences of the Swiss population. When I started as a pharmacist, most patients refused generics and only used branded medication, now it is the opposite where mostly generics are handed out to the patients. Branded medication is handed out only very rarely and most often it is when the inactive substance is different between the generic and the branded version.

SJ: what can you say about the generic drug market?

VdB: A lot of pharmaceutical companies are the one producing a generic medication once the patent is expired by just changing the name of the medication. if the generic is a new generic, the price difference can be as much as 50 percent but sometimes the price is the same.

SJ: I have recently read about a worldwide drug shortage and that most antibiotics are produced in the same place, what can you say about that?

VdB: There is a major problem with drug shortage in Switzerland for the past few years. The problem is the globalization and outsourcing, resulting in many medications to be produced in very few production sites in India and China. If a problem occurs at their production site, many countries suffer from drug shortage as they highly depend on very few suppliers. Switzerland is a small country and their medication orders are relatively small too compared to other countries, which results in Switzerland's medication orders not to be treated in priority compared to other countries which a much higher medication order.

SJ: there is a popular belief that unused returned drugs are sent to third world countries, is that true?

VdB: Unused pills used to be sent to third world countries in the past but not anymore. The pills that are brought back to the pharmacies, that have not been used by the patients are all destructed and none of it is sent to third world countries. This is to avoid putting these third world countries population in danger as pharmacists do not know how the pills were stored at the patient's home. NGO's and other associations buy the medication at a much lower price directly from the pharmaceutical companies to send them to third world countries.

## **Appendix 4: Qualitative Interview Summary with Doris Corda Penna, Regulatory Affairs Manager at Eli Lilly, 20.03.2020**

Questions asked during the interview:

- Pouvez-vous vous présenter et raconter votre parcours ?
- Comment est-ce que l'industrie pharmaceutique est-t-elle régulé en Suisse et quelles sont les procédures à suivre ?
- Quel est l'antibiotique le plus utilisé ou le plus prescrit ?
- Que pensez-vous du gaspillage de médicament due aux emballages uniformes ?
- Quels seraient, selon vous, les plus gros challenge de changer le système de distribution ?
- Que pensez-vous du système de distribution actuel ?
- Comment est-ce que les hôpitaux reçoivent-t-il les antibiotiques ?

### **Translated summary of the interview conducted in French**

SJ: Sophie Janett

DCP: Doris Corda Penna

SJ: Could you please introduce yourself, talk about your career so far and what is your role in the company?

DCP: Active since 2001 in pharma industry, PhD in bio chimie, clinical research, worked in many sectors also governance and quality, since 2006 responsible for regulatory affairs department, mainly works in oncology and injectable drugs.

SJ: how is the Swiss pharmaceutical industry regulated, what are the procedures to follow?

DCP: Switzerland is in a blister packaging distribution system, when registering with swissmedics, information about drug stability according to packaging used has to be transmitted, would be a very complex process for pharmaceutical companies if they have to submit stability reports of the drugs for new packaging, as the stability reports are for a period between 6 to 12 months. High admin implication. Every change has to be notified and approved. Studies have to be delivered to swissmedic showing that the drug remains stable in its packaging. This would be a huge process on the technical process to have the new packaging forms approved. Every change made has to be notified to authority Switzerland only works with blisters, after discussion with a pharmacist, most blisters are adapted to the prescribed treatment. It would be interesting to see how much is really wasted. Pharmaceutical companies really try to match their blisters to the most frequent prescribed treatment. Swissmedic asks why this kind of blister has been chosen and pharma has to explain why this number of pill is in the blister. BAG is responsible to supervise all prescription only medication, they will give the price and make sure the number of pills in the packaging is adequate for a certain treatment. During the manufacturing process are various counts done to ensure that nobody interfered during production. Quality norms are in place to make sure each pack is counted at specific



points during production. The number of pills in a blister are based on an average treatment posology.

SJ: what is the most used or prescribed antibiotic in Switzerland?

DCP: Most used antibiotic is co-amoxicillin, given for sore throat and wounds

SJ: What do you think about medication waste due to prepacked boxes?

DCP: Is not sure that with the law currently in force, a lot of medication is wasted. Waste might also be mostly about the patients not taking their medicine until the end. Patients are also responsible to take their treatment until the end because that is also a reason for waste.

SJ: What would be the biggest challenges in changing the antibiotic system?

DCP: The logistic aspect also has to be taken into consideration, especially for the pharmacist, what he will have to put in place in order to change the distribution system like in Canada. If the distribution system changes that would mean that the pharmacies would not only be a dispensing unit but would also turn into a production site as they have to prepare the exact number of pills, stick the label on it and inform the patient. The pharmacist is the only one allowed to do that, the logistical aspect is therefore immense. Therefore only a few pharmacies in Switzerland still produce some preparation onsite. All this has to be done under very strict regulations. Switzerland has stricter regulations compared to other countries. The producing pharmaceutical company tries to find right packaging, the authorities try to control the packaging needed are available and the OFSP will only refund packaging that make sense for prescription only. Canadian and US pharmacies probably have a certain infrastructure in place for this kind of distribution system that Switzerland has not, which would be a major change for the Swiss system. The major problem in Switzerland is that the leaflet is mandatory, this is not the case for Canada or the US. A leaflet has to be with every sold medication. Leaflet will give information for the patients; however, dosage and treatment lengths will not be available in the leaflet. The information for professionals will be at swissmedic where posology can be found. Dosage might depend on the age and weight of the patients or if the doctor estimates a longer treatment is making more sense. Prescribed treatment will also depend on the severity of the illness, the age and the weight of the patient

SJ: What do you think of the current distribution system?

DCP: Current system in Switzerland is time efficient at pharmacy level, control by pharmacist only takes a few seconds. Changing the distribution system in Switzerland would be a massive change Medication usually comes from factory and are stocked in their destination countries where the pharmaceutical companies have an important inventory, or they delegate the inventory management to third party. Never had the request to have medication in bulk. Happened a few times in the 90's but very quickly changed to only blisters.

SJ: How are antibiotics dispensed in Hospitals?

DCP: Hospital also receive blisters, but they receive "uni-dose" blisters meaning that each blister will include the name, dosage and composition of the drug to ease the process. Blisters are pre-cut and each blister has a series number.

## **Appendix 5: Qualitative Interview Summary, Sebastien Marti, Head Pharmacist of a Pharmacie Plus, Neuchâtel, 15.08.2020**

Questions asked during interview:

- Quels ont été les critères de sélection pour participer à ce projet pilote et quelles étaient les procédures à suivre ?
- Comment avez-vous vécu le projet pilote ?
- Comment ont réagis vos clients ?
- Que pensez-vous du système de distribution actuellement en place ?
- Ayant fait une partie de vos études aux USA, avez-vous expérimenté leur mode de distribution d'antibiotiques ?
- Quel est / quels sont les antibiotiques que vous vendez le plus ?
- Dans quels emballages sont-ils disponibles ?
- Estimez-vous que les emballages correspondent aux traitements prescrits par les médecins ?

### **Translated summary of the interview conducted in French**

SJ: Sophie Janett

SM: Sebastien Marti

SJ: How was the canton of Neuchâtel selected for the pilot project?

SM: First the canton got selected and the cantonal pharmacist called the Cantonal organization of pharmacists (ONP) to ask for volunteer pharmacies who would like to participate in the pilot project. At least 12 pharmacies were needed and each one of them was asked to record between 50 and 60 cases. Zug was also selected but their dispensing form is through the doctors and the repackaging of antibiotics doesn't fall in their competencies. Several doctors in the canton Zug were asked to answer several questions but nothing more. The pharmacies participating received all the necessary information and support material such as forms to be signed by the clients willing to participate. The received instructions were clear.

SJ: What are your first impressions after a few weeks conducting the pilot project?

SM: The project itself was not really complicated to conduct but relatively constraining. Only the pharmacist was allowed to conduct the re-packing procedures which was adding more work and stress. In the beginning a lot of clients were very favorable to participate, but the procedure was only followed few times since many times it was not the patient himself retrieving the medication or the prescribed treatment was corresponding to the packaging size. Only an estimate 20 percent of the packages needed to be adapted. There is a high pressure for pharmacies to optimize the processes in place, the staff is under time constraint and quality pressure, this pilot project mostly added stress. One of the challenges with the pilot project is if the patient's condition is not improving and additional antibiotics are needed, resulting in additional work for the pharmacist. Seems that for the moment the constraints are too high compared to the benefits

SJ: have you ever experienced the same distribution system like in Canada?

SM: An experience with the distribution in the USA was made due to a foot infection, the experience was positive

SJ: Do you feel like the available antibiotic packages fit the prescribed treatment?

SM: The antibiotic packages available are most of the time adequate for the treatment, the most frequent case antibiotic treatment has to be adapted to the patient is for children due to their weight variation resulting in various modifications for their antibiotic syrups.

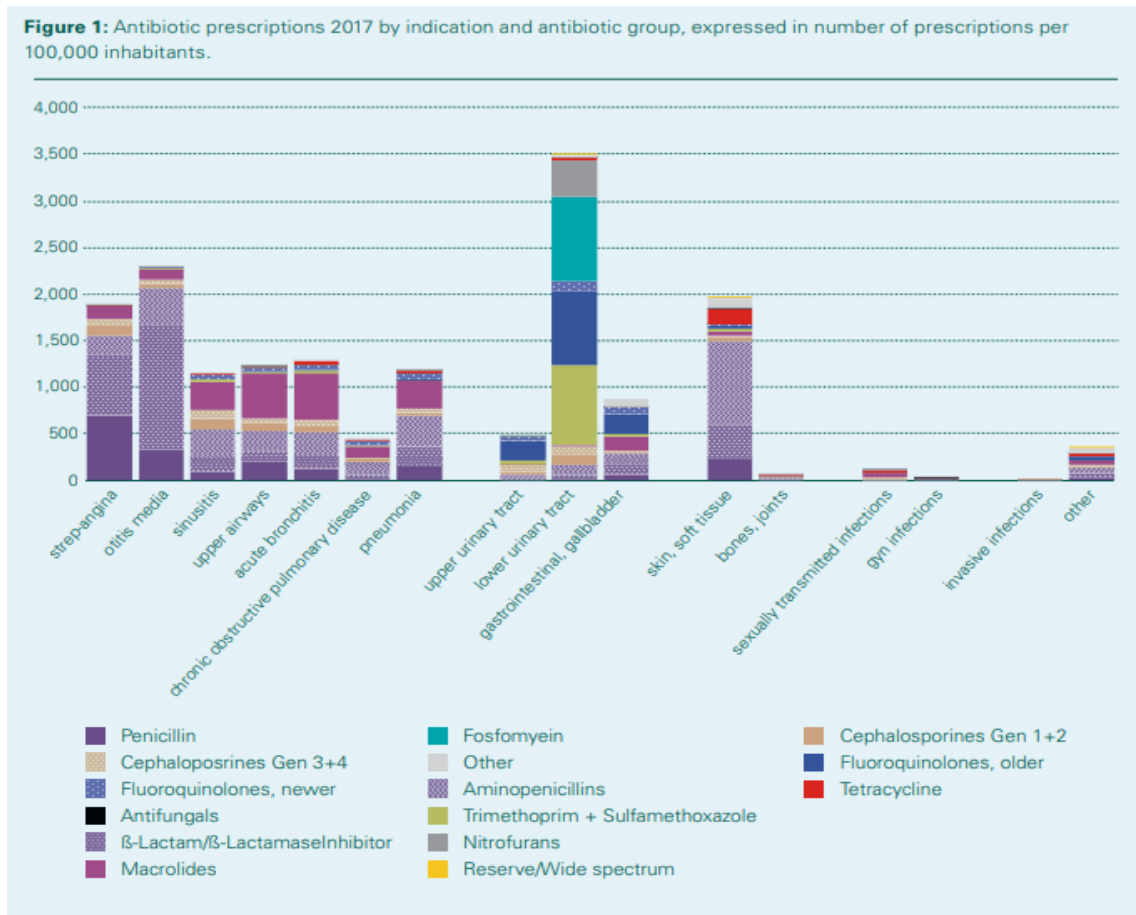
SJ: What is the most frequent prescribed antibiotic?

SM: Most frequently dispensed antibiotic is co-amoxilin which comes in packages of 3, 10, and 20 pills. Looking at the prices from various producers for a 20-pill package with a 625mg dosage, Axapharm, Zentiva, Helvepharm sell it for CHF 28,35. Sandoz is at CHF 29.-, and Mepha is priced at 37.10. The original active substance called Augmentin is priced at CHF 39.70. As the Mepha alternative is so much more expensive, it is not sold in Mr. Marti's pharmacy.

SJ: how do doctors prescribe? Do they prescribe the exact medicine or the active substance?

SM: The name on the prescription will depend, sometimes the exact name is written and sometimes the active substance. If a branded medication is favored, then the patient is informed that the insurance might only pay 80 percent compared to 90 percent if generic is taken. Pharmacists do not have any guideline from higher instances to favor the cheapest available alternative.

## Appendix 6: Number of Antibiotic Prescriptions per 1000 Inhabitants in Switzerland, 2017



Source: (Federal Office of Public Health and Federal Food Safety and Veterinary Office. 2018)

## Appendix 7: Survey Questions in English

The survey was also available in French and German.

Section 1 of 4

### Bachelor Thesis - Antibiotics

I would like to explore if a new distribution system of antibiotics can be implemented in Switzerland. Where the exact amount of pills required for your treatment would be prepared at the pharmacy individually for every patient in order to reduce waste.

Chose your preferred language \*

English

Français

Deutsch

Section 2 of 4

### Antibiotics in Switzerland

Description (optional)

Please choose your gender \*

Female

Male

Prefer not to say

⋮

Multiple choice ▾

Please select your age range

- 18-24 ✕
- 25-35 ✕
- 35-50 ✕
- 50+ ✕
- Add option or [add "Other"](#)

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📄
🗑️
Required 
⋮

Please select your residence region \*

- Romandie
- Swiss German part
- Ticino

⋮

Please select your Health Insurance Company \*

- SWICA
- Helsana
- CSS
- Assura
- Visana
- Concordia
- Other...

How much premium do you pay per month? \*

- less than CHF 300
- CHF 300 - 500
- + CHF 500

What deductible do you have? \*

- CHF 300
- CHF 500
- CHF 1'500
- CHF 2'500

How many times a year do you take antibiotics? \*

- never
- Rarely (every other year)
- Occasionally (1-2 times a year)
- Sometimes (3-4 times a year)
- Often (5-10 times a year)
- Very often (+10 times a year)

⋮

Does your deductible influence your antibiotics consumption? \*

- Yes
- No



Have you ever received more antibiotics than the required amount for your treatment? \*

- Yes
- No
- Don't remember or didn't pay attention

If you answered with Yes to the previous question, what did you do with the antibiotic surplus?

- Brought them back to the Pharmacy
- Kept them but didn't use them
- Used them for another illness without consulting my doctor
- Gave them to a third person for them to use

...

Would you appreciate receiving the exact amount of antibiotics needed for your treatment? \*

- Yes
- No

Do you chose the generic if it is available? \*

- Yes
- No

What is the reason you chose not to take the generic?

Short answer text  
.....