

Global Pharma Market & Covid-19 Impact

MARKET INSIGHTS SERIES (#14)

2019-2024 Perspectives

**“Wrong decisions are often due
to weak market insights”**

Introduction



Smart Pharma Consulting proposes to share insights regarding 8 topics that are essential to play and to win in the pharmaceutical industry

- This position paper provides specific insights for those who want to anticipate the global pharma market evolution over the 2019-2024 period, while considering the impact of the Covid-19
- We have selected 8 topics for which we share our knowledge and thoughts:

Part A - Pharma Market Insights

1. Size and Dynamics by Geography
2. Size and Dynamics by Business
3. Attractiveness
4. Access to Market



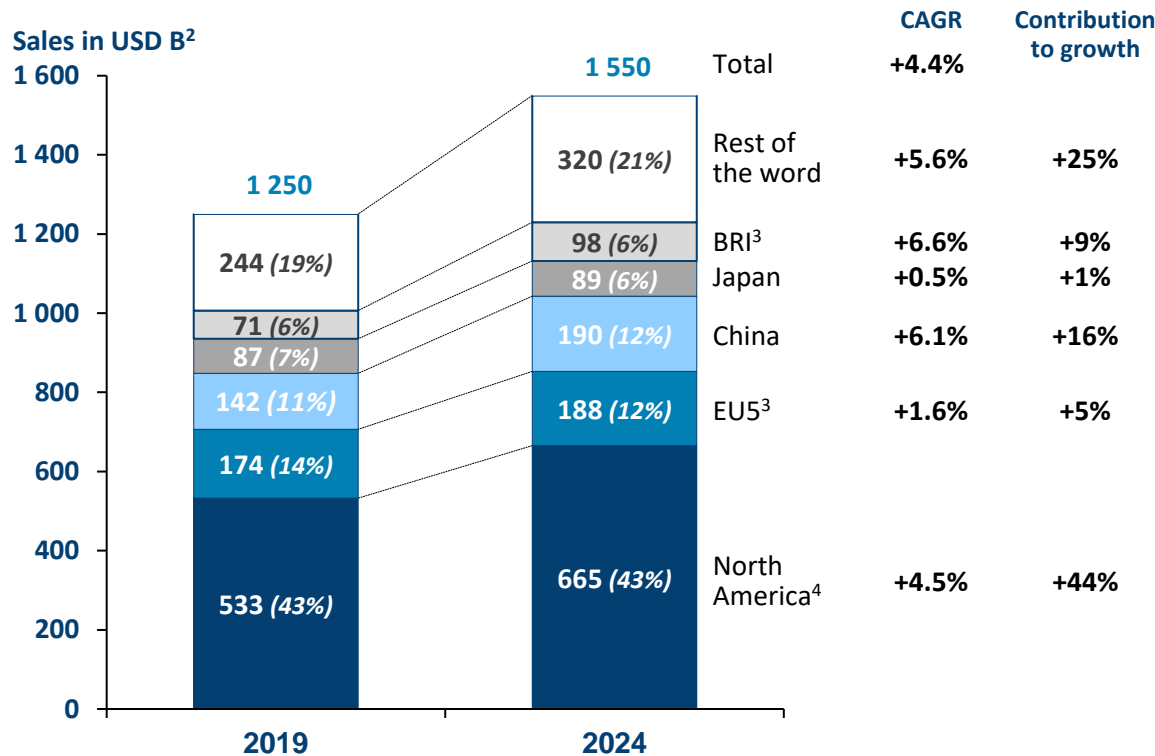
Part B - Pharma Company Insights

5. Strategic Directions
6. R&D Operations
7. Manufacturing & Supply Chain Operations
8. Medico-Marketing & Sales Operations

Part A – Pharma Market Insights – 1. Size and Dynamics by Geography



Sales of EU5¹ should grow slowly by 2024 due to stringent cost containment measures leading to a two-point decrease of their weight in the global pharmaceutical market



- The global pharma market is expected to grow with of a CAGR of +4.4% by 2024 including the impact of Covid-19, that should negatively impact volumes over 4 to 6 months in 2020 and lead to higher pressure on prices worldwide in the next 5 years
- EU5 countries account together for only 14% of the global pharma market (Germany: 4%, France: 3%, Italy: 3%, UK: 2% and Spain: 2%) and should see their weight drop by 2 points by 2024, due to higher price pressure than in the average of the other countries
- North America should continue to weigh for 43% of the global pharma market in value and contribute to 44% to worldwide market growth over the 2019 – 2024 period

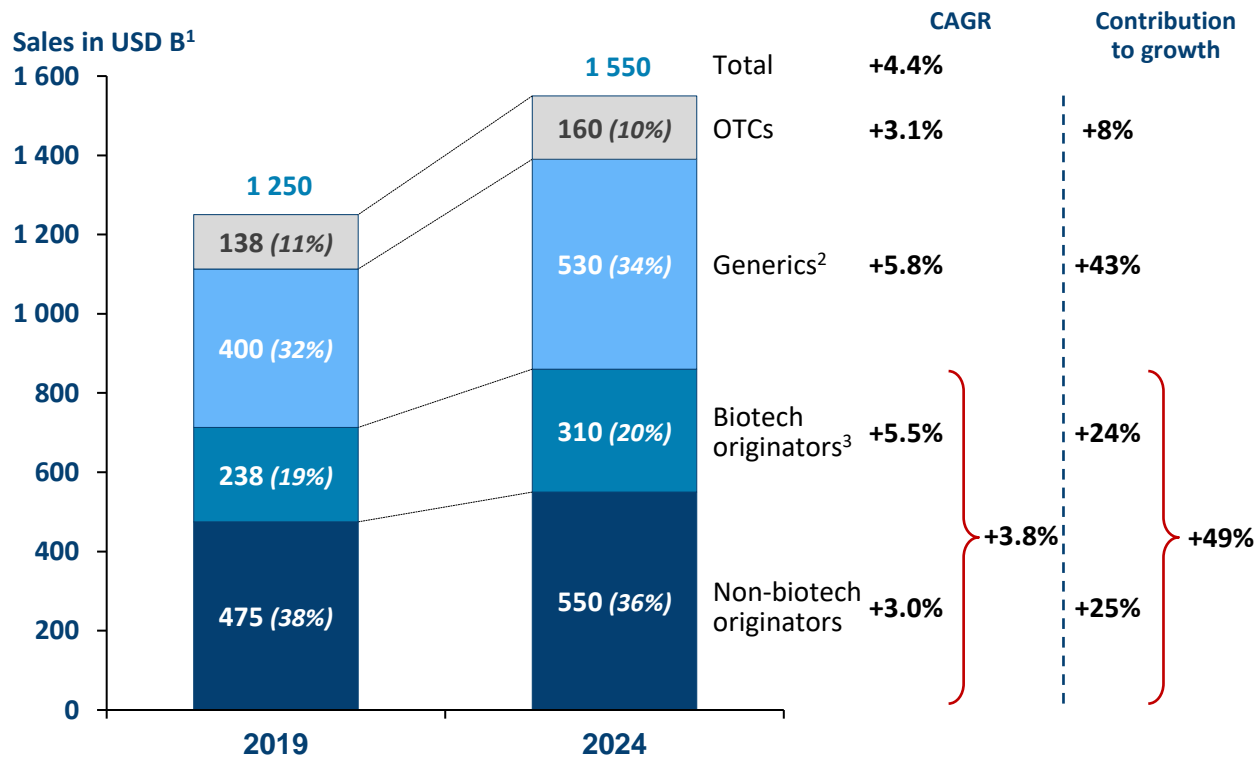
Sources: IQVIA Institute (March 2020) – Smart Pharma Consulting estimates

¹ France, Germany, Italy, Spain, UK – ² Ex-factory price before rebates – ³ Brazil, Russia, India – ⁴ USA and Canada

Part A – Pharma Market Insights – 2. Size and Dynamics by Business



All the business segments of the pharma market will be affected by the Covid-19 crisis through a volume effect in 2020 and a strong price pressure over the 2019-2024 period



- **OTCs**, which should remain the smallest segment of the global pharma market, has been significantly **affected** by the **Covid-19** crisis, especially **during the lockdown** period and the **following months**
- **Generics** and **biosimilars** should continue to **grow in volume** due to patents expiry, but **pressure on prices** should **intensify** on this market segment
- **Biotech originators** should become the main **driver of innovation** in the next 5 years
- **Non-biotech originators** should be less dynamic, but they should remain the **largest segment** of the global pharma market

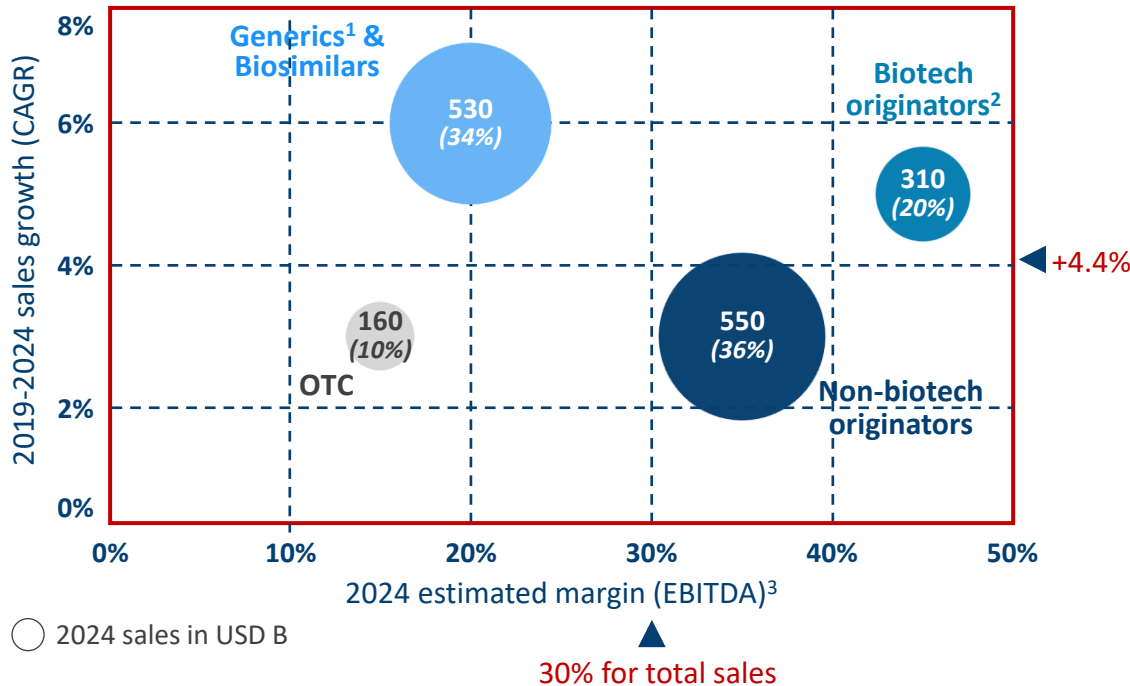
Sources: IQVIA Institute (March 2020) – Smart Pharma Consulting estimates

¹ Ex-factory price before rebates – ² Including branded and unbranded generics and biosimilars, excluding OTC – ³ Excluding biosimilars, already included in the “Generics” segment

Part A – Pharma Market Insights – 3. Attractiveness



By 2024, the sales growth of the pharma market should be essentially driven by generics and biotech originators, but pharma companies should lose two points of profitability



- By 2024, the **global pharma market** should reach USD 1,550 B and grow at a pace of **+4.4% per year**, i.e. 1.8 point of percentage above the forecasted worldwide economic growth, but **0.6 point below the pre-Covid-19 estimates**
- The average **EBITDA** of the Pharma industry should **decrease** from **~32%** in 2019 to **~30%** in 2024, mainly as a result of increasing price pressure
- In 2024, the average profitability of pharma companies should remain more than 4 times higher than the average of all other business sectors
- The **biotech** segment will **remain very attractive** but **biosimilar** competition will **ramp up**
- The OTC segment appears to be the least attractive

Worldwide economic growth – CAGR 2019-2024: +2.6%

Sources: IQVIA Institute (January 2019) – Smart Pharma Consulting estimates

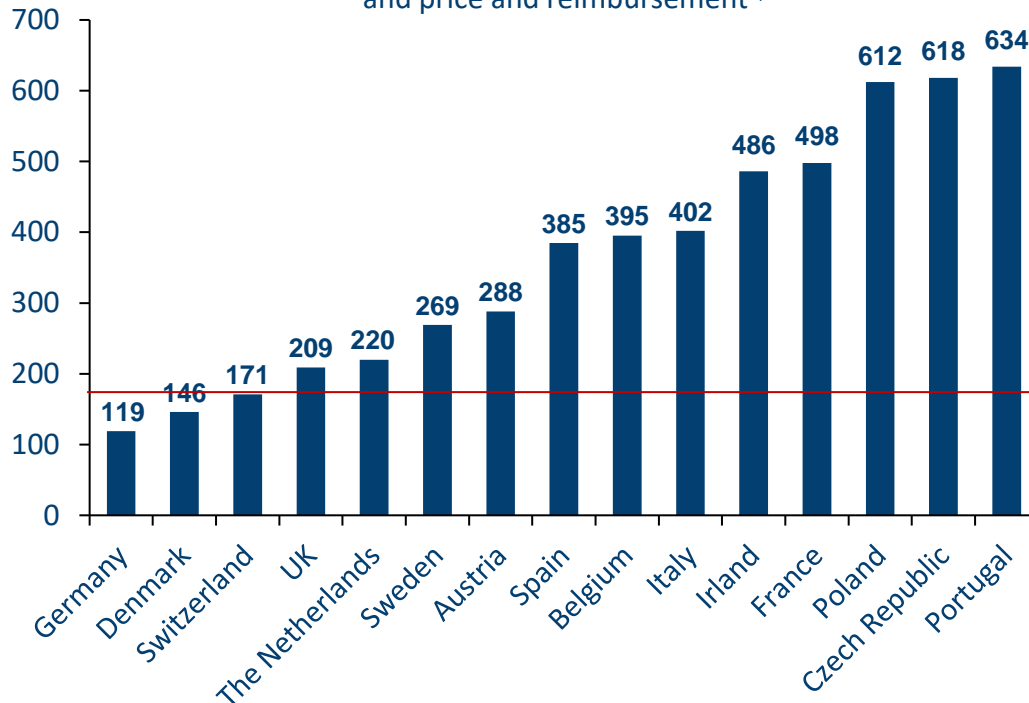
¹ Including branded and unbranded generics and excluding OTC – ² Excluding biosimilars, already included in the “Generics” segment – ³ Earnings before interest, taxes, amortization and depreciation

Part A – Pharma Market Insights – 4. Access to Market



The Covid-19 crisis will have a negative impact, irrespective of the countries, over the 2019-2024 period due to lockdown restrictions and its economic consequences

Median time in days between marketing authorization and price and reimbursement^{1,2}



2018 analysis based on a sample of 121 products approved by EMA (European Medicines Agency) between January 2015 and December 2017

- The Covid-19 pandemics should defer the availability of new medicines in all countries, due to:
 - Lockdown measures having delayed the assessment of drug registration and market access negotiations
 - The induced economic crisis which will lead to stricter cost containment measures
- In most European countries, delays between marketing authorization and drugs availability exceed the 180 days recommended by the European Commission
- The UK and Germany have no delay since reimbursement and price negotiations occur once the product is in the market
- Delays vary widely, due to the time required to obtain their inclusion on reimbursement list and to agree on a price
- Delays are harmful for pharma companies which face a loss of revenues¹ and patients who do not have access to innovation
- The slowing down of the pricing and reimbursement approval process is used by several countries to contain the cost of new drugs with a price likely to be higher than the existing ones
- The delay is also often due to the difficulties for the drug pricing committee and the pharma company to come to an agreement

Sources: Patients W.A.I.T. Indicator – EFPIA (April 2019) – Smart Pharma Consulting analyses

¹ Excluding early access programs for breakthrough innovations (e.g. ATU in France) –
² For drugs receiving their first marketing authorization between 2015 and 2017

Part A – Pharma Market Insights – 4. Access to Market



Drug price pressure imposed by public or private payers is going to intensify, more than ever, irrespective of the value created

Historical Trends

- Payers¹ put in place **increasingly drastic measures** to **control** drug **cost growth**
- **Drugs** account for ~20% of the total healthcare costs², but are used by payers as the **main lever of cost-containment**³
- HTA⁴ agencies and drug pricing committees **control drug cost** through:
 - The definition of the **target population**
 - The **positioning** of the drug in the **therapy**
 - The **price** set per **unit** of the drug
 - A **capping** of the drug turn-over reimbursed
- Progressive shift from **pay-per-product** to **pay-per-performance** pricing model

2020 Impact

- **Delays** in drug assessment due to **lockdown** (part-time activities, backlog assessment put on hold)
- **Redirected priorities** to assess technologies related to the **Covid-19**
- Price **negotiations** becoming **tougher** due to **tighter budgets** resulting from financial disruption, across the board
- Considering the anticipated worldwide **financial recession**, HTAs and payers should put **more emphasis** than ever on **assessing the value of drugs** for patients and healthcare systems

2021 – 2024 Impact

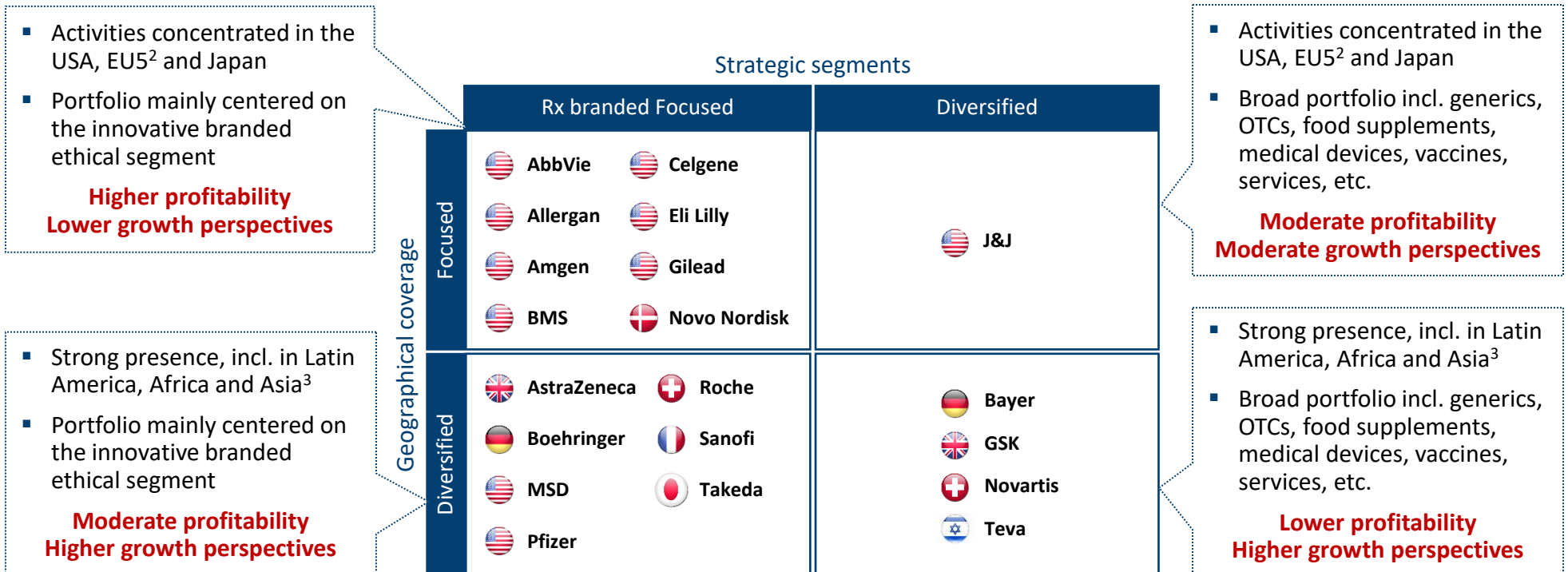
- Strong **squeezes** drug (innovative, me-too, biosimilars, generics, vaccines) **prices** which are likely to **affect by ~2 points the average profitability** of the pharma sector
- **Value-based pricing** models, incl. pay-per-performance, will **become the rule**, especially for **innovative drugs**, if the implementation is **not too complex**
- Generalization of a **budget approach** by disease (e.g. € 700M budgeted for antidiabetic drugs on a given year) with a **mechanism of drawbacks** per drug prescriber for that disease

Part B – Pharma Company Insights – 5. Strategic Directions



Best performers are focused on innovative Rx-bound drugs and generate an important share of their revenues from the USA, which is the most profitable and dynamic market

Top 20 pharma companies Strategic Mapping¹



Note: **Rx Branded focused:** Original Rx-bound drugs and vaccines ≥ 75% of total product sale – **Geographically focused:** >50% of sales in a single geographical region (e.g. USA, Europe, Japan, etc.)

Sources: Companies annual reports (2018) – Smart Pharma Consulting analyses

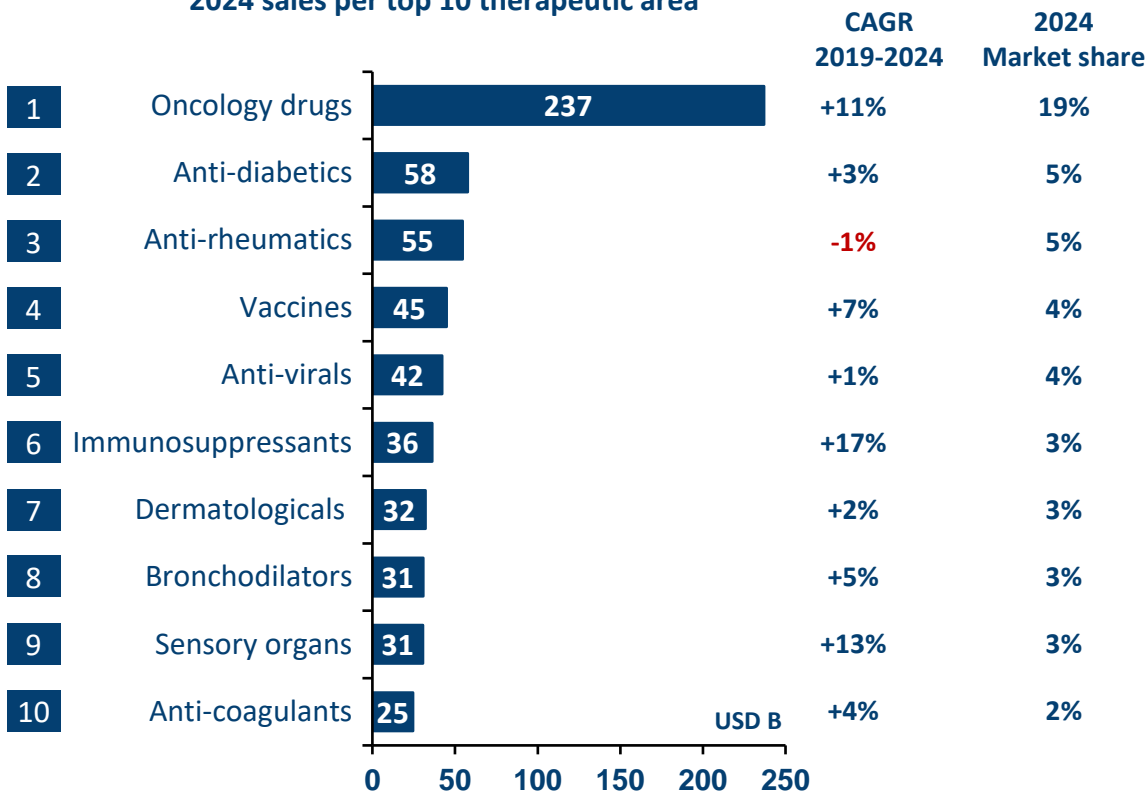
¹ Top 20 pharma companies based on their prescription sales – ² France, Germany, Italy, Spain, UK – ³ Including segments of the population with lower income and/or from rural areas

Part B – Pharma Company Insights – 6. R&D Operations



The important growth in oncology will be mainly driven by anti PD-1 products while immunosuppressants will benefit from an increased incidence of chronic diseases


2024 sales per top 10 therapeutic area



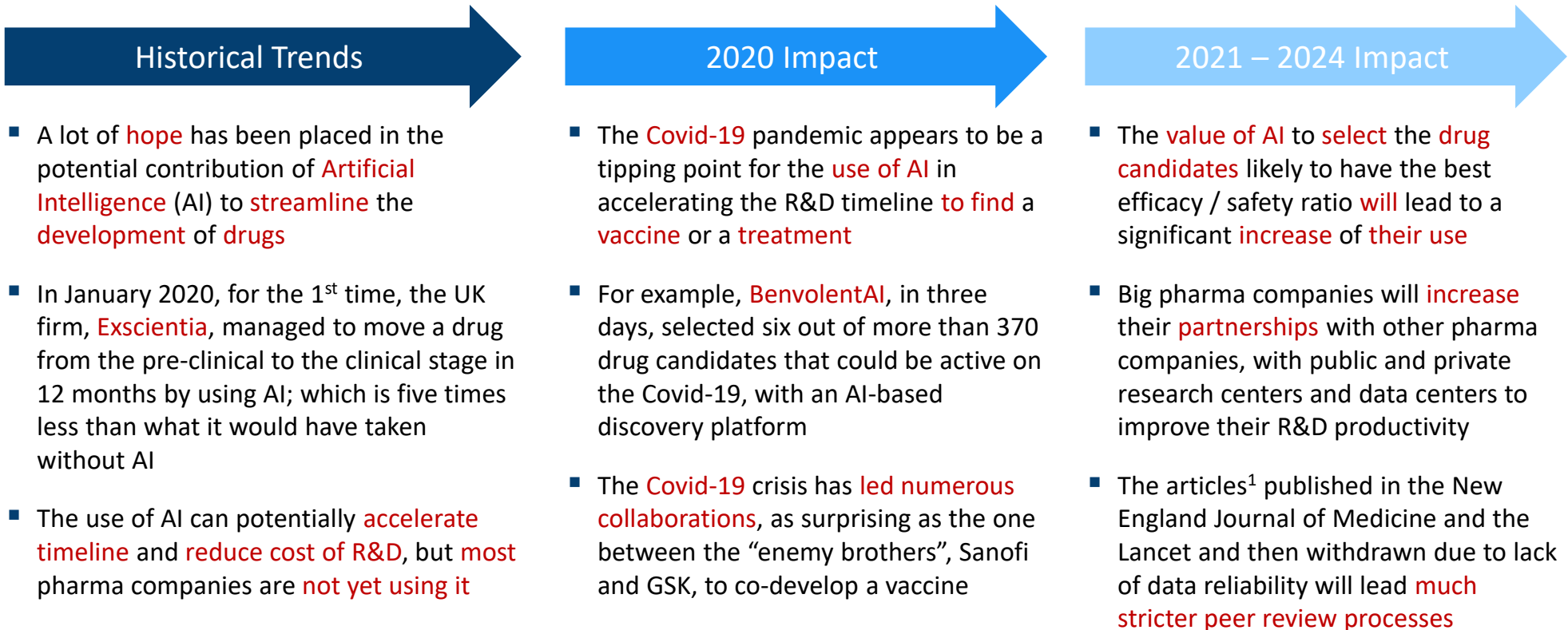
- The 2024 therapeutic area forecasts shows the steadily **increasing weight** of **specialty products**, **sustained by** the development of **new biological drugs**
- **Oncology** prevails as the leading therapeutic area and will be notably **driven by** the growth of **PD-1 inhibitors**
- **Immunosuppressants** will have the **highest CAGR** through 2024, driven by the incidence of chronic diseases and the use of immunotherapeutic agents in clinical development for other therapeutic areas
- **Biosimilars** are beginning to make their mark on **the anti-rheumatic segment**, which should see a decline in its CAGR despite the high drive in sales from JAK inhibitors
- If a vaccine and/or a treatment for the **Covid-19** were discovered, the **Vaccines** and the **Anti-virals** segments **could be boosted** over the period

Sources: World Preview 2019 – Outlook to 2024, Evaluate Pharma (June 2019) – Smart Pharma Consulting estimate

Part B – Pharma Company Insights – 6. R&D Operations



The Covid-19 crisis should contribute to accelerate AI use and further increase partnerships between pharma players to speed up the development of new drugs



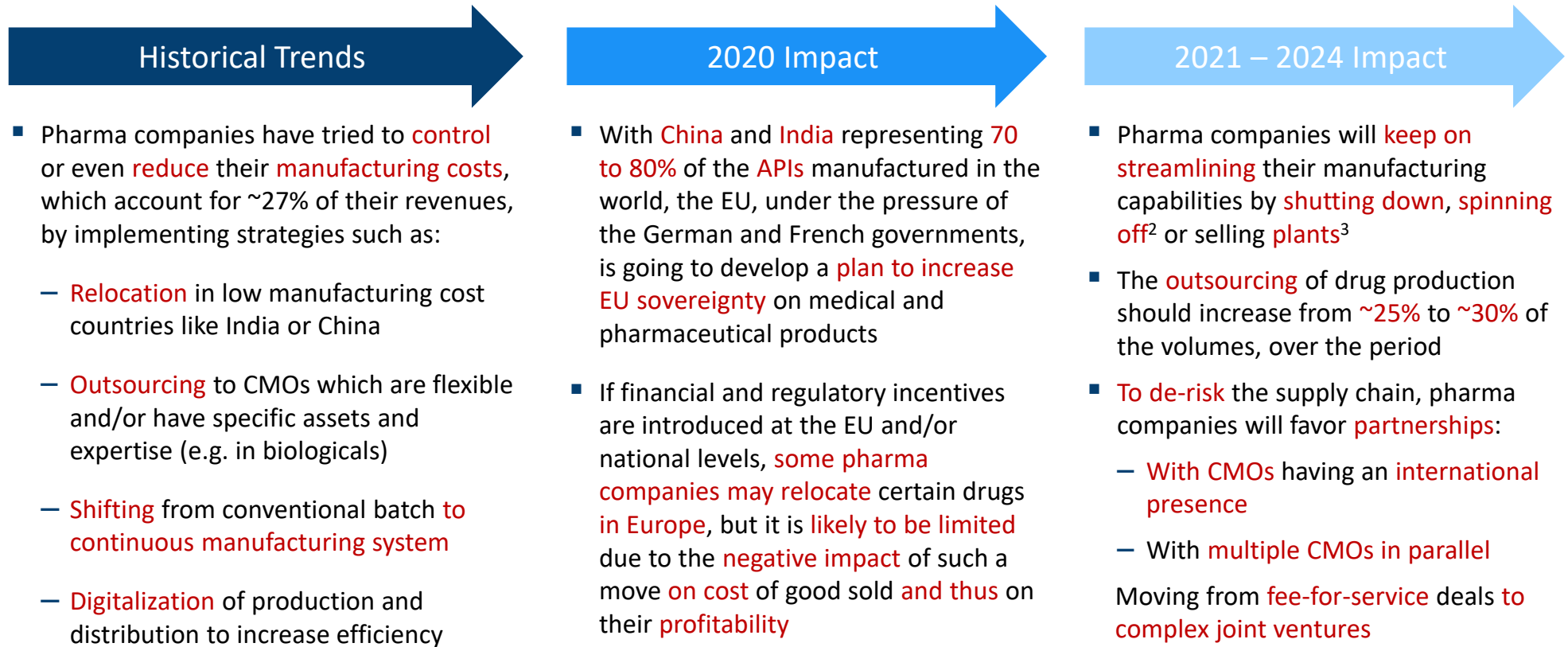
Sources: Smart Pharma Consulting analyses – Exscientia website – BenvolentAI website

¹ Two articles related to the Covid-19

Part B – Pharma Company Insights – 7. Manufacturing & Supply Chain Operations



The Covid-19 crisis might lead to relocate the manufacturing of certain essential drugs in Europe, while CMOs¹ should account for ~30% of the drugs produced by the end of 2024



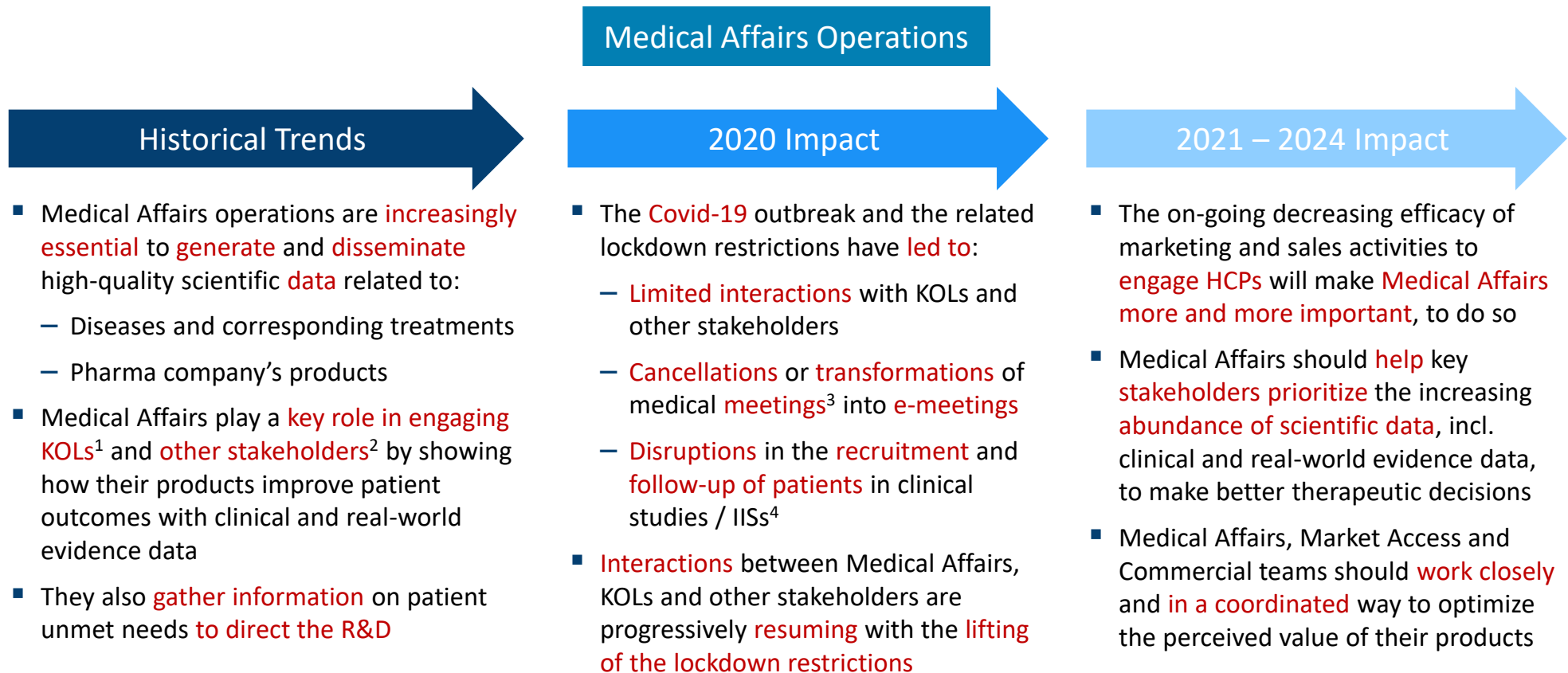
Sources: Smart Pharma Consulting analyses – E. Wilson, NS Healthcare, May 25, 2020

¹ Contract Manufacturing Organizations – ² For instance, Sanofi has recently announced that it will spin off its API business into a separate company by 2022 – ³ In general, to CMOs

Part B – Pharma Company Insights – 8. Medico Marketing & Sales Operations



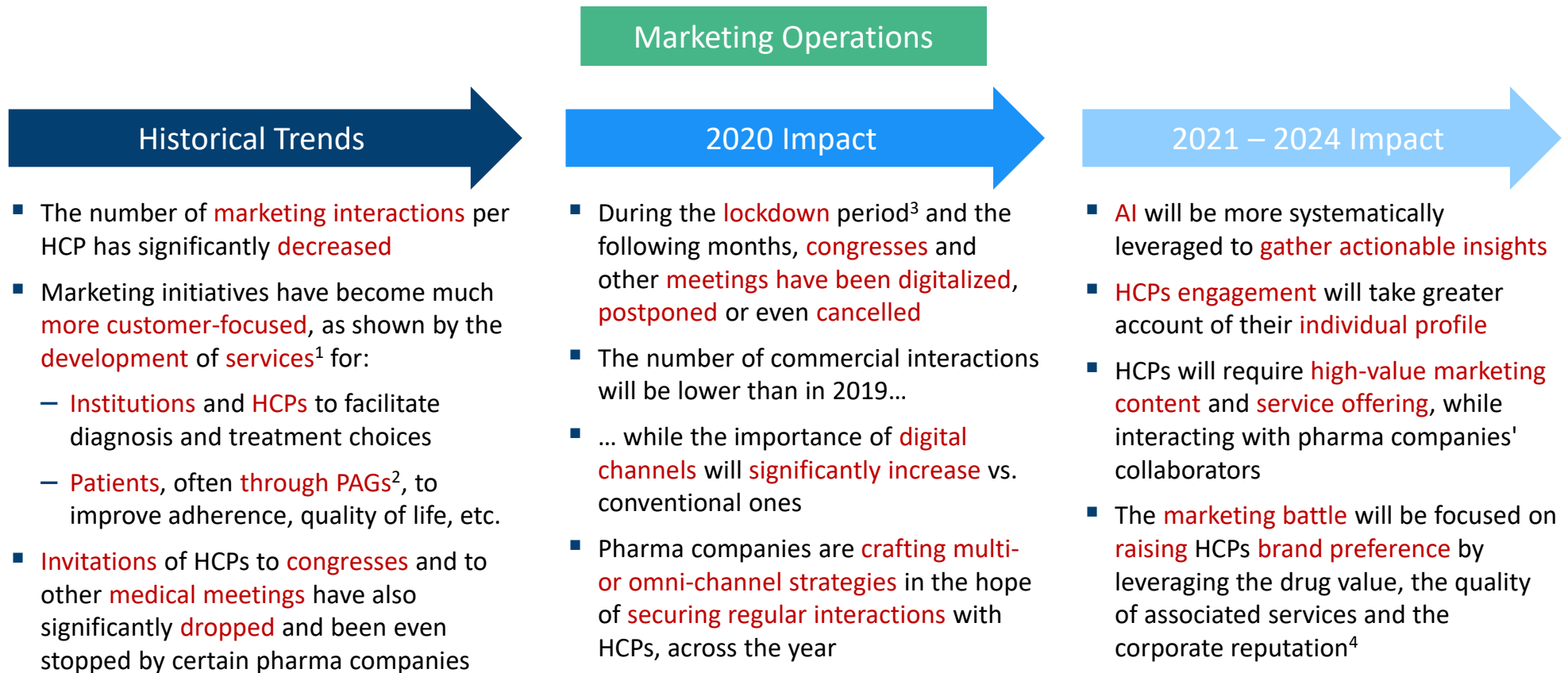
Medical Affairs will become, more than ever, essential to engage KOLs and other key stakeholders to take the full benefit of the products pharma companies offer



Part B – Pharma Company Insights – 8. Medico Marketing & Sales Operations



Pharma marketing strategies should, more than ever, focus on offering high-value content and building strong relationships, so that to raise HCPs preference for marketed brands



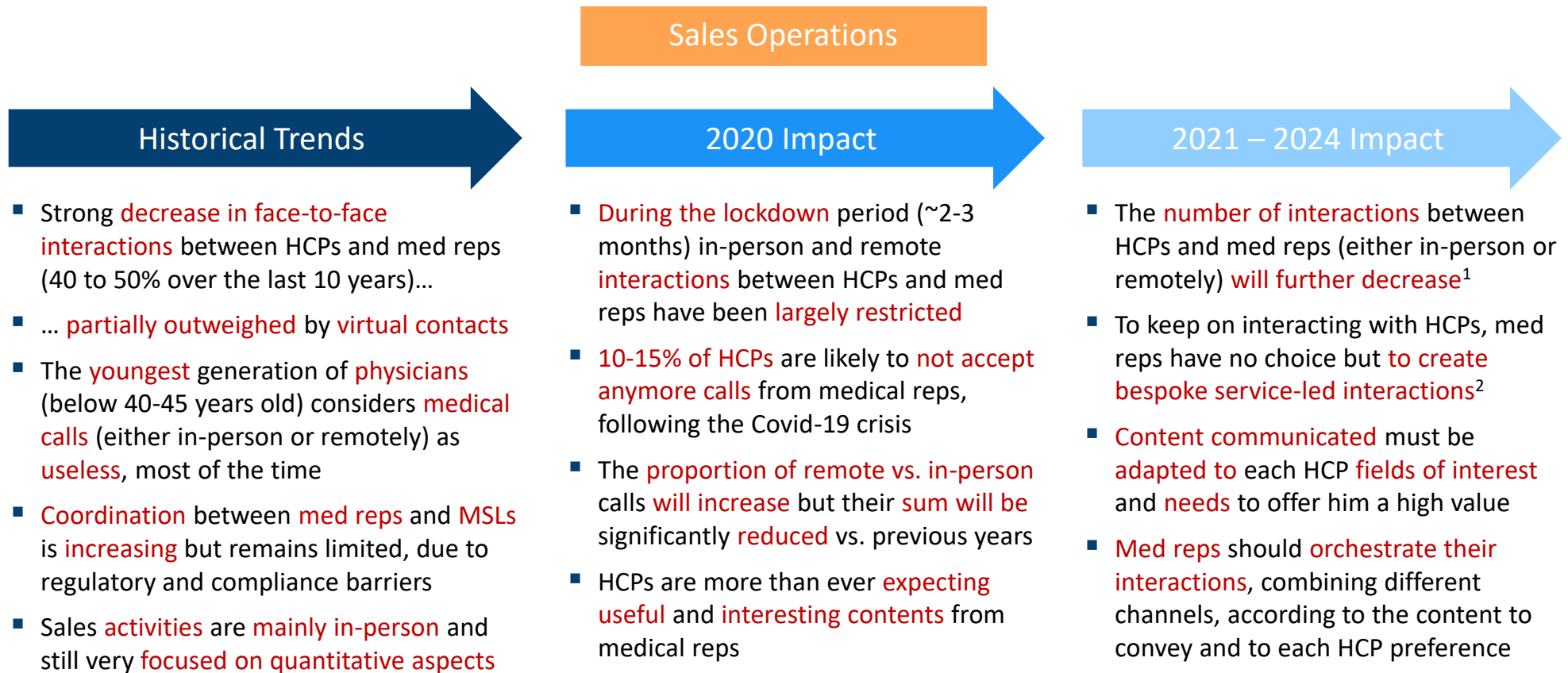
Sources: Smart Pharma Consulting analyses

¹ Conventional or digital, including Apps – ² Patient Advocacy Groups – ³ Two or three months, depending on the countries – ⁴ See the “Brand Preference Mix” concept and tools developed by Smart Pharma Consulting: <https://smart-pharma.com/wp-content/uploads/2019/07/Stakeholders-Brand-Preference-Mix-2016-EN-web.pdf>

Part B – Pharma Company Insights – 8. Medico Marketing & Sales Operations



To positively influence HCPs, med reps should be able to carry out regular and highly valued interactions – either in-person or digital – and propose them useful services



Sources: Smart Pharma Consulting analyses

¹ By 30% to 40% between 2019 and 2024 – ² See our position paper: <https://smart-pharma.com/wp-content/uploads/2019/12/Service-led-Medical-Calls-VW.pdf>

Conclusions



The Global Pharmaceutical Market will remain very attractive despite a much stronger pressure on drug prices, partly outweighed by early and broader access to patients

Global Pharma Market Perspectives 2019-2024

Market Opportunities

- Despite the Covid-19, the **pharma market** should **increase by 4.4%** p.a., on average, over the 2019-2024 period
- **Access** to high **quality healthcare** is the **top priority** of governments and citizens
- Boosted opportunities to discover new treatments – such as for a Covid-19 vaccine – through partnerships:
 - **Public-Private** with academics¹ or public funds²
 - **Private-Private** with other pharma companies³

Market Threats

- **Increasing price pressure** on all categories of drugs (innovative or not, reimbursed or not) from public and private health insurers; and from patients for OTCs
- **Higher risks** and **stricter regulations** re. R&D and registrations, leading to higher costs to launch innovations
- Increasing **difficulties** to **interact with healthcare professionals** to inform them or create partnerships due to lack of interest and time, and regulatory constraints

Implications

- The **Global Pharma Market** will **remain** one of the **most dynamic** and **profitable** industrial **sectors** over 2019-2024, **despite** a decrease from 5.0% to 4.4% of its CAGR and from 32% to 30% of its profitability, due to the **Covid-19 pandemic**
- Drastic **budget constraints** of payers and willingness of governments to give patients, **early and broad access to innovations**, will lead pharma companies to **accept lower prices** than in the past that should be partly **offset by higher volume sold**

Conclusions



The future of pharma companies should be bright, provided they adopt a focused strategy, keep on improving their operational efficiency and design a lean organization

Global Pharma Companies Perspectives 2019-2024

Pharma Companies Strengths

- **Improving portfolio management** with a more focused strategy on the most attractive strategic segments
- **Breakthrough innovative** drugs to come by the end of 2024
- **Increased manufacturing efficiency** with Artificial Intelligence
- Better **clinical studies quality** and development of **real word evidence data** contributing to optimize drugs benefits
- **Reduction** or **removal** of **marketing** and **sales** investments having **no** or **limited business impact**

Pharma Companies Weaknesses

- **Weak negotiating power** of pharma companies vs. public or private payers (e.g. HMOs in the USA)
- **Lack of robust strategy** as shown by frequent changes of priorities amongst numerous pharma companies¹
- **Rigidity** and **complexity** of internal **processes** preventing pharma companies from optimally seizing opportunities and addressing threats¹
- **Underperforming marketing** and **sales** investments

Implications

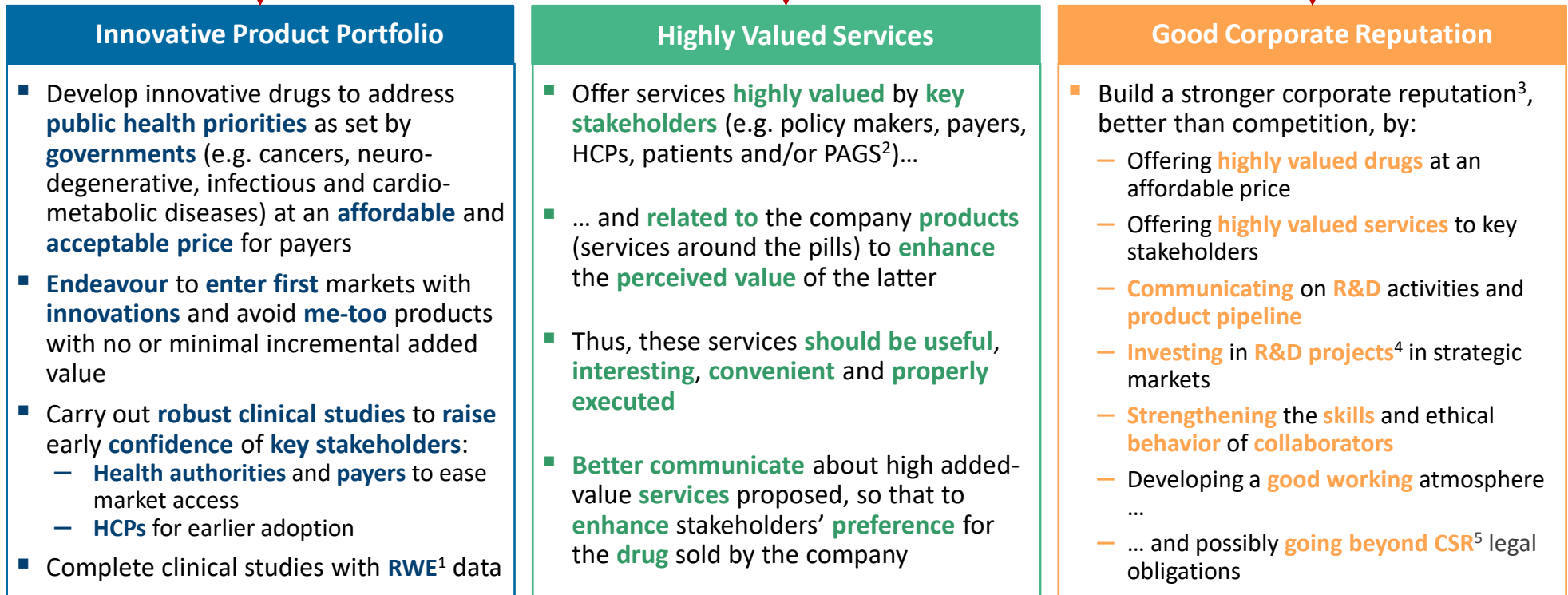
- **R&D-based** companies should **focus** on a limited number of **attractive TAs** and **countries** with the USA being the top priority
- The **potential** for **efficiency** and **efficacy improvements** along the **value chain** of pharma companies is important, especially in **R&D, marketing** and **sales operations**
- Pharma companies' organizations should need to **simplify their processes** and **become further agile**

Conclusions



Best performing pharma companies have in common to market better drugs, offer highly valued services and have a good reputation, driving the preference of their stakeholders

Strategic Priority: **Fight for Key Stakeholders Preference**



Consulting firm dedicated to the pharmaceutical sector operating
in the complementary domains of strategy, management and organization

The Market Insights Series

- The Market Insights Series have on common to:
 - Be well-documented with recent facts and figures
 - Highlight key points to better understand the situations
 - Determine implications for key stakeholders
- Each new issue is designed to be read in 15 to 20 minutes and not to exceed 20 pages

Issue #14

Global Pharma Market & Covid-19 Impact 2019-2024 Perspectives

- We have estimated the likely evolution of the market, following the Covid-19 crisis, through the analysis of 8 specific topics:

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Smart Pharma Consulting Editions



- Besides our consulting activities which take 85% of our time, we are strongly engaged in sharing our knowledge and thoughts through:
 - Our teaching and training activities
 - The publication of articles, booklets, books and expert reports
- More than 80 publications, in free access, can be downloaded from our website, of which:
 - 18 business reports (e.g. The French Pharma Market)
 - 9 position papers in the “Best-in-Class Series”
 - 14 position papers in the “Market Insights Series”
 - 8 position papers in the “Smart Manager Series”
 - 10 position papers in the “Smart Tool Series”
- Our research activities in pharma business management and our consulting activities have shown to be highly synergistic
- We hope that this new publication will be useful for you
- We remain at your disposal to carry out consulting projects or training seminars to help you improve your operations

Best regards

Jean-Michel Peny