Pharma Affordability Dashboard

it's about managing Growth

The benefits of pharmaceutical innovations are often not fully rewarded and overshadowed by the cost discussion [1]. The cost of health care continues to rise, but financial resources are limited, leading to a distribution struggle for funding. The topic of this newsletter is how to cope with and deal with growth as a central influencing and decision-making factor for pharmaceuticals.

Does Horizon Scanning provide answers to calculating and managing affordability?
Horizon Scanning for pharmaceuticals is a systematic process for identifying, evaluating, and monitoring new health technologies impacting the life sciences industry, healthcare, and health policy (cf. [2]). Early awareness of innovative technologies and their impact sets initiative-taking frameworks for resources, investment, policy, and regulation. In the short term, horizon scanning can hardly influence market dynamics and in the medium term, only a limited influence on the necessary market adjustments is possible.

Estimation and Calculation:
With the basic formula: Price x Volume x Use (#new products x $ per treatment x # patients) we hardly get an answer on short and mid-term market development.

- The number of NAS increased by 3-13% across six regulatory authorities comparing the period 2014-2018 and 2019-2023[i]. So, there is no «Orphanization» issue.
- The median annual list price for a new drug in the U.S. was $300'000 in 2023. That was 35% more than $222'000 in 2022[ii].
- Summarizing and forecasting sales trends from different pharmaceutical market sectors is a major challenge, as the individual sectors are subject to considerable uncertainty (cf. Table 1).

[i] CIRS R&D Briefing 93. https://www.rarediseases.uzh.ch/dam/jcr:3598d71b-f173-4c29-bfb2-ff571e20e4ca/CIRS%20RD%20Briefing%2093%20-%20six%20agency%20briefing.pdf

[ii] Quarz : new drug prices US (median annual list prices). https://qz.com/drug-prices-pharma-rare-diseases-2023-1851281956

Table 1: Growth of Pharma Market Sectors

	• The World prescription drug market, including generics and orphans, is estimated at 1,408 $bn in 2026. The growth (CAGR) 2021-2026 is estimated at 6.4%.	• Evaluate Pharma (2021)
Generics	• Generics account for less than 10% of global prescription drug sales (7.1% in 2026). Prescription volume can be as high as 80-90% and in the U.S. alone, generics & biosimilars have resulted in savings of around 400$bn in 2022.	• Evaluate Pharma (2021) • aam Report (2023)
Orphans	• With 11% growth (CAGR 2020-2026), the orphan share of the global Rx market will be around 19% in 2026 (own calc.) • Narrowing growth gap vs. non-orphans	• Evaluate Pharma (2021) • Evaluate Orpan Report (2024)
Obesity	• 6.15 $bn in 2024 to 37.94 $bn in 2032 (CAGR 25.5%) • 24 $bn in 2023 to 131 $bn in 2028 (CAGR 24-27%) • Broad forecast uncertainty of around 40 $bn to 130 $ bn in 2028 (limitation, reimbursement)	• Fortune Business Insight (2024) • IQVIA (2024) • IQVIA (2024)
CGT's	• 21.28 $bn in 2024 to 117 $bn in 2034 (CAGR 18.6%) • In 2026 CGT is expected to be 29.51 $bn which is around 2.1% of the prescription market of 1.408 $bn (own calc.) • The CGTs account for 10% of US FDA approvals in 2023	• Precedence Res. (2024) • Precedence Res (2024) Evaluate Pharma (2021) • Cell & gene (2024)

Evaluate Pharma: World Preview 2021 Outlook to 2026 ; Orphan Drug Report 2024
aam (Association for Accessible Medicines): The U.S. Generic & Biosimilar Medicines Saving Report, September 2023
Fortune Business Insight: https://www.fortunebusinessinsights.com/anti-obesity-drugs-market-104783
IQVIA: https://www.iqvia.com/locations/emea/blogs/2024/10/2024-the-obesity-markets-inflection-point
Precedence Research: https://www.precedenceresearch.com/cell-and-gene-therapy-market
Cell & gene: https://www.cellandgene.com/doc/2024-market-outlook-for-cell-gene-therapies-0001

- *Horizon Scanning sets long term frameworks for resources, investment, policy, and regulation. Short- and midterm impact is limited.*
- *The annual growth rate combines the market growth of the individual pharmaceutical market segments minus the savings from the cost containment measures.*
- *The annual growth rate, or CAGR for a given period, are excellent tools to monitor affordability.*

Pharma Affordability Dashboard

The Basic Pharmaceutical Growth Rate:

First, let us think about a reasonable basic annual growth rate of pharmaceuticals. As for most industries, real GDP growth plus inflation is the base. Real GDP growth for the OECD was 2.3% for the period 2013-2019 [3]. According to the European Central Bank, the best way to achieve price stability is through an inflation rate of 2%[iii]. Overall, a base growth rate of around 4.5% is an acceptable base for pharmaceuticals[iv]. Currently around 6% is more realistic. Leading pharmaceutical companies recorded revenue growth of 6% (CAGR) in 2016-2020 and R&D expenditure growth rate of 6% (CAGR) in 2001-2020 [4]. However, annual R&D costs increased at a rate of 8.5% above general inflation [5]. Although the gross profit margin of pharmaceutical companies is much higher than that of S&P 500 companies, the difference between the net profit margin is only 3.6% when only companies with R&D expenses are considered [6].

[iii] European Central Bank: https://www.ecb.europa.eu/press/pr/date/2021/html/ecb.pr210708~dc78cc4b0d.de.html

[iv] Many will argue that the basis for growth should be higher by adding a risk premium. On the other hand, pharmaceutical innovations benefit from a kind of market monopoly with years of patient protection.

The Framework for Pharmaceutical Growth:

Average (real) health care cost growth continues to outpace GDP growth by around 0.3%[v] [3], [7] which is the fundamental financing issue. Health-to-GDP ratio seems to be stable between 10-12% in many countries. However, small annual changes can lead to a 1-2 percentage point increase in the Health-to-GDP ratio in a period of 5-10 years, which is in the order of many national defense budgets or a significant part of the education budget. In addition the growth of health prices can be compared with general price growth; in France cumulated relative growth (2000-2020) of health prices are only 2% above generial price growth (c.f. U.S. +14%, NL +6%) [8].

The pharmaceutical growth rate should be compared with the combined growth rate of other medical services. However, it is more feasible to compare it to the overall growth rate of healthcare. In Switzerland, the annual growth gap between pharmaceuticals and healthcare was around 2%, making pharmaceuticals an important cost driver [9]. This is pretty much in line with 1-2% historical and projected growth differences (OECD [10], US [11]).

The proposed Pharma Affordability Dashboard:

A pharmaceutical growth rate of 4.5% is an acceptable baseline, while a growth rate of over 6% requires faster and stronger price adjustments. Currently, the global growth forecast for prescription drugs for 2026 and 2028 is 6.4% and 6.1% (CAGR) [vi], respectively, with generics already included. This would be borderline acceptable if both the conditions of excess health care growth vs GDP and excess growth of pharma vs total health care were between the green and yellow areas in the proposed dashboard (Figure 1). Today, the two proposed framework conditions are rather in the advanced yellow range. Consequently, the 6% growth rate in the pharmaceutical industry must be reduced through cost-cutting measures.

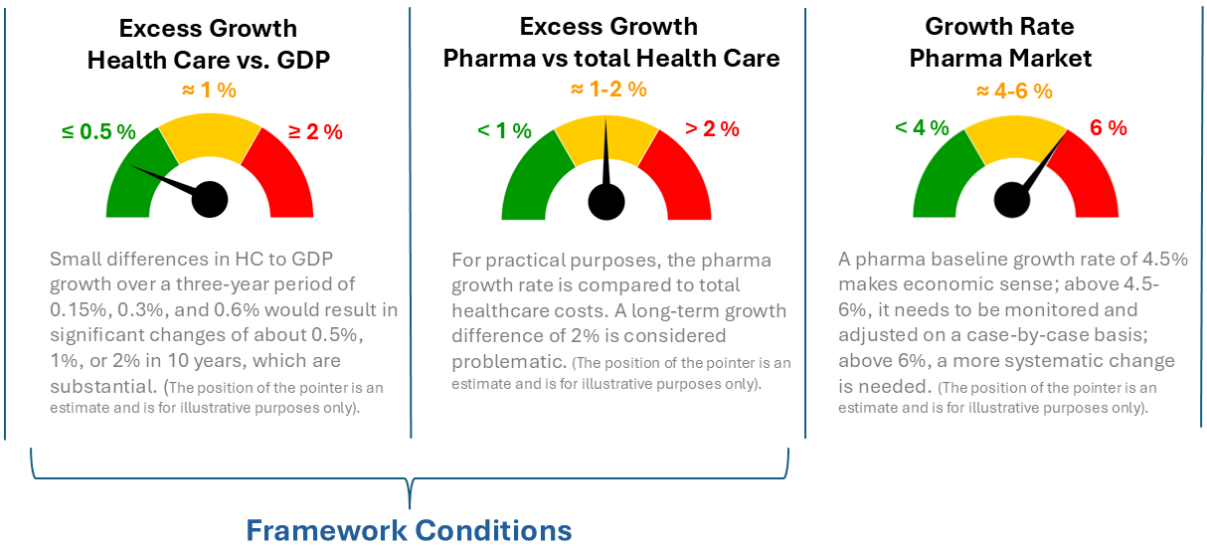

Figure 1: Pharma Affordability Dashboard

[v] Real GDP growth 2.3% OECD Countries average 2013-2019 [3]. Average annual (real) Health Care growth per capita 2.6% (2015-2019) [7].

[vi] Evaluate Pharma Word Preview 2021 (CAGR 2021-2026) and 2022 (CAGR 2021-2028).

- *Drug prices come under increasing pressure when healthcare costs rise faster than GDP and the pharmaceutical market rises more than healthcare.*
- *A growth differential of around 1% between pharmaceuticals and healthcare seems acceptable, while a difference of more than 2% is likely to trigger additional, more far-reaching measures to contain costs.*
- *A pharmaceutical growth rate of 4.5% is an acceptable baseline, while a growth rate of over 6% requires faster and stronger price adjustments.*

How to deal with and manage Pharmaceutical Growth Rate

We need successful, high-selling medicines. This can only be achieved if the expectations and needs of doctors and patients are met above average in terms of efficacy and tolerability. In many cases, success cannot be predicted, and most pharmaceutical companies have only around three «big» products. The key is always to find a balance between incentives for the development of pharmaceutical innovations and cost control for high-turnover products. Since the current conditions in the healthcare sector are unfavorable, the authorities are forced to take measures to keep the growth rate of the pharmaceutical industry below 6%. The challenge for the pharmaceutical industry is to find the right balance between savings from all products and savings from individual products. Table 2 provides an overview of current opportunities to reduce the pharmaceutical growth rate to an acceptable level.

Table 2: Management of Growth

		Approach	Effect	Considerations
ALL PRODUCTS	Generics & Biosimilars	▪ The same at much lower price	▪ Off-patent savings	▪ Price pressure leads to consolidation and supply problems
	Re-Evaluation	▪ Reassessment of cost/benefit ▪ Price comparison (international and domestic)	▪ Leads normally to lower price	▪ Selection of comparator ▪ Fair comparison
	Disinvestment	▪ Identifying unnecessary or harmful analyses and treatments	▪ Cancel as a compulsory benefit (Delisting)	▪ Financing of activities ▪ Acceptability
	Mandatory Rebates	▪ Temporary rebate as needed	▪ Lowers growth rate of pharma market	▪ Regardless of the value of a drug ▪ Easy to apply
SINGLE PRODUCT	MEAs	▪ Discounts and rebates to compensate for medical and economic uncertainties	▪ Early sales ▪ Savings through net pricing ▪ Risk/Benefit-sharing	▪ Development of medium and long-term sales ▪ Budget Impact
	VBHC	▪ Generation of patient value along the continuum of care	▪ Cost reduction by improving health care delivery process	▪ How are process-related cost reductions divided into price increases for individual service providers and savings for cost bearers?

Today, the pharmaceutical growth rate is mainly driven by new, high-value innovations. Some succeed in achieving an unexpectedly high sales volume, for which a volume-dependent price adjustment seems to make sense (cf.[12], [13]). Ultimately, true breakthrough innovations should never be limited by the growth rate, e.g. Hepatis C, Corona, etc. An additional fund should be set up for the co-financing of such products, which would be proactively fed jointly by the public authorities and industry, e.g. through savings made.

- *The challenge for the pharmaceutical industry is to find the right balance between savings from all products and savings from individual products.*
- *True breakthrough innovations should never be limited by the growth rate. An additional fund should be set up for the co-financing of such products.*

Limitation

This newsletter deals with growth topics in the market access sector. Some data and opinions may be disputable, but the main purpose is to illustrate the concept. No claim is made to completeness and correctness; Additions, corrections and comments are welcome. There are a lot of different markets, sales and price data with different definitions, for example. The circumstances in countries are different, but the basic concept should be adaptable. Access to breakthrough innovations should not be limited by a growth limit.

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