NAVIGATING SWITZERLAND 'S PHARMACEUTICAL PRICING FRAMEWORK: LEGAL AND MARKET ACCESS PERSPECTIVE

Can business still predict legal & regulatory outcomes?

Lunch Conference AIBL, October 30, 2026

Gilles Aebischer
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OM Pharma in summary

Founded in **1937**

Headquartered in **Meyrin, Geneva**

CHF 197.3M Net Sales (FY2025)

422 employees worldwide (FY2025)

Global Reach: Presence in 100 countries through 90+ international partners

Bacterial Lysate Manufacturing Site in Meyrin, Geneva

Therapeutic Areas

- Respiratory & Infectious Diseases
- Urology & Women's Health
- Central Nervous System (CNS)
- Vascular Diseases
- Hospital Care

A leader in the Prevention of Recurrent Respiratory and Urinary Tract Infections

How many of you would advise a client to invest hundreds of millions of Swiss francs in a project if the applicable legal framework were defined only partly by legislation and mainly by evolving administrative practice?

01 The Pharmaceutical Landscape

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03 Expertise, Administrative Discretion and Judicial Review

04 Regulatory Practice and its Consequences



01

The Pharmaceutical Landscape

Pharmaceutical is a key pillar the Swiss economy

53% **of Swiss exports in 2025**

Chemicals and pharmaceuticals

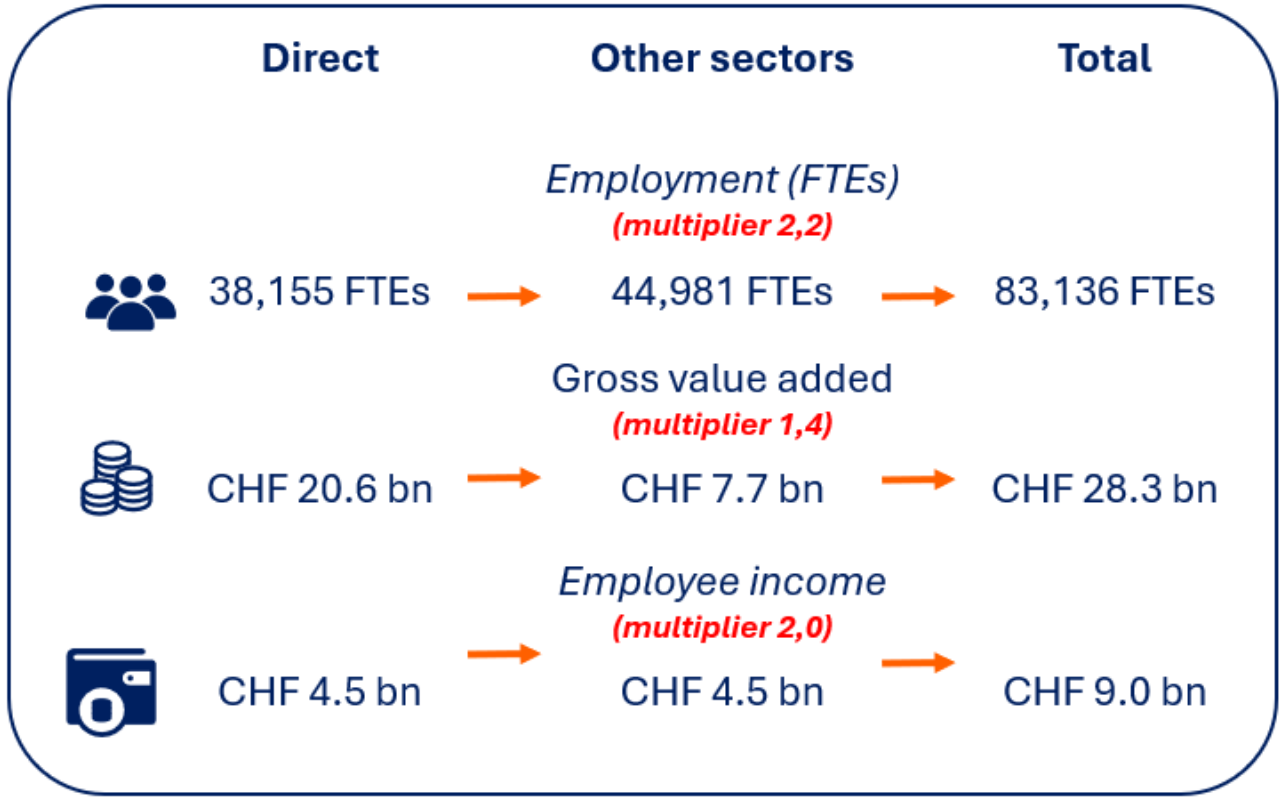
~250,000 **Direct & indirect pharmaceutical jobs**

6 % **Of the Swiss GDP directly**

>40% **of Swiss growth over the decade 2014-2024**

Source: BAK Economics, The Importance of the Pharmaceutical Industry for Switzerland, 2024.
Swiss Federal Office for Customs and Border Security (FOCBS/OFDF), Foreign Trade Statistics.

Economic footprint Life Sciences in Western Switzerland



SWI swissinfo.ch Switzerland's voice in the world since 1935 FR

The life sciences are an economic lung for French-speaking Switzerland, but the population is not very aware of it. This is what emerges from a study presented by the Groupement Romand de l'Industrie Pharmaceutique (GRIP), which calls for better framework conditions.

October 06, 2026 - 14:00 1 minute

(Keystone-ATS) Life sciences "have become one of the main economic pillars of Western Switzerland: they account for more than 83,000 jobs, generate CHF 28 billion in added value and alone explain 42% of the region's real growth," said GRIP co-president Gilles Aebischer on Tuesday, during the presentation of the BAK Economics study to the media gathered on the Biopôle campus in Lausanne.

However, the French-speaking part of Switzerland does not perceive the economic weight of this sector on their territory. Indeed, according to a survey by the gfs.bern institute, in the majority of French-speaking cantons, 59% of respondents cite life sciences as one of the most important sectors for the Swiss economy, but only 12% for their own canton.

Source: BAK Economics, The Life Sciences Sector in Western Switzerland, 2026.

Pharmaceutical Basics

Why predictability matters in a long-cycle, high-risk industry

1 Long-term investment

10-15 year development cycles
Significant upfront investment

2 Scientific risk

High attrition
Uncertain scientific outcomes

3 Regulatory oversight

Marketing authorization
Continuous post-market oversight

4 Market access

Pricing & reimbursement
Commercial viability

In a long-term, high-risk industry, regulatory predictability is a condition for investment and innovation.

A few figures on the probability of success



Source: [1] Kim Y, Lee S. Yakhak Hoeji. 2026;70(3):214–222. Based on licensed pre-clinical projects
[2] Clinical Development Success Rates and Contributing Factors 2011-2020, BIO I QLS Advisors I Informa UK Ltd (2021). Overall figures.

At the heart of (sometimes) conflicting health economics interests

Governmental authorities

- Approve pharmaceuticals with positive risk/benefit ratio
- Determine «right» pricing and reimbursement
- Foster innovation & economy

Patient:

- Access to quality medicines
- Pay affordable drug price and/or low insurance premium
- Looking for proper use of public money



Insurance/Payors

- Improve long-term patient outcome
- Ensure predictable/sustainable spending
- Manage cost (down)

Business stakeholders

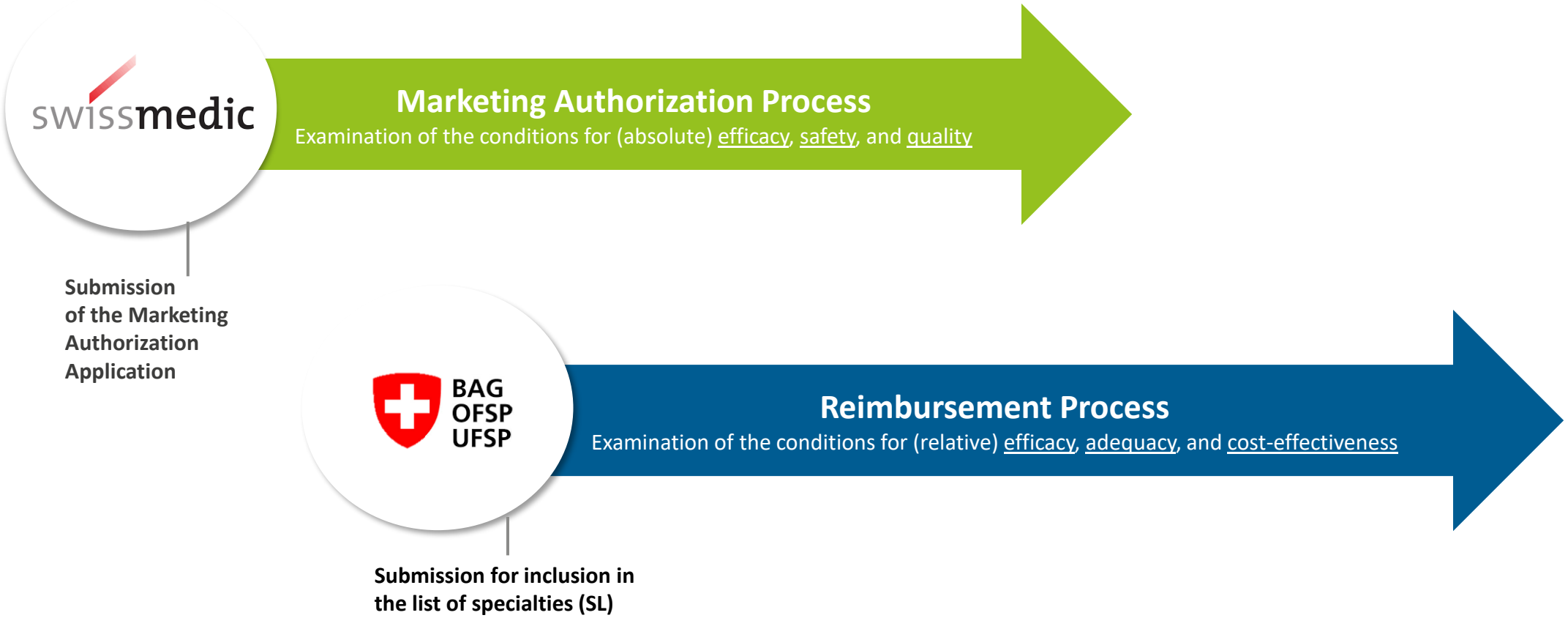
- Ensure a profitable venture
- Finance high investment in R&D with high attrition rate
- Compensate for increase in operating/manufacturing costs

02

Swiss Market Access & Pricing in a Nutshell

Marketing Authorization and Reimbursement

Standard Process



Source: Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA).
Federal Health Insurance Act (KVG/LAMal)

Price Setting at the Federal Office of Public Health (FOPH)

For Original Medicines

Cost-effectiveness criteria is assessed based on a comparison with

1) prices charged abroad (**External Reference Pricing**; **ERP**);
2) and a comparison with other medications (**Internal Reference Pricing**; **IRP**), each accounting for half.

$$\frac{ERP + IRP}{2} = Price$$

ERP = 

IRP = **Comparison with reimbursed comparators in the Swiss market (SoC)**

Source: Art. 32 al. 1 LAMal.
Art. 65 et seq. OAMal.
Art.30 et seq.OPAS

03

Expertise, Administrative Discretion and Judicial Review

The Changing Nature of Regulation

Administrative guidance is not new. What has changed is its density, technicality and practical regulatory significance.

Predominantly formal framework

LEGISLATION

ORDINANCES

Layered regulatory environment

GUIDELINES & TECHNICAL DOCUMENTS

ADMINISTRATIVE PRACTICE

Where is the rule effectively shaped?

An Example of Regulatory Density

swissmedic

Merkblatt / Aide-mémoire / Scheda informativa / Information sheet
Dokumentenklassen- und Typen

Bezeichnung der Dokumentenklassen und – typen und deren Abkürzungen / Désignation des classes et types de documents et leurs abréviations / Denominazione delle classi e dei tipi di documenti e delle abbreviazioni / Description of the document classes and types and their abbreviations

Dokumentenklasse	Dokumententyp	Deutsch	Français	Italiano	English
GE – Gesetz		Gesetz / Verordnung	Loi / Ordonnance	Legge / Ordinanza	Law / Ordinance
GR – Grundsatz		Grundsatz	Principe	Principio	Management
	GF – Grundsatz Führung	Grundsatz Führung	Principe de gestion	Principio della gestione	Management principle
	GL – Grundsatz Leistung	Grundsatz Leistung	Principe de prestation	Principio della prestazione	Performance principle
	GS – Grundsatz Support	Grundsatz Support	Principe de support	Principio del supporto	Support principle
SR – Strategie		Strategie	Stratégie	Strategia	Strategy
	SD – Strategisches Dokument	Strategisches Dokument	Document stratégique	Documento strategico	Strategic document
AW – Anweisung		**Anweisung**	**Instruction**	**Istruzione**	**Instruction**
	AA – Arbeitsanweisung	Arbeitsanweisung	Instructions de travail	Istruzioni di lavoro	Working instructions
	HB – Handbuch	Handbuch (aller Art)	Manuel (de tout genre)	Istruzione Manuale (di tutti i tipi)	Handbook (all types)
	MB – Merkblatt	Merkblatt	Aide-mémoire	Scheda informativa	Information sheet
	LL – Leitlinie	Leitlinie	Ligne directrice	Linea guida	Guideline
	WL – Wegleitung	Wegleitung	Guide complémentaire	Guida complementare	Guidance document
	PU – Publikation	Publikation	Publication	Pubblicazione	Publication
PZ – Prozess		**Prozess**	**Processus**	**Processo**	**Process**
	PB – Prozessbeschreibung	Prozessbeschreibung	Description de processus	Descrizione del processo	Process description
RL – Richtlinie	RL – Richtlinie	Richtlinie	Directive	Direttiva	Guideline
HD – Hilfsdokument		**Hilfsdokument**	**Document d'aide**	**Documento d'aiuto**	**Support document**
	VZ – Verzeichnis	Verzeichnis	Liste	Elenco/Lista	Directory
	TA – Tabelle	Tabelle	Tableau	Tabella	Table
	TI – Technische Interpretation	Technische Interpretation	Interprétation technique	Tecniche interpretazione	Technical interpretation
VO – Vorlage		**Vorlage**	**Modèle**	**Modello**	**Template**
	AH – Anhang	Anhang	Annexe	Allegato	Attachment
	CB – Clichébrief	Clichébrief (aller Art)	Lettre type (de tout genre)	Lettera modello (di tutti i tipi)	Model letter (all types)
	CL – Checkliste	Checkliste	Liste de contrôle	Lista di controllo	Checklist
	FO – Formular	Formular (aller Art)	Formulaire (de tout genre)	Formulario (di tutti i tipi)	Form (all types)
	VL – Vorlage	Vorlage (aller Art)	Modèle (de tout genre)	Modello (di tutti i tipi)	Template (all types)
	TB – Textbaustein	Textbaustein	Elément de texte	Modulo di testo	Text element
	FD – Flussdiagramm	Flussdiagramm	Diagramme de flux	Diagramma di flusso	Flowchart

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The Core Tension

Expertise is necessary. Discretion is inevitable. Review must remain effective.

1 Technical expertise

Complex regulation requires specialized assessment.

→

2 Administrative discretion

Expert judgment cannot be fully predetermined.

→

3 Effective judicial review

Discretion must remain transparent, reasoned and reviewable.

The legal question is not whether authorities should have discretion, but how that discretion is structured and controlled.

When does judicial deference risk weakening effective review?

Example 1: Judicial Deference to Technical Expertise

Extract from therapeutic products case law reflecting the "**Ohne-Not**" doctrine

Original extract

Bien qu'étant au bénéfice d'un plein pouvoir de cognition, le Tribunal ne peut pas substituer sa propre appréciation à celle de l'autorité de première instance lorsqu'il s'agit d'examiner – comme c'est le cas en l'espèce – des questions qui requièrent des connaissances techniques. Aussi l'autorité de juridiction administrative doit-elle respecter le pouvoir d'appréciation reconnu à l'autorité administrative de première instance, en ne s'écartant pas sans nécessité et motif pertinent de la solution opportune ou convenable retenue par celle-ci (ATF 135 II 296 consid. 4.4.3). Plus le pouvoir d'appréciation de l'autorité de première instance est important, plus le Tribunal de céans est appelé à faire preuve de retenue en exerçant son propre pouvoir d'appréciation, ce qui suppose toutefois que l'autorité inférieure ait clairement et précisément motivé sa décision (cf. ATF 133 II 35 consid. 3 ; TAF C-5006/2019 du 31 mars 2021 consid. 3.3).

English translation

Although the Court has full power of review, it may not substitute its own assessment for that of the authority of first instance when examining, as in the present case, matters requiring technical expertise. Accordingly, the administrative court must respect the discretion afforded to the administrative authority of first instance and should not depart, without necessity and relevant grounds, from the appropriate or reasonable solution adopted by that authority (BGE 135 II 296, consid. 4.4.3). The broader the discretion enjoyed by the authority of first instance, the greater the restraint the Court must exercise when exercising its own discretion, provided, however, that the lower authority has clearly and precisely stated the reasons for its decision (cf. BGE 133 II 35, consid. 3; Federal Administrative Court, C-5006/2019 of 31 March 2021, consid. 3.3).

Reference: Swiss Federal Supreme Court, ATF 133 II 35, p. 39.

Example 1: Judicial Deference to Technical Expertise

A legitimate institutional rationale, with a rule-of-law limit

Institutional rationale

Specialized authorities possess technical expertise that courts may not be able to reproduce fully.

Judicial approach

Courts generally refrain from replacing technically or politically informed assessments without compelling reasons.

Rule-of-law tension

Excessive deference may make factual or technical assessments difficult to challenge effectively.

How can courts respect specialized expertise while still ensuring effective review of facts, methodology and legal limits?

Source: Swiss Federal Supreme Court, ATF 133 II 35, p. 39.

Example 2:
Can Judicial Review Cure an Incomplete Administrative Record?

1 **Swissmedic**

Reclassification to category B
Initial factual record questioned

2 **Federal Administrative Court**

Additional reasoning
Facts considered commonly known (C-4968/2019)

3 **Federal Supreme Court**

Different legal basis considered
Outcome upheld; issue partly open (2C_49/2022)

Legally defensible

- Documented risk of misuse may justify intervention
- Courts apply the law ex officio
- Substitution of legal grounds may be permissible

Judicial-review concern

- Robustness of the initial fact-finding
- Correcting law vs supplementing facts
- Extent to which review methodology was addressed

Does ex officio application of law allow a court to correct legal reasoning, or also compensate for an insufficiently established factual record?

Other Areas Influenced by Administrative Practice

Different policy tools, a recurring question of legal certainty

Health Technology Assessments

POLICY OBJECTIVE
Evidence-based allocation of healthcare resources

PRACTICAL IMPACT
Additional evidence, possible duplication, assessment uncertainty

QUESTION
How can criteria and institutional roles be transparent while avoiding unnecessary duplication?

Pricing models

POLICY OBJECTIVE
Facilitate access while managing uncertainty and expenditure

PRACTICAL IMPACT
Contractual complexity, reporting obligations, reduced predictability

QUESTION
What transparency and normative guidance is appropriate for individualized arrangements?

Volume & payback mechanisms

POLICY OBJECTIVE
Manage expenditure and budget impact

PRACTICAL IMPACT
Volume caps, budget caps, revenue-linked adjustments, paybacks

QUESTION
How should triggers and financial consequences be defined for predictability and equal treatment?

Recurring issue: material business effects where decisive criteria may not always be fully apparent from formal legislation.

04

Regulatory Practice and its Consequences

Example: Who Bears the Cost of Regulatory Change?

Original extract (2C_49/2022)

7.6. En l'espèce, on est en présence de la modification d'une autorisation de mise sur le marché de deux médicaments. En effet, lorsque Swissmedic octroie une telle autorisation, il précise la catégorie de remise du médicament (cf. art. 40 al. 1 OMéd). La classification d'un médicament dans une catégorie de remise est ainsi indissociablement liée à l'autorisation de mise sur le marché. Dès lors que ces catégories sont redéfinies, l'autorisation de mise sur le marché doit être modifiée. Swissmedic a agi d'office, à la suite de la révision législative, en attribuant une nouvelle catégorie de remise aux médicaments de la recourante. Cela étant, il aurait également pu être prévu qu'il incombait aux détenteurs d'autorisations de requérir une modification de leurs autorisations de mise sur le marché, dès lors que la catégorie à laquelle appartenait leurs médicaments était supprimée. Il apparaît ainsi que la recourante est touchée par la modification législative en cause car elle détient une autorisation de mise sur le marché. Le lien de causalité réside donc dans la titularité de l'autorisation. La détentrice (personne assujettie) d'une autorisation modifiée (objet) d'office par Swissmedic est donc soumise à émolument sur la base de l'art. 65 LPTh.

English translation

7.6. In the present case, the matter concerns an amendment to the marketing authorisations for two medicinal products. When Swissmedic grants such an authorisation, it specifies the dispensing category applicable to the medicinal product (cf. Art. 40 para. 1 TPO). The classification of a medicinal product in a dispensing category is therefore inextricably linked to its marketing authorisation. Where those categories are redefined, the marketing authorisation must consequently be amended. Following the legislative revision, Swissmedic acted ex officio by assigning the appellant's medicinal products to a new dispensing category. That being so, the holders of authorisations could equally have been required to apply for an amendment to their marketing authorisations where the category to which their medicinal products belonged had been abolished. It therefore follows that the appellant is affected by the legislative amendment at issue because the appellant holds a marketing authorisation. The causal link thus lies in the holding of that authorisation. The holder (subject of the measure) of an authorisation amended ex officio by Swissmedic (object of the measure) is therefore subject to a charge under Art. 65 TPA.

Reference: Swiss Federal Supreme Court, ATF 133 II 35, p. 39.

Who bears the Cost of Regulatory Change and Unpredictability?



Why it matters

The company may not have initiated the change, yet evolving expectations can require dossier updates, additional data and resources.

Economic dimension

Administrative fees and implementation delays and costs can make regulatory uncertainty itself a measurable business burden.

Why Legal Certainty Matters

Investment decisions

Long time horizons require foreseeable conditions.

Innovation incentives

Risk capital depends on a stable regulatory pathway.

Timely patient access

Predictability supports sustainable translation from science to access.

Legal certainty connects investment, innovation and patient access.

Key Takeaways

Pharma is a **high-risk industry driven by science**, dealing with long-term development cycles and a **strictly controlled market access and pricing power**.

With the **increase of administrative norms**, guidance, etc supplementing laws and ordinances, pharma companies face **regulatory unpredictability** challenging their ability to make reasonably foreseeable business cases and decisions.

Legal certainty remains a **cornerstone of investment, innovation and economic competitiveness**, be it in pharma, in Switzerland and in any other industries and geographies.

Thank you

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