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Whilst political arbitration remains necessary, multi-year frameworks present legitimate industry demands requiring careful implementation.

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*Virginie Beaumeunier, head of France's CEPS, brings deep expertise in competition law and economic regulation to pharmaceutical pricing. Her background—including roles at the Finance Inspectorate and Competition Authority—shapes her approach to balancing innovation, cost control, and industrial sovereignty. This interview highlights France's evolving regulatory landscape, marked by a shift toward evidence-based pricing, greater predictability, and consideration for environmental and industrial policy goals***.**

Could you begin by outlining your primary mandate and vision for CEPS during your first five months in this role?

My appointment represents a convergence of economic regulation expertise with healthcare policy imperatives., I have cultivated a background in competition and regulatory economics, particularly through my leadership of the General Directorate of Competition, Consumer Affairs and Fraud Prevention—itself a CEPS member organisation. My experience at the Competition Authority as Rapporteur General provided valuable exposure to healthcare sector dynamics, including contentious generic medicine cases and comprehensive studies on pharmaceutical distribution networks. As Inspector General of Finance, I am very concerned by control of public expenditure.

The pharmaceutical landscape has undergone remarkable transformation over the past three decades. Previously, we encountered relatively few innovative products, and even the most advanced therapeutics carried costs that appear modest by contemporary standards. Today, we observe not only an acceleration in novel product introductions but also increased complexity through multiple indication extensions—a phenomenon that presents particular regulatory challenges.

My mandate centres on reconciling what might appear irreconcilable: maintaining public expenditure discipline whilst ensuring patient access to innovative treatments under sustainable reimbursement conditions, and simultaneously encouraging sovereignty and industrial development. The COVID-19 crisis has heightened awareness of supply security imperatives, whilst the President’s broader reindustrialisation agenda has particular resonance in pharmaceuticals given France’s deindustrialisation trajectory

How do you address the structural challenges inherent in France’s segmented healthcare system?

The siloed functioning of different healthcare sectors—between pharmaceuticals and medical devices, hospital and community care, and various health professionals—represents a fundamental impediment to coherent policy development. This fragmentation complicates the pursuit of holistic system approaches, with few stakeholders maintaining comprehensive perspectives on healthcare delivery.

Industry advocates legitimately argue for broader evaluation frameworks when pharmaceuticals reduce hospitalisation durations or prevent admissions entirely. We observe compelling examples in diabetes management, where innovative medical devices complement evolving pharmaceutical interventions. Similarly, emerging obesity treatments generate claims regarding broader morbidity impacts that extend beyond traditional pharmaceutical assessment boundaries.

However, our regulatory framework operates within annual Social Security financing legislation constraints, necessitating what may appear as occasionally abrupt regulation whilst accommodating demands for broader therapeutic impact recognition. This tension requires evidence-based evaluation approaches. Drawing from my competition law background, I emphasise the necessity for robust demonstration of positive effects or externalities claimed for any product, whether pharmaceutical or medical device.

What role does health economics play in your pricing methodology evolution?

Health economics provides a comparative framework for product evaluation that, when comprehensively applied, can accommodate positive externalities whilst maintaining analytical rigour. This approach, outlined in my orientation letter, presents implementation challenges but offers potential convergence opportunities for our diverse objectives.

We are collaborating with the High Authority for Health (HAS) to enhance our advisory processes, ensuring that evaluations better serve our respective institutional needs. This represents a critical instrument for fostering convergence amongst competing priorities. However, progress requires substantive evidence rather than unsupported assertions or claims.

Another priority involves enhancing predictability for enterprises—a legitimate industry concern given our annual pricing review cycles. Companies understandably struggle with unanticipated revenue reductions, creating explanatory difficulties for French subsidiaries within international corporate structures. Whilst we cannot abandon pricing adjustments —they reflect natural market dynamics where competition and volume increases typically reduce prices—we must improve our approach to this regulatory simulation of market forces.

How do you balance international price competitiveness with domestic budgetary constraints?

Industry representatives frequently emphasise European price comparisons, noting that French prices rank approximately 10 percent below EU averages. Our pricing criteria incorporate European reference pricing from four countries—Germany, United Kingdom, Italy, and Spain—with ASMR4 products specifically referenced to the lowest European price, naturally positioning France at the bottom for these categories.

However, actual pricing reality differs significantly from published list prices, with confidential rebates affecting numerous products. In France, rebates apply to 6 percent of products but represent substantially higher expenditure proportions, approaching EUR 10 billion against EUR 30 billion total social security pharmaceutical expenditure for 2024. This creates information asymmetries, since in Germany, Italy, and Spain, we may have visibility on list prices, but the actual transaction prices remain unknown.

All countries, including the US, negotiate confidential rebates, which makes it difficult to assess true international price competitiveness. However, we are increasingly hearing from laboratories that French list prices are being used as reference points—not only by smaller or less well-resourced countries, but potentially even within the framework of U.S. public programmes like Medicare and Medicaid or China. While there remains a significant gap between political announcements and actual implementation in the U.S., the possibility that French list prices could influence reimbursement benchmarks abroad adds a layer of complexity to our own pricing strategy. It reinforces the importance of maintaining a coherent, evidence-based approach that anticipates downstream effects in global markets.

That said, we must be pragmatic. France needs reliable access to therapeutic innovation and operates in a globally competitive environment. We recognise the industry's call for geographic price differentiation and are open to it—where it is justified by therapeutic value and broader policy considerations. The challenge lies in striking the right balance: encouraging innovation and maintaining industrial competitiveness, while ensuring long-term sustainability and equitable access.

Timelines for market access continue to be a source of concern, what steps are being taken to accelerate the overall process?

Negotiations can sometimes drag on unnecessarily—even for marginal price differences,. In many cases, the process is prolonged because laboratories begin with pricing expectations that are not aligned with the actual therapeutic value of the product. This often leads to a counterproductive dynamic, where the CEPS responds with very low offers in return, and both parties become stuck in a cycle of unproductive rounds. At times, we see price gaps of up to 100-fold between the initial industry proposal and our first offer, which clearly signals a breakdown in realistic positioning.

A more constructive approach, based on transparency and mutual trust, is essential. Encouragingly, some companies are already adopting more pragmatic starting points, aligned with CEPS's published methodologies and legal criteria. Our ambition is to streamline discussions and avoid unnecessary rounds. There is no intrinsic value in conducting 25 iterations when a fair and balanced outcome can be reached in five or six. Faster negotiation should not be mistaken for a lack of rigour; rather, it reflects maturity in the process.

Equally important are the delays that follow once an agreement is reached. The current timeline from signature to official publication—sometimes extending up to three months—is unacceptable.

These lags are largely due to internal administrative procedures and ministerial approvals. To address this, we are in the process of modernising our information systems, which are currently outdated. This overhaul should significantly improve internal coordination and reduce unnecessary bottlenecks. Ultimately, our objective is clear: regulatory needs must not stand in the way of timely patient access to treatment.

What mechanisms are you implementing to support industrial sovereignty whilst maintaining pricing discipline?

Article 65 of the social security Finance Law has evolved from permissive to mandatory consideration of supply security guaranteed through production site location. We now require comprehensive supply chain descriptions in economic interest notes accompanying all applications, enabling assessment of attractiveness and industrial sustainability implications.

Laboratories seeking price recognition for domestic production must submit detailed applications processed by the General Directorate of Enterprises. Maximum price valorisation for localisation considerations reaches 15 percent above traditional CEPS methodology. This framework addresses supply security concerns—if significant production occurs in the US and protectionist policies emerge, theoretical supply risks could materialise.

The COVID-19 experience highlighted these vulnerabilities, particularly regarding plasma-derived products with substantial US sourcing. I personally support the principle that domestic or European production security justifies premium pricing, provided we maintain supply guarantees and avoid unsustainable approaches. However, we must bear in mind that there are other tools to foster France’s attractiveness for pharmaceutical industry, not depending on social security finance.

How do you manage the tension between innovation rewarding and budget management?

Our challenge involves maintaining access to mature but essential products—such as antibiotics or various psychotropic medications—whilst providing appropriate innovation incentives. Innovation often benefits limited patient populations initially, with oncology indication extensions exemplifying this pattern through highly restricted mutation-specific approvals that subsequently expand.

The challenge emerges when volume increases complicate downward price renegotiation. We must ensure mature product availability under economically sustainable conditions for both industry and social security whilst providing reasonable innovation access. However, innovation rewards must remain proportionate, particularly given indication extension strategies where logical volume-price relationships should apply.

We are exploring enhanced product lifecycle visibility through predetermined review schedules established at initial inscription, potentially incorporating two-year pricing reviews based on objective criteria with guaranteed stability periods. Current stability periods exist theoretically but lack clarity and contain numerous exceptions, reducing predictability for laboratories.

What innovative approaches are you developing for advanced therapy medicinal products?

Article 54 provides new frameworks for innovative therapy medicinal products, particularly gene and cell therapies characterised by potentially single-administration protocols with enduring effects, personalised production requirements, and substantial manufacturing costs.

We are implementing “pay-for-performance” mechanisms involving initial forfeit payments at administration followed by patient monitoring protocols. If products deliver promised single-treatment cures, we require verification over extended periods—two, five, or ten years—necessitating practitioner collaboration for patient registries and monitoring systems.

The framework incorporates fractional payments with defined cessation criteria for treatment failures, alternative therapy requirements, or patient mortality. This represents sophisticated performance-based contracting requiring careful data protection protocols given sensitive health information handling requirements.

How do you envision environmental considerations influencing pharmaceutical regulation?

Environmental considerations present legitimate long-term concerns requiring immediate foundational work. Localisation preference partly addresses carbon footprint reduction through transport minimisation, though complete domestic production chains remain rare.

The most effective environmental measure involves consumption reduction—the least polluting medicine is the unconsumed one. This emphasises prevention, appropriate usage, and waste elimination. When patients request excessive quantities that remain unused, we witness direct environmental and economic inefficiency.

Industry production and packaging improvements deserve recognition, though we must carefully consider whether pharmaceutical pricing should accommodate additional environmental objectives. Our pricing instrument already addresses multiple targets—expenditure control, access provision, sovereignty, and reindustrialisation—potentially risking to reach none of them.

Alternative mechanisms, such as reimbursement prioritisation for products with superior carbon profiles within therapeutic classes, might prove more effective than pricing adjustments. We must avoid overburdening our primary regulatory instrument whilst maintaining environmental progress.

What digital transformation initiatives are you pursuing?

Our digital evolution encompasses multiple dimensions. Immediate improvements include laboratory portal enhancements and internal database modernisation, improving staff efficiency and processing timelines. Production implementation targets next year.

Advanced therapy medicinal products require sophisticated data transmission and registry management systems. More broadly, we are exploring real-world evidence integration for product performance assessment, extending performance-based contracting concepts beyond innovative therapies to traditional pharmaceuticals.

France possesses substantial health data resources that remain fragmented across individual hospital and research teams with limited interconnectivity. Whilst data protection vigilance remains appropriate, we might benefit from reduced proprietary system approaches and enhanced collaboration between laboratories, hospitals, and research teams. The Health Data Agency should address these challenges, particularly given artificial intelligence opportunities for enhanced clinical studies.

What are your strategic priorities for the coming years?

Our functional improvements focus on negotiation dynamics enhancement, benefiting both patients and industry through increased confidence and predictability. This requires mutual

departure from adversarial positioning towards collaborative realism.

We are developing trajectory-based approaches providing enhanced enterprise predictability whilst maintaining expenditure control guarantees. Whilst political arbitration remains necessary, multi-year frameworks present legitimate industry demands requiring careful implementation.

Attractiveness and reindustrialisation initiatives must generate strong enterprise signals through pricing mechanisms and remise deduction systems whilst securing long-term supply guarantees. If we invest in industrial development only to face production relocation after three years, we achieve nothing.

Success depends on trust-building amongst negotiation partners. We operate within legitimate economic and commercial activities requiring transactional loyalty and transparency. Whilst disagreements remain inevitable, we must maintain mutual openness through published doctrines, enhanced predictability, and dynamic, realistic negotiation approaches that enable sustainable development.

What message would you convey to international pharmaceutical stakeholders regarding France’s attractiveness?

France maintains exceptional clinical research capabilities contributing significantly to international attractiveness. Despite financial challenges, our social protection system provides unique global solvency guarantees. Although our global market share continues declining, we remain committed to innovation and attractiveness promotion.

Our improvement opportunity lies in more holistic, comprehensive health system approaches. Widespread stakeholder willingness exists; we must now transition from conceptual discussion to practical implementation. The foundation exists for meaningful progress in this direction.

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