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On June 27 the third edition of our new global series, Life Sciences and Health Care Horizons, took place in Paris with discussions focused on the pricing and financial regulation of health products after the latest reforms. We are excited to share the following highlights from Paris, and we look forward to future discussions as we forecast and help clients prepare for what’s to come.

In its June 2019 report on the situation and prospects for public finances, the French Cour des Comptes (the supreme body for auditing the use of public funds in France) warned of the risks to social security expenditure as early as 2020. Ongoing and additional pressures will therefore be placed on pharmaceutical companies and medical device manufacturers. The French Government should continue to use its legislative and regulatory tools, in particular the claw-back clause [clause de sauvegarde] and the various claw-backs mechanisms.

In this context, our panelists stressed the importance of strategic thinking when considering early market access, in particular taking into account recent developments in financial regulatory mechanisms. They then exchanged views on how to challenge unfavorable health technology assessment and conduct price negotiations.

The "temptation" of early market access: advantages and disadvantages

Mikael Salmela, partner in our European Life Sciences Regulatory practice, first recalled the early market access regimes in France: Nominative Temporary Authorizations for Use (nATU) and Cohort Temporary Authorizations for Use (cATU). Mikael then stressed the need for in-depth strategic thinking before opting for an early market access route. Before the entry into force of the French Health Insurance Fund Financing Act (hereinafter the “Financing Act”) for 2019, ATUs were granted per medicinal product and only before the first marketing authorisation (MA) for the product in question. This regime did not meet market demands, particularly in oncology where additional therapeutic indications can be quickly developed. The Financing Act for 2019 extended the early access regime to new therapeutic indications (i.e. extensions of indications) after the granting of the MA. From now on, cohort ATUs are delivered by therapeutic indication. Market access can therefore be achieved in successive phases, therapeutic indication by therapeutic indication. Regulatory texts are expected to clarify the contours of this new regime.
Mikael presented the application procedure and the implementation of cohort ATUs, with the submission of an application file containing the Protocol for Therapeutic Use and collection of information (PTU). The PTU should detail practical terms and conditions governing the prescription and dispensing of the medicinal product and patient follow-up to prevent the development of adverse effects. It plays an important role in collecting data on real life use. Although it is drafted on the basis of a template provided by the French Health Authority (ANSM), pharmaceutical companies may adapt the PTU, must draft it carefully and ensure its completeness. Mikael stressed the importance of this document as a strategic tool for pharmaceutical company liability management.

A second document is strategic in the ATUc regime: the Periodic Summary Reports (PSRs) to be produced by any exploitant of ATU medicinal products. PSRs include all the information and data collected during the ATU in application of the PTU. Pharmaceutical companies must specify all actions implemented after the assessment of the efficacy data and problematic situations must be discussed (medication errors, misuse, drug interactions). Mikael insisted on the answers to be provided by the pharmaceutical company, which may have repercussions in terms of liability.

When the MA is granted, the post-ATU regime is triggered. The Financing Act for 2019 created a derogation allowing direct access to the post-ATU regime for medicinal products that would not have benefited from the ATU program before their MA was granted. It thus allows the French Government to authorize early market access to a product that has not received an ATU before the granting of its MA, but which would meet all its conditions. A decree on the modalities of direct access in post-ATU is expected.

The Financing Act for 2019 also created a new obligation for continuity of initiated treatments that occurs at the end of the post-ATU regime.

Finally, Mikael summarized some of the advantages and disadvantages of choosing an early access strategy, including the collection of real life data, the impact on market share and competition issues, and the trade-offs to be made in the event of limited resources, particularly for new therapies that are sometimes complex to manufacture.

**Financial regulation of early market access to medicinal products and medical devices**

Charlotte Damiano, partner in our European Life Sciences Regulatory practice drew on her ten years of experience in the field of financial regulation (pharmaceutical taxation) to share her insight into the new provisions of the Financing Act for 2019.

The financial regulation of early access is the most problematic issue because of its complexity. Charlotte presented the different ATU claw-backs mechanisms and weighed the old and new ones.
With respect to changes in the financial regulation of health products, 2019 is just as rich as 2017. The system becomes more complex with almost every Financing Act.

The Financing Act for 2019 created a confidential temporary price referred to as "compensation", set by the competent Ministers. The temporary price mechanism is applicable to extensions of indications under ATU and to the new early access without ATU. In all cases, ATU claw-backs may apply once the definitive price is agreed with the Healthcare Products Pricing Committee (CEPS).

Charlotte denounced the predictability and retroactivity problems faced by pharmaceutical companies, for example biotechs that develop a single product - which she supports in their negotiations with health authorities.

Charlotte noted, thanks to her experience working with key market players, that mechanisms put in place two years ago had never been applied by the authorities to date. However, this has clearly not prevented the legislator from further complicating the existing financial regulatory mechanisms.

Sébastien Michel, Head of Market Access and Public Affairs at Mylan, shared his experience. While the ATU regime has worked relatively well for 20 years, it has become, as developments have progressed, much more complex and unpredictable. Mr. Michel provided relevant information on the framework within which public policy actions are carried out.

According to Mr. Michel, this complex mechanism creates difficulties, particularly in planning investments in an industrial tool, and hinders the arrival of innovations on the market. He also raised the contradiction between the Government, which is very ambitious in this area, and the administration, which is struggling to be ambitious.

In this context, Charlotte mentioned the important role of derogatory financing and concluded by summarizing the regulatory and financial elements to be taken into account in establishing an early market access strategy.

Charlotte and Mikael closed this panel by mentioning the creation, by the Financing Act for 2019, of an early access regime for innovative medical devices. Details will be provided by future regulatory texts.

**Unfavorable health technology assessment and price negotiations**

As an introduction, Charlotte discussed with the seminar participants the cases of unfavorable assessment encountered.

Mr. Michel considers that the medium- and long-term approach is sacrificed in favor of a short-term approach. He denounced the lack of multi-year predictability with amendments made each year in the Financing Act. The current health technology assessment system is not adapted to recent developments in his view, and a reform is necessary.
Charles-Henri Caron, counsel in our Litigation practice, presented the results of the 2018 activity report of the Transparency Committee (in charge of the health technology assessment of medicinal products in France). In the process of the assessment, there is a possibility of adversarial debates before the publication of the Transparency Committee's opinion. In particular, pharmaceutical companies may make observations and request a hearing. According to Charles-Henri, the use of experts and KOLs can be crucial in discussions on the actual benefit [Service Médical Rendu – SMR] and the improvement in actual benefit [Amélioration du Service Médical Rendu – ASMR].

Charles-Henri presented the recent case law of the French Administrative Supreme Court which confirms that it is not possible to lodge an appeal against the opinions of the Transparency Committee because they constitute preparatory acts only. The appeals must rather be lodged against the decisions of the Ministers refusing to include the medicinal product on the positive list of reimbursed products.

Charles-Henri then spoke about price negotiations and price decreases after an unfavorable assessment. Different "primary" and "secondary" legal criteria are taken into account when setting the price or price reduction. Charles-Henri presented the recent case law of the French Administrative Supreme Court on these subjects as well as on the refusal of price increases.

Charlotte finished up by presenting the regulation of the net price through ATU claw-backs and the claw-back clause [clause de sauvegarde].

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If you are interested in attending one of the remaining programs, please contact Jenna Blouse.
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