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Barriers to Healthcare: Does Law have a Role to Play in Solving the Problems?

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Introduction

- Payment models may contribute to overcome or create obstacles to access for healthcare.
- The economics of healthcare is nowadays a global issue, but problems have many faces.
- For medicines, in Europe and in other jurisdictions, pricing, reimbursement and market access have been known as the "fourth hurdle" for a long time.
- Laws and regulations cannot cure, but they do have a role in solving the problems.



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Some areas of concern in the field of medicines:

- Scope of the procedures that need to be followed before an approved medicine is generally available.
- Criteria used by pricing and reimbursement authorities.
- Territorial issues.
- Length of the procedures.
- How to deal with individual cases in the meantime.
- How to approach product withdrawals.
- Off-label use and compounding.



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How can the law help:

- **Scope of the procedures that need to be followed.**
 - Ensure that efficacy, safety and quality are not re-evaluated.
- **Criteria used by pricing and reimbursement authorities.**
 - Objective and well defined criteria which are not discriminatory.
 - Transparency and motivation of decisions.
- **Territorial issues.**
 - Avoid regional or local duplicities.



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How can the law help:

- **Length of the procedures.**
 - Reduce them but also widen scope of "positive silence" situations.
- **How to deal with individual cases in the meantime.**
 - Facilitate early access programs on a named patient basis.
 - Access to the product in the "private" market.
- **How to approach product withdrawals.**
 - Avoid therapeutic gaps while ensuring that companies may obtain a fair reward.



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How can the law help:

➤ **Off-label use.**

- Years ago, a pre-marketing tool severely scrutinized by authorities.
- Nowadays, sponsored by authorities in some specific cases.

➤ **Compounding.**

- A legal solution for traditional personalized treatments when modern pharmaceutical legislation was enacted.
- Nowadays, a cost-containment tool used in many hospitals.



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Some ideas that may help:

- **Open the doors to HTA activities.**
 - Companies have data which may be verified.
 - Gain knowledge from each healthcare providers group.
- **Build attractiveness (and trust) for managed entry agreements.**
 - Price volume agreements.
 - Risk-Sharing agreements.
 - Disease management programs.



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How can lawyers help:

- Difficult role when discussing price+reimbursement issues:
 - Administrative law constraints.
 - Navigate through the Stockholm syndrome.
- Educate and advocate for respect for basic general principles.
- Be flexible when discussing Managed Entry Agreements.



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Thank you for your attention

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