Conference report on the Young INGRES Roadshow event YI @ Kellerhals Carrard

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The second Young INGRES roadshow event,"Pharma and MedTech in Practice: Turning Rules into Reality," was hosted by Kellerhals Carrard Basel KlG in Basel, the heart of the pharma and medtech industry, on 21 May 2026. The event focused on regulatory requirements in the pharma and medtech sectors and featured three experts: Aline Bolli, Legal and Compliance Counsel at Sandoz Switzerland; Lorenzo Ponti, Legal Counsel in the Legal Department for Medical Devices at Swissmedic; and Axel Maspero, Legal Counsel at Novocure. Each speaker offered a complementary perspective on regulatory developments and the interface with intellectual property within their respective organizations.

Welcome speech

The Young INGRES team – Dr. Sandra Marmy-Brändli, Dr. Angelika Krull, Dr. Lorena Piticco, Dr. Janine Daum, and Dr. Timmy Pielmeier – together with the two hosts, Eliane Haas and Vera Vallone, welcomed the participants to the second roadshow event and expressed their pleasure that the concept of a series of IP events across Switzerland had been so well received and could now be held for the second time. The speakers were then introduced not only through their professional backgrounds, but also by a few charming fun facts, which gave the audience an engaging first glimpse of the personalities behind the titles.

From the luxury to the pharma industry: marketing in a complex regulatory environment

Aline Bolli, Legal and Compliance Counsel at Sandoz Switzerland, opened the session by contrasting the creative and often emotion-driven approach of the luxury industry with the far more restrictive regulatory environment of the pharmaceutical sector in regard to marketing. She first outlined the general principles of advertising in Switzerland, noting that marketing communications must not be misleading or confusing to consumers – a guideline that leaves plenty of room for creativity. In pharma, however, communication is shaped not only by general advertising law, but also by a dense framework of sector-specific rules and legislation, including the Therapeutic Products Act (TPA), the Ordinance on the Advertisement of Medicinal Products (OPuM), Swissmedic guidance, industry self-regulation and internal company policies.

She explained that these strict requirements are due to public health concerns and the need to prevent misuse of medicinal products. In this context, marketing is treated as medicinal information. Advertising must therefore be truthful, balanced, and consistent with the approved product information and Swiss marketing authorization. The intended audience must also be respected, particularly because the rules differ for prescription and non-prescription medicines. Even seemingly neutral statements may be regarded as unlawful advertising, where they implicitly suggest therapeutic benefits or go beyond the authorised scope of the product. Her overarching message was one of "compliance by design".

Aline Bolli also highlighted the practical consequences of this framework for marketing teams and legal advisers. Claims must be assessed in their full context, and social media poses additional challenges, as even user interaction, influencer sharing or employees' private accounts may trigger regulatory concerns. Her overall conclusion was that, in the pharmaceutical industry, the legal and regulatory framework strongly shapes communication strategies and significantly limits creative freedom.

The legal framework of medical devices – an insider's perspective

Lorenzo Ponti, Legal Counsel in the Legal Division for Medical Devices at Swissmedic, offered an insider's perspective on the Swiss regulatory framework for medical devices and the role of Swissmedic as the competent authority. He explained that Swissmedic's mandate extends across the entire lifecycle of medical devices, from market access to oversight and enforcement, with the overarching aim of protecting public health. He also illustrated the sometimes controversial boundaries of the authority's competence by referring to examples such as the "Sarco" capsule, which contradicts the medical purpose under therapeutic products legislation and cannot be classified as a medical device.

He further highlighted the economic importance of the Swiss medtech sector and outlined the development of the legal framework in Europe and Switzerland, from earlier systems relying heavily on self-responsibility of manufacturers and less on conformity assessment bodies (notified bodies) to the much stricter regime introduced in response to safety scandals, in particular through the EU Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR). At the same time, he noted that the regulatory environment remains dynamic and currently shows trends of de-regulation.

Using software-based products as examples, Lorenzo Ponti illustrated how difficult it can be to determine whether a product qualifies as a medical device and, if so, how it should be classified. He showed that the intended purpose of a product is decisive in this assessment: a simple fertility calendar may fall outside the regime, whereas apps involving biometric data, providing diagnostic help or offering contraceptive functions may trigger much stricter requirements. His key message was that intended purpose, the correct classification and further regulatory compliance must be addressed from the outset as part of a "compliance by design" approach, thus picking up on Aline Bolli's earlier point.

MedTech in practice: turning rules into reality

Axel Maspero, Legal Counsel at Novocure, concluded the event with a practical perspective on the role of in-house counsel in a medtech company. He described the sector as highly dynamic and increasingly shaped by complex international regulation, particularly in areas such as advertising, data protection and compliance. Against this background, he showed that the legal function in medtech extends well beyond intellectual property and requires close involvement in commercialization, market access and internal training. His contribution made clear that bringing a product to market is a cross-functional process requiring close coordination between legal, regulatory and commercial teams.

Using product branding as a case study, Axel Maspero illustrated how legal and regulatory considerations shape a product's identity from an early stage. He emphasized that branding in medtech is not merely a marketing issue, but also touches on safety, compliance and trademark strategy. Therefore, naming strategies are constrained not only by trademark availability, but also by regulatory limitations, while claims must be assessed in light of cultural differences, translation risks and the risk that marketing statements may inadvertently expand a product’s intended purpose. He also pointed to the recurring tension between commercial ambitions and the limits imposed by clinical evidence and regulation.

A further key theme of his presentation was the mediating role of legal counsel. Axel Maspero explained that in-house lawyers must often reconcile diverging stakeholder interests and translate legal constraints into workable business solutions. This requires early involvement, clear governance and stakeholder education. He concluded by stressing the importance of local nuance and long-term lifecycle thinking, showing that effective medtech counsel must combine legal expertise with commercial awareness and strong communication skills.

Q&A

The event concluded with a lively Q&A session in which the speakers addressed practical issues at the intersection of regulation, innovation and commercial communication. One topic concerned artificial intelligence, in particular when AI-based products may qualify as medical devices and how the EU AI Act and the still-developing Swiss regulatory approach may affect the sector.

The panel also explored the fine line between educational campaigns and product advertising. Using public awareness initiatives such as obesity campaigns as an example, the speakers showed that communications may become promotional where they are closely connected to a specific product, or manufacturer. The speakers underlined that such distinctions are highly context-dependent and must be assessed on a case-by-case basis.