

Consequences of 2021: medical devices, Horizon and the stock exchange

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The first consequence concerned medical devices. On 26 May 2021, the same day the Federal Council abandoned the framework agreement, the Union's Medical Devices Regulation became applicable. The Mutual Recognition Agreement of 1999 would have required an update of its chapter on medical devices to remain effective. The Union refused to agree to that update without progress on the institutional questions. Swiss manufacturers of medical devices thereby lost their privileged access to the internal market and had to appoint authorised representatives in the Union and adapt their labelling, while Switzerland unilaterally recognised European certificates in order to keep supplies to its own hospitals.¹ The same occurred one year later for in vitro diagnostics, a field of importance for Roche Diagnostics.² The pharmaceutical chapter on good manufacturing practice, which matters most to the large Basel groups, continued to function because it required no update, although the risk that it might later become outdated hung over the industry.

The second consequence concerned research. Because the Union treated Switzerland as a non-associated third country in Horizon Europe from 2021, Swiss researchers could no longer apply for grants of the European Research Council and lost the coordinating role in many collaborative projects. The Confederation financed transitional measures through SERI and the Swiss National Science Foundation, which preserved funding but could not replace the prestige of a European grant and the networks that came with it.³ For the University of Basel, the Biozentrum and the ETH department in Basel described in Part G, Chapter I, this meant a period of uncertainty in recruitment. Several Swiss-based researchers moved their grants to institutions in Union member states.

The third consequence concerned the financial centre directly. In December 2017 the Commission had granted the Swiss stock exchange

regime equivalence under the Markets in Financial Instruments Regulation, but only for one year, which was later extended until 30 June 2019. The time limit was openly linked to progress on the framework agreement.⁴ When it lapsed, investment firms in the Union would have been prevented by the share trading obligation of Article 23 MiFIR from trading Swiss shares on Swiss exchanges. The Federal Council responded with a protective measure that it had prepared by ordinance in November 2018: from 1 July 2019, foreign trading venues needed recognition by FINMA to admit Swiss equities, and Union venues were denied such recognition.⁵

The measure worked. Since trading in Swiss shares concentrated on the SIX Swiss Exchange, whose liquidity even increased, the expiry of equivalence proved less damaging than many had feared.⁶ The episode nevertheless revealed two lessons that remain relevant for the scenarios. Equivalence decisions are unilateral acts of the Union that can be withdrawn for political reasons. Switzerland, for its part, can sometimes defend its interests with targeted countermeasures, although only in fields where it possesses real market power.

1 Notes

1. Regulation (EU) 2017/745 of 5 April 2017 on medical devices (MDR), applicable since 26 May 2021; on the non-update of chapter 4 of the MRA and the consequences for Swiss manufacturers, see the publications of Swissmedic, the State Secretariat for Economic Affairs (SECO) and Swiss Medtech. To be verified. ↩
2. Regulation (EU) 2017/746 of 5 April 2017 on in vitro diagnostic medical devices (IVDR), applicable since 26 May 2022, and the corresponding non-update of the MRA. To be verified. ↩
3. On the treatment of Switzerland as a non-associated third country in Horizon Europe (2021–2024), the transitional measures financed by the Confederation and the effects on ERC applications, see the publications of SERI and the Swiss National Science Foundation. To be verified. ↩
4. Commission Implementing Decision (EU) 2017/2441 of 21 December 2017 on the equivalence of the legal and supervisory framework applicable to stock exchanges in Switzerland, limited to 31 December 2018 and extended by Implementing Decision (EU) 2018/2047 until 30 June 2019. To be verified. ↩
5. Ordinance of 30 November 2018 on the recognition of foreign trading venues for the trading of equity securities of companies with registered office in Switzerland (SR 958.2), activated on 1 July 2019; later

incorporated into the Financial Market Infrastructure Act. To be verified. ↩

6. On the effects of the Swiss protective measure on trading volumes in Swiss equities after 1 July 2019, see the publications of SIX Group and the State Secretariat for International Finance (SIF). To be verified. ↩

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