

# Audit of compliance management system

## Swissmedic

### Key facts

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Swissmedic is the Swiss supervisory and licensing authority for medicines and medical devices (therapeutic products). Its influence on pharmaceutical companies is considerable. In view of the financial stakes involved, there is a real risk of conflicts of interest. In order to prevent them and to guarantee Swissmedic's independence, the changes to the law in 2019 strengthened the requirements for integrity and transparency concerning conflicts of interest. However, these changes did not introduce a standardised compliance management system. Both Parliament and the Federal Council preferred to maintain a decentralised management system based on Codes of Conduct for employees and members of the Management Board, commissioned experts and the Agency Council. The role of the Agency Council was strengthened and now covers the three Codes of Conduct.

The audit by the Swiss Federal Audit Office (SFAO) focused on the existence and implementation of the compliance system. The design analysis consisted of verifying its compliance, suitability, risk orientation and coordination with the risk management system. The effectiveness review focused on the adequacy and correctness in terms of business ethics and human resources.

The compliance management system complies with federal requirements, although it still needs to be refined. This relates to the effectiveness of the completeness and accuracy checks on the data delivered by employees and members of the Management Board, as well as for experts. Consolidating the compliance functions and extending the scope of control to include internal databases would provide the Management Board and the Agency Council with additional assurance that Swissmedic is independent of private industry. The SFAO believes that the Agency Council should strengthen its involvement in compliance matters and obtain consolidated and direct communication from the Management Board. It should promote better integration and synergy between the compliance management system and the risk management system.

### **Rules of conduct defined and implemented in accordance with federal requirements**

The Codes of Conduct are adequately enforced. The procedure for appointing members of the Agency Council, which is overseen by the General Secretariat of the Federal Department of Home Affairs, covers the main risks of incompatibility of functions. The review criteria established by the Agency Council are sufficiently clear to ensure consistent and transparent application of the rules concerning conflicts of interest.

The SFAO did not identify any cases of undeclared conflicts of interest among the members of the Agency Council, members of the Management Board, employees or experts in human medicine. The principle of independence vis-à-vis the private sector is embedded in Swissmedic's processes and culture. In the SFAO's opinion, however, there is room for improvement by establishing a clear and coordinated external communication strategy between the Management and the Agency Council. This should prevent any apparent lack of independence in dossiers that are presented publicly.

## **Potential for improvement in terms of compliance requirements and effectiveness**

With the exception of the Executive Director, the other members of the Management Board are not subject to a systematic cooling-off period during their notice period. For this reason, the SFAO recommends that Swissmedic examine the possibility of introducing cooling-off periods for all members of the Management Board and even for other employees who have a decisive influence on major decisions or who have access to essential information.

The Therapeutic Products Act refers to the prosecution authorities and the SFAO as potential recipients of reports of irregularities. However, the Code of Conduct for employees does not provide for this possibility and thus limits the circle of recipients to immediate line managers. The SFAO recommends that the Code of Conduct be amended to ensure legal compliance and clear internal communication of the rules.

The Federal Council's independence in selecting the members of the Agency Council is reduced by the rules on representation and the autonomy of the cantons. In terms of transparency, the SFAO noted that Swissmedic's Code of Conduct is not published. Its website does not list any secondary affiliations of members of the Management Board. The SFAO therefore recommends that Swissmedic publish all this information.

Compliance management is based almost exclusively on the principle of self-declaration. Those responsible for the compliance functions do not have the necessary independence and control resources vis-à-vis the strategic and operational lines to check the declarations of interests for completeness. Swissmedic should support the arrangements for declaring and reporting irregularities by means of cross-sectoral and targeted controls.

## **Compliance management and integration need strengthening**

The compliance management system is coordinated with risk management. As with the internal control system (ICS) and the risk management system, the Agency Council should have enhanced powers with regard to the compliance system. Centralisation of functions and integration between the three governance functions would give both the Management Board and the Agency Council a comprehensive and consolidated overview of the issue of independence vis-à-vis the industry.

In this respect, the SFAO recommends strengthening the compliance function by separating it from the operational side, by establishing a systematic and direct communication channel with the Agency Council and by providing it with widespread access to individual strategic and operational data. Similarly, the governance functions (ICS, risk management, compliance system) should be strengthened and better integrated. The SFAO points to the integration models developed in other decentralised federal entities with supervisory tasks such as FINMA and Innosuisse.

**Original text in French**