

# Pharma & Life Science Hot Topics

Has a health authority prohibited the sale of your pharmaceutical products in Europe, because you are a Swiss established company?

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# Pharma & Life Science Hot Topics

## Sale of pharmaceutical products within the EU by non established companies - background



- **Recent developments** show that health authorities increase audits and prevent the sale of pharmaceutical products within the EU by companies located outside of the EU, if they do not have a correct wholesaler license in place
- **Legal basis:** The pharmaceutical legislation, Art. 76 of the directive 2001/83EG, the anti-counterfeiting directive 2011/62 and correspondent legal acts implemented in 2015 in different EU member states
- **Consequences/major challenges:**
  - Restructuring the current Swiss business model
  - Significant changes in the supply chain
  - Direct and indirect tax implications in Switzerland and in the European Union
  - ERP system and contract adaptations
  - etc.

# *Pharma & Life Science Hot Topics: Sale of pharmaceutical products within the EU by non established companies*

## **Key questions**

1. Is your pharmaceutical company established in Switzerland?
2. Do you sell pharmaceutical (end-) products/drugs in the EU?
3. Is the wholesaler license used issued on the name of another company than that one that sells the products in the EU?

## **PwC's solution**

If the answer of all three key questions is yes, we recommend to have your business reviewed and optimized. We have developed a pragmatic solution that works in practice from a regulatory, direct and indirect tax as well as legal perspective – in line with local Swiss and European regulations

## **Call for action / Your benefits**

We would be pleased to discuss further with you and offer a solution that is perfectly customized to your requirements and needs, in order to ensure a smooth, cost efficient and compliant sale of pharmaceutical products in the EU



## **Dr. Sandra Ragaz**

*Director - Leader Pharma & Life Science indirect taxes Switzerland*

PricewaterhouseCoopers AG, Zurich Switzerland

Phone: +41 58 792 44 69

E-mail: [sandra.ragaz@ch.pwc.com](mailto:sandra.ragaz@ch.pwc.com)

