

# **REFORM OF THE EU PHARMACEUTICAL LEGISLATION**

How EU and Swiss radiopharmaceuticals  
will be concerned

**Konrade von Bremen**

CEO

SWAN Isotopen AG

# AGENDA


- **The reform of the EU Pharma Law**
- **But where are radiopharmaceuticals?**
- **Europe's Beating Cancer Plan**
- **The new EU pharma regulation and directive**
- **Radiopharma need a dedicated status**
- **The Suisse approach**
- **Outlook**



European Journal of Nuclear Medicine and Molecular Imaging (2023) 51:20–24  
<https://doi.org/10.1007/s00259-023-06472-1>

## EDITORIAL

# The revision of the pharmaceutical legislation — it is time to act for nuclear medicine in Europe

Marianne Patt<sup>1</sup> · Clemens Decristoforo<sup>2</sup> · Amélie de Martini<sup>3</sup> · Michel Koole<sup>4</sup> · Wim J. G. Oyen<sup>5,6,7</sup> · Oliver C. Kiss<sup>8</sup> 

Published online: 23 October 2023  
© The Author(s) 2023

# THE REFORM OF THE EU PHARMA LAW



## Pharmaceutical package

DG SANTE

## The political objectives of the reform

**A**ccess

Single market

**A**vailability

Shortages

**A**ffordability

Budgets

Innovation & Competitiveness

Regulatory  
simplification &  
Innovation

Environment

Combat  
AMR



## EUROPE'S BEATING CANCER PLAN LET'S STRIVE FOR MORE

#EUCancerPlan

### **SAMIRA Action plan adopted in February 2021**



- The EU first comprehensive plan for action to support a safe, high quality and reliable use of radiological and nuclear technology in Healthcare
- It is the Energy sector's contribution to Europe's Beating Cancer Plan guided by DG Energy



# The new EU pharma regulation and directive

› [EJNMMI Radiopharm Chem. 2024 Jan 2;9\(1\):2. doi: 10.1186/s41181-023-00230-2.](#)

## Position paper to facilitate patient access to radiopharmaceuticals: considerations for a suitable pharmaceutical regulatory framework

Aruna Korde <sup>1</sup>, Marianne Patt <sup>2</sup>, Svetlana V Selivanova <sup>3 4</sup>, Andrew M Scott <sup>5 6</sup>, Rolf Hesselmann <sup>7</sup>, Oliver Kiss <sup>8</sup>, Natesan Ramamoorthy <sup>9</sup>, Sergio Todde <sup>10</sup>, Sietske M Rubow <sup>11</sup>, Luther Gwaza <sup>12</sup>, Serge Lyashchenko <sup>13</sup>, Jan Andersson <sup>14 15</sup>, Brian Hockley <sup>16</sup>, Ravindra Kaslival <sup>17</sup>, Clemens Decristoforo <sup>18</sup>

# The new EU pharma law & The Swiss way to regulate radiopharmaceuticals



DER SCHWEIZERISCHE BUNDESRAT  
LE CONSEIL FÉDÉRAL SUISSE  
IL CONSIGLIO FEDERALE SVIZZERO  
IL CUSSEGL FEDERAL SVIZZER

Verfügung über die Einsetzung der Fachkommission für  
Radiopharmazeutika (FKRP)

## Der Schweizerischen Bundesrat

geschützt auf Art. 48 der Strahlenschutzverordnung verfügt die

1. **Einsetzung** einer ausserparlamentarischen Kommission

Die Fachkommission für Radiopharmazeutika FKRP am 9.11.2011

2. **Notwendigkeit**

Die FKRP ist das einzige Gremium, das in seiner Zusammensetzung die erforderliche Fachkenntnis zur Beurteilung der Zulassungsdossiers von Radiopharmazeutika besitzt. Der zuständigen Behörde Swissmedic und dem BAG fehlt das notwendige Knowhow, um Wirksamkeit, Sicherheit und Qualität dieser besonderen Arzneimittel ohne Unterstützung der FKRP kompetent genug überprüfen zu können.



# OUTLOOK



## The radiopharmaceutical renaissance: radiating hope in cancer therapy

The commercial success of second-generation radiopharmaceuticals in oncology has re-ignited interest in this modality, resulting in a surge of dealmaking and increased venture financing for companies in the field.

Credit: iStock/Getty Images Plus

- Radiopharmaceuticals came out of the niche and attract more and more big pharma companies and potent investors
- Exciting times with growing opportunities and risks

BIOTECH

## Intrigued by Novartis and Lilly deals, investors pour money into radiopharmaceuticals

By Annalee Armstrong · Dec 8, 2023 10:02am

Radzina et al.  
EJNMMI Radiopharmacy and Chemistry (2023) 8:27  
<https://doi.org/10.1186/s41181-023-00211-5>

EJNMMI Radiopharmacy  
and Chemistry

REVIEW

Open Access

## Novel radionuclides for use in Nuclear Medicine in Europe: where do we stand and where do we go?



Maija Radzina<sup>1,2,3</sup>, Laura Saule<sup>1,3\*</sup>, Edgars Mamis<sup>1,2</sup>, Ulli Koester<sup>4</sup>, Thomas Elias Cocolios<sup>5</sup>, Elina Pajuste<sup>1</sup>, Marika Kalnina<sup>1</sup>, Kristaps Palskis<sup>2,6</sup>, Zoe Sawitzki<sup>5</sup>, Zeynep Talip<sup>7</sup>, Mikael Jensen<sup>8</sup>, Charlotte Duchemin<sup>2</sup>, Kirsten Leufgen<sup>9</sup> and Thierry Stora<sup>2</sup>

# NUCLEAR MEDICINE EUROPE

the industry association



**THANK YOU**