Curriculum Vitae

Personal information

Momir Radulovic

Work experience

1. Executive Director
December 2018 - present
Agency for Medicinal Products and Medical Devices of the Republic of Slovenia, www.jazmp.si

- Strategic planning and management ~ €11,4m (204% growth 2024 vs 2018)
- Number of Staff overseen ~ 165
- Successful Agency's Crisis management and recovery after financial setback in 2017, 2018 Increased Change management, efficiency gains, capacity building and achieved financial stability and resilience
- Regulation of human and veterinary medicines, SI as Rapp or CoRapp in EMA centralized procedures and MNATs (7), and as RMS in MRP/DCP (35)
- Implementation of EU Pharma Strategy with 2021 SI Presidency proposal (access to antibiotics and repurposing) to build resilient European Health Union with joint EU solutions pull incentives, non-for-profit production for medicines with low commercial interest, EMA extended mandate, HERA, …
- Inspectorate for GMP, GCP, GDP and Pharmacies
- Medical devices regulation and surveillance
- Designation and supervision of Notified bodies for medical devices
- National Pharmacovigilance, Histovigilance and Hemovigilance centre
- Regulation and inspectorate of blood and blood products, human tissues, and cells
- Regulation and control homeopathic and natural-origin medicinal products, active substances, illicit drugs groups II and III
- Regulation of List prices of Medicinal Products
- National Pharmacopoeia Authority
- Policy impact on **accessibility, availability and affordability** of medicines and actively contributing many meaningful initiatives: **Capacity building**, **Critical medicines list**, **Treatment optimization**, **Pull incentives** for antimicrobials, **Repurposing**, **Solidarity mechanism**, **Supporting innovation** in breaking down the silos, **Green API initatives** – **OneEarth approach**

2. Heads of Medicines Management Group Vice Chair
Sep 2024 – present
www.hma.eu

3. EU Network Training centre (EU NTC) CoChair
EMA/HMA
https://www.ema.europa.eu/en/about-us/how-we-work/european-medicines-regulatory-network/eu-network-training-centre-eu-ntc

4. EMA Management Board Member
December 2018 – present
https://www.ema.europa.eu/en/about-us/who-we-are/management-board/members

5. EURIPID Chair of the Board of Participants
June 2022 - present
European Integrated Price Information Database https://euripid.eu/organisation/

6. Business Unit Head Vaccines and HIV
May 2018 – Nov 2018
GSK, Slovenia
P&L responsibility ~ $5m and Portfolio optimization; Global Strategy implementation for 40 vaccines and 10 HIV medicines; GSK Tender Business Project Lead; EFPIA National Industry Board Vaccines Working Group Project Lead; Vaccines Europe - Slovenian representative

7. Sabbatical year – taking time off, time is our most valuable asset
Jun 2017 – Apr 2018 Everywhere

8. Market Access and Health Policy Lead Central Asia, Caucasus, and Mongolia
Apr 2016 – Jun 2017
Roche Central Asia, Caucasus, and Mongolia
P&L Responsibility ~ $20m, working in VUCA environment in low and middle income countries; Internal Consulting Project Lead of Business model change evaluation and implementation (Moldova, Uzbekistan, Azerbaijan, Armenia); Cluster Launch Readiness Project Lead; Cluster Portfolio optimization and prioritization Lead with applied Access measures; Cross functional implementation Cancer programs; Implemented Market Access Strategy and capacity building through centralized Access framework

9. Deputy General Manager, Business Unit Head Oncology&Haematology
Jan 2015 – Mar 2016
Roche Kazakhstan
P&L Responsibility ~ $30m, working in VUCA environment, achieved 15% growth in Onco Sales vs 2014 despite 104% currency devaluation (KZT worst-performing currency in 2015); Lead Marketing and Sales team; Generated stakeholder insights through network mapping, stakeholder panels, expert consultation, and research to understand stakeholder value/decision drivers; Achieved distribution channel change and signed direct delivery mAB w MoH; Payer Evidence Planning & Generation with Patients Registry update with IARC/WHO; Implemented Risk sharing approach to drive access, long term commercial arrangement with MoH with Drug utilization model

10. Various Roles in Marketing, Sales and e-marketing in Roche
Dec 2005 – Dec 2014
Roche Slovenia, Roche Poland, Roche Russia, Roche Adriatic
Drug utilization models for RA Patient Registry, Lead Breast Cancer Awareness Campaign, Roche Top 10 Global Award; Carried out HER2 testing improvement initiatives (NEQAS HER2 testing validation, IHC vs FISH concordance data); Cross functional Project with Roche Dia - switch to 30 Ventana machines with 45k HER2 tests in a year, became a market leader in immunohistochemistry segment in 2 yrs); implemented e-marketing campaigns; Developed Sales with Sales Force Value proposition demand tools based on customer insights - Market Research; In 2014 achieved 69% volume growth in Herceptin Sales vs 2012 ~ $130m.

Education and training

Master of Pharmacy; Certified Pharmacist
Oct 1998 – Oct 2005
Faculty of Pharmacy, University of Ljubljana; Ministry of Health / Slovene Chamber of Pharmacies

Additional information

Publications

Projects

- EU Project Coordinator JA **IncreaseNET** - Supporting the increased capacity and competence building of the EU medicines regulatory network
- WP Leads in **CHESSMEN**, **JAMS 2.0**, **CAPRICORD**
- participating in **SAFE CT**, **EURIPID, JA EU4H11, CT CURE, EU JAMRAI**

2.0, more info at https://www.jazmp.si/en/eu-projects/

Memberships

- European Commission **Pharmaceutical Committee member** https://health.ec.europa.eu/medicinal-products/pharmaceutical-committee-veterinary-pharmaceutical-committee-and-expert-groups/human-pharmaceutical-committee-meetings_en
- European Commission **AI Board Sub-group member** AIA/MDR+IVD https://digital-strategy.ec.europa.eu/en/policies/ai-office
- Accelerating Clinical Trials in the EU **(ACT EU) PA4 Co-Lead**: https://www.ema.europa.eu/en/news/accelerating-clinical-trials-eu-act-eu-better-clinical-trials-address-patients-needs
- European Clinical Research Alliance on Infectious Diseases (ECRAID) Observer to Supervisory Board: www.ecraid.eu
- EATRIS **REMEDi4ALL consortium Policy Board member** European innovation platform to enhance repurposing of medicines for all: https://eatris.eu/projects/remedi4all-building-a-sustainable-european-innovation-platform-to-enhance-the-repurposing-of-medicines-for-all/
- MoH Community Pharmacy Extended **Expert Group member**: https://www.gov.si/zbirke/delovna-telesa/rsk-za-lekarnisko-farmacijo/
- Novel Medicines Platform **(NMP) Working Group member**: https://www.who.int/europe/groups/the-novel-medicines-platform
- DIA Europe 2025 **Steering Committee member**: https://www.diaglobal.org/en/flagship/dia-europe-2025

Other Relevant Information