Post licensing evidence generation through reimbursement data

Dimitra D. Lingri
Lawyer – DEA
Head of Legal Department
Amsterdam, 18.06.2019

The reasons for developing a registry in a reimbursement fund

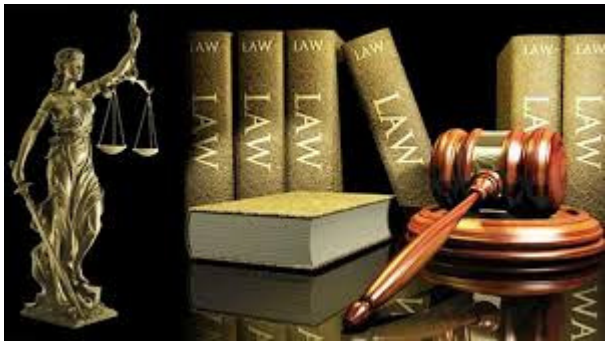
- **Optimal use of available resources** based on RW evidence generated ⟷ **equal access to medicines**
- **Interoperability** with other databases (diagnostic and therapeutic protocols), development and monitoring of key performance indicators ⟷ **mechanism for pharma expenditure monitoring**
- Collection and analysis of generated data ⟷ more efficient application of diagnostic and therapeutic guidelines

The legal provisions for developing a registry in accordance with personal data law


ΕΦΗΜΕΡΙΣ ΤΗΣ ΚΥΒΕΡΝΗΣΕΩΣ

ΤΗΣ ΕΛΛΗΝΙΚΗΣ ΔΗΜΟΚΡΑΤΙΑΣ

Ministerial Decree 2014
Law 4238/2014 par.8 (scope of EOPYY)



Which registries have been developed so far and why

HEPATITIS C , CHRONIC MYELOGENIC LEUKAEMIA

Specific reason Hepatitis C	Hepatitis C registry is connected with the negotiation agreement for DAAs
Specific reason for Chronic Myelogenic Leukaemia	To monitor TKIs cessation in patients with deep molecular response

The Special Legal provision for developing the e-PA (Electronic Prior Authorization System) registry

- Art. 265 L. 4512/2018 : a general electronic registry is developed at EOPYY in order to monitor the provision of special categories of high cost medicines.
- Ministerial Decision n. 44486/2018 Definition of de minimis elements required by the a physician for the completion of the e form.
- Ministerial Decision n. 33003/2018 Definition of criteria of selection of doctors deciding upon submitted e forms.

Categories of medicines included

E-Prior Authorization System

- High Cost Medicinal Products(62 & Radiopharmaceuticals) & Products not marketed in the country
- Off label medicinal products
- Medicinal products for exceptional circumstances (not included in the Positive List yet)
- Medicinal products for compassionate use

Benefits and expectations

Benefits	Strong negotiation tool Strong monitoring tool Creates value to all stakeholders Identifies eligible patients
Expectations	Interoperability Development of KPIs Open data Confounders Handling of missing data Potential comparison of RWE with EPAR.

Questions

Dimitra Lingri
E-mail: diligri@eopyy.gov.gr/
Phone number: +30 2108110811