

**INTERNATIONAL MEETING
ON RUPATADINE 2020**

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Pharmacovigilance

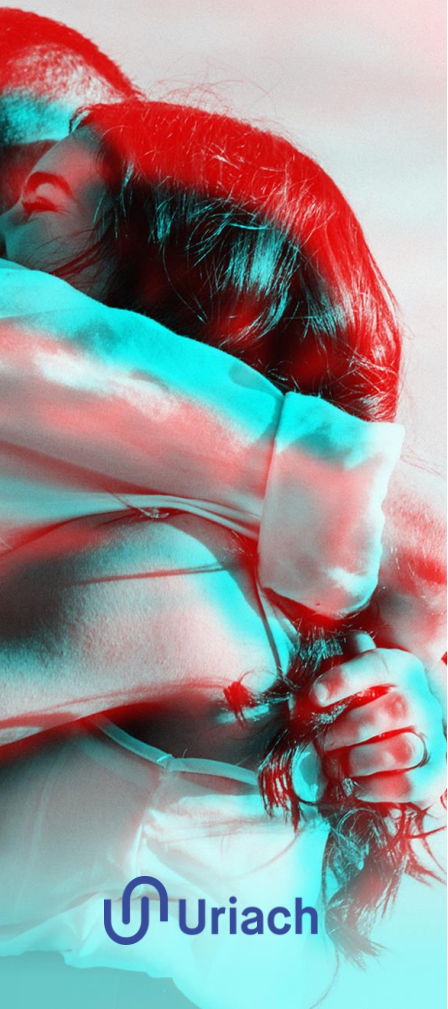


Pharmacovigilance

- **1. Pharmacovigilance in a nutshell**
- **2. Pharmacovigilance at Uriach**
 - Why?
 - What for?
- **3. Pharmacovigilance and us**
 - How can I help?
- **4. Questions & Answers**



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Pharmacovigilance in a nutshell

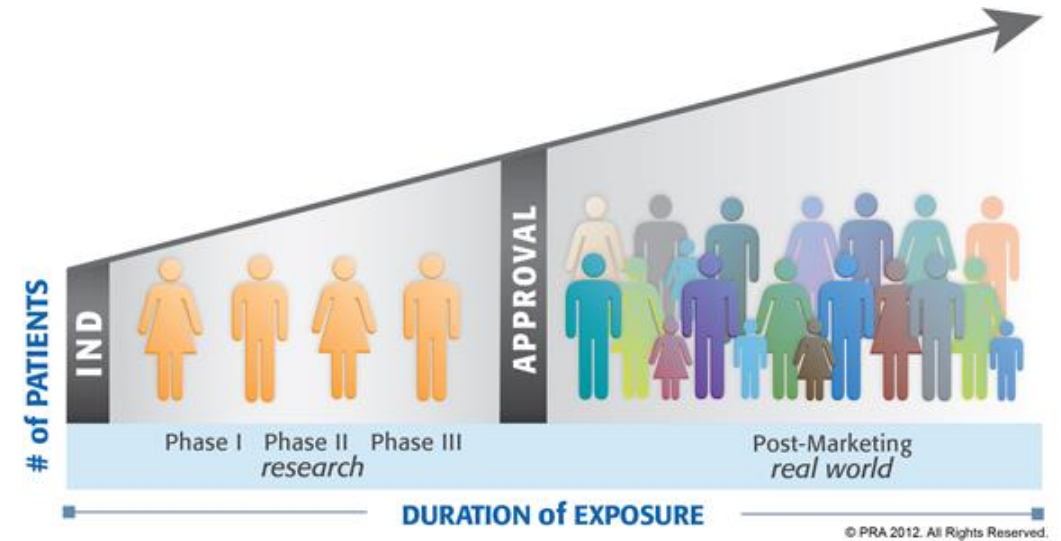


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What is Pharmacovigilance?

“the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.”



Current therapeutic use vs Clinical trials:

- More patients exposed
- Special populations exposed
- Higher probability of concomitant diseases
- Higher probability of interactions



What is an adverse drug reaction (ADR)?

Special situations

Pregnancy

Lack of efficacy

Overdose

Misuse and abuse / overuse

Medication and administration errors

Occupational exposure

Suspected transmission of infectious agents via a medicinal product

Counterfeits

Reports from lawsuits

Deaths

Off-label use

Disease progression related to the use of the product

Drug interactions, drug addiction and withdrawal syndrome



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Pharmacovigilance summarized in 2 words

*“Pharmacovigilance system:
a system used by the marketing
authorisation holder [...] designed to monitor
the safety of authorised medicinal products
and detect any change to their **risk-benefit
balance.**”*

*Directive 2001/83/EC on the Community code relating to medicinal products
for human use*



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Risk vs Benefit



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Pharmacovigilance at Uriach



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Pharmacovigilance... why?

- **Uriach** has a wide variety of products: **prescription and generic drugs, OTCs, cosmetics, medical devices, food supplements**
- We are a health company with international sales in **over 70 countries** worldwide
- This represents a significant challenge for compliance with **pharmacovigilance obligations and responsibilities.**
- But more than that...



...pharmacovigilance for what and for whom?

PATIENTS

- Improve the CARE provided to patients and the management of their doubts or needs
- Keeping patients SAFE while using medication

HEALTH CARE PROFESSIONALS

- Offer a SUPPORT SERVICE to doctors, nurses, pharmacists, etc.
- Ensure an OPTIMUM BENEFIT / RISK RATIO of our products

COMPANY

- Contribute to the image of PRESTIGE and SERIOUSNESS of our brands
- Improve the POSITIONING of products
- ADDED VALUE in front of CLIENTS

COMUNICACION

- Encourage the establishment of good communication with consumers and health personnel, RETAIN our customers and achieving maximum CONFIDENCE in our products

HEALTH AUTHORITIES

- Compliance with LEGISLATION (European, Japan, Canada, etc)
- Support to INTERNATIONAL PARTNERS
- CENTRALIZED SERVICE of international Pharmacovigilance (QPPV in the EU, Preparation of PSUR, RMP, PSMF,, Notification of cases, Registration in Eudravigilance, etc)

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Pharmacovigilance and us



How can I help?

How to act: If you receive an adverse drug reaction to one of our products or information about any of those “special situations”

SPECIAL SITUATIONS

Pregnancy

Lack of efficacy

Overdose

Misuse and abuse / overuse

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How can I help?

How to act: If you receive an adverse drug reaction to one of our products or information about any of those “special situations”



You should:

- ✓ Collect data from the healthcare professional or consumer: Name, telephone, email ...
- ✓ Gather as much data as possible, although it is enough to have Drug / reaction
- ✓ Notify Pharmacovigilance quickly (ideally within 24 hours)

How can I help?

And, what will Pharmacovigilance do?:

- Contact the reporter and collect as much information as possible
- Analyze the case
- Assign causality
- Consult the literature and experts, if necessary
- Consult the Uppsala Monitoring Center, if necessary
- Communicate expeditiously to the Health Authorities, if applicable
- Wait for later information to prepare the follow-up / final report
- Include the information in our files
- Inform you and the people involved about Uriach

Summary



Pharmacovigilance is an opportunity

- If we are prepared to act immediately
- If we know that we can all receive first-hand information regarding the safety of our products and
- If we are aware that we are all a key part of our pharmacovigilance system.

Then we can have any possible reaction to our products well controlled and we can give:

- ✓ A good service to the patient / consumer
- ✓ A good service to the doctor and other health professional
- ✓ A good service to all partners / clients of the company
- ✓ An image of PRESTIGE and SERIOUSNESS of Uriach

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Questions, doubts?

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*Muchas
Gracias*



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