EMA Workshop on the collaboration with General Practitioners/Family Physicians

Which concrete areas of collaboration between EMA and PHC/GPs

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GPs EMA GROUP

EFPC

Riga
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GPs EMA GROUP

- creation of an expert group of GPs/FPs
  April 19th 2016 EMA - London

- from three major organisations
- EFPC - UEMO - WONCA

GPs EMA GROUP

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- how general practice may be impacted by regulatory actions
- what type of input collected at primary care level would be most valuable/feasible to inform regulatory decision-making processes

INTERACTION EMA - GPs/ PC

- help EMA gain a better understanding of how medicines are being used in real life and the potential impact of specific regulatory actions on patient care

- raise awareness amongst GPs on how they can inform regulatory discussions on the benefits and risk of medicines so that decisions take into account the reality of clinical practice

The needs of pharmaceutical care and concerns for GPs

The GP is the central figure of a NHS, having to satisfy the primary health care, hospital and community continuity, disease prevention.

Among its tools the Drug has a key role.

GPs and EMA

Collaboration

Identify which type of input achievable at GP level

Highlight the context of his work
and the critical issues that the GP faces daily
often in an original or exclusive way

The GP, daily, has to deal with

) demographic transformations:

Aging population

Migration

Frail patients with increased prevalence of complex and / or chronic-degenerative deseases

2) massive technical and scientific development ↑

humanistic shape impoverishment ↓

doctor-patient relationship, more problematic

3) development and availability of an increasing number of innovative drugs, for customize the treatments

Related aspects to demographic changes

Polypathology , Chronicity, Fragility

Complex Patient

Polypathology

- existence or appearance of any distinct additional clinical entity during the course of a specific disease (disease index) for which the patient is monitored

Fragility

- precarious homeostatic control
- increased risk of alterations on the skill level
- loss of self-sufficiency as a result of medical interventions, acute episodes or stress

Drug treatment of complex patients

Three major factors

1) use different drugs in combination
2) long term drug use
3) risk of increasing the level of fragility or induce heart failure as a result of the adverse effects of drugs and/or interactions

Ethnic medicine and assistance to the immigrant

The foreign patient: double fragility (as a foreigner and how sick)

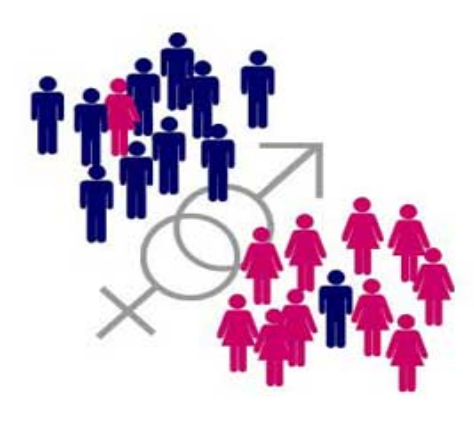
Professional problems for GPs

- **linguistic**
- **cultural** (different conceptions of illness and doctor's role, taboos, religious prescriptions etc.)

Gender Medicine

Differences between men and women in:

- Presentation and Frequency of Diseases
- Drug Response



Adherence to therapy

- **Respect of drugs posology** in the doses and times specified by the doctor (correct dosage);
- **Persistence therapeutic**, as continuation of the c[illegible] time period recommended by the doctor.

Drug interactions positive and negative

- Strengthening of the effect of one of the drugs
- Synergistic effect (agonism), with different mechanisms of action which lead to a greater effect of single
- Reduction of the effect of one or more drugs (antagonism);
- New and unexpected reaction.

Nutrient /drug interactions

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Function of the doctor-patient relationship in the drug use

In the relationship come into play several factors:

- the patient's expectations
- the doctor's response (medical scientist, friend, confidante ...)
- the said and the unsaid between doctor and patient
- verbal misunderstandings
- availability repeating
- reassurance of the patient
- empowerment autonomy of patient

Can GPs do better?

Improve the prescription further:

- Electronic Measurement Software
  and memory of the prescriptions
- Indicators and personal standards (networks)
- Personal Audit
- Reduce therapeutic inertia
- Improve adherence:
  - Experiment with new strategies
  - Improving the organization of study

Functions of a GPs Group

(Creating) a Working Group on "evaluation of the use of drugs in PC", whose working areas, with a view to cost-effectiveness, are to assign to drugs:

- Adaptability for use in MG
- Security, Drugs Risk Minimization (plan)
- Clinical value
- Expression of views on the appropriateness of prescribing in PC products in accordance with GCP, with a focus on patient safety
- Production of an orientation on the major issues of Prescription for PC
- Increased appropriateness of use of drugs through optimal

Functions of a GPs Group

All this could be analyzed and managed as part of a specific group of GPs or some their component, at any authorization stages of a drug:

- Pre-submission
- Evaluation
- Post authorization

in the fields :

- Scientific Advice / Protocol Assitance Procedures
- Scientific Advisor
- Scientific Committe consultations
- Review of documents
- Evaluation of specific medicine

The GPs and Scientific Information

GPs feel the need of a proper and independent information

- EMA could promotes proper and independent public information targeting citizens and health professionals,
- Available of the recommendations and information notes on the use of medicines, also with the help of Pharmacovigilance EMA.

Format of collaboration to be piloted with a group of GPs and how such group could be established as a pool of EMA experts

- PC involvement in processing of the route in Drugs Risk Minimization (plan), also from the first marketing.
- The input, from a clinicians standpoint, to add value into the regulatory decision-making process , through the involvement of GPs in the HTA assessment (*EMA role in this field actually in discussion*) in support of the Place in Therapy of drugs.
- Detection and Analysis of Drugs concerning morbidity that is very relevant for PC.

Format of collaboration to be piloted with a group of GPs and how such group could be established as a pool of EMA experts

- Evaluation of the experience of medications in real clinical practice, also through data collect, by Participation in: Observational Study, PAS, PAES, Registries, Adaptive Path Way, Pharmacovigilance activity, etc, in order to continuously improve benefit-risk assessment of medicines throughout their life-cycle for a best “place in therapy”.
- Involvement in the review of product information and additional risk minimisation measures .
- Dissemination of the EMA communication to GPs and Patients through their national communication channels.