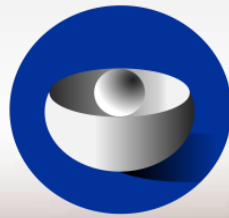


*EMA Workshop on the collaboration with
General Practitioners/Family Physicians*

Involvement of GPs in EMA activities



What would be the impact in general practice?

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EFPC

F.I.M.M.G Scientific Manager

London April 19th 2016

The needs of pharmaceutical care and concerns for GPs

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

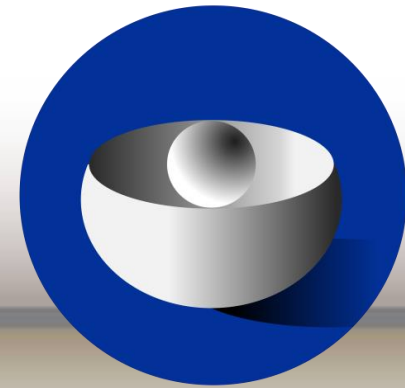


Among its tools the Drug has a key role.





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

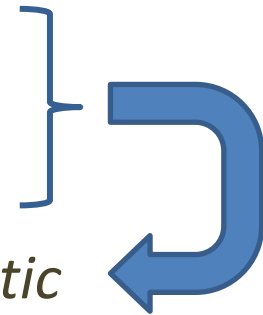
The GP, daily, has to deal with

1) demographic transformations:

- Aging population
- Migration
- Frail patients with increased prevalence of complex and / or chronic-degenerative diseases



2) massive technical and scientific development  }
humanistic shape impoverishment 
doctor-patient relationship: more problematic



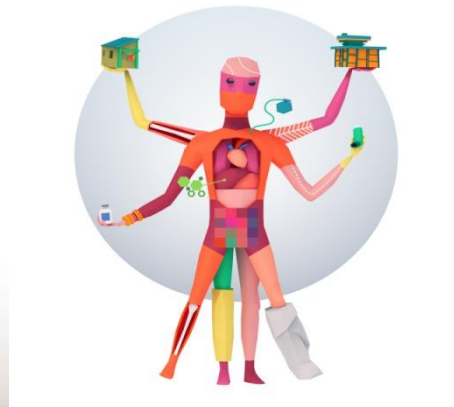
3) development and availability of an increasing number of innovative drugs, for customize the treatments

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

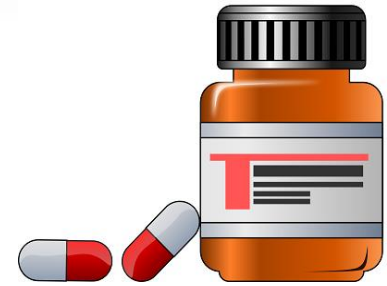
Fragility

- 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



Improve the effectiveness, efficiency and security of (poly) drug therapies

Some major indication
with the intervention of regulatory authorities
also to:

1. stimulate implementation of clinical research on the use of drugs in complex patient
2. set up specific training courses for GPs and specialists on the appropriate use of drugs in complex patient
3. review the grading system of supply and distribution

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.)



Ethnic medicine and assistance to the immigrant

Professional problems for GPs

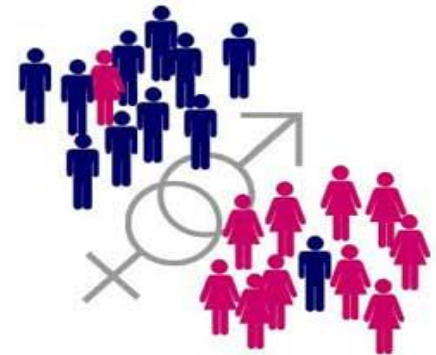
Clinical

- Use of “curious” terminology , unclear or otherwise interpreted by the patient
- Unlike meaning attributed to symptoms and signs for which some of them cannot be shown
- Physical examination made difficult by patient’s physical characteristics
- Interference with the therapy compliance of superstitions or beliefs
- Possible presence of unusual diseases, not used to thinking

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 cure for the 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

Change of bio-availability profile

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



Conclusions and operational proposals

The GP is able to

- Produce system information for:
 - epidemiological survey audit purposes,
 - continuing professional development,
 - education - governance - assessment of costs;
- Be supportive to clinical decision-making processes and continuity of care;
- Develop research projects in primary care.

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 patient care
- Definition of a greater collaboration between the GP and the Specialist
- Continuous Assessment of *the place in therapy* of the MG use drugs

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 Assistance Procedures
- Scientific Advisor
- Scientific Committee 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 promote 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.



The GPs and Scientific Information

An accurate information
on the efficacy and safety of a specific drugs,
compared to other competitors.

Information dissemination
of guidelines and consensus conferences,
as well as their translation into clinical practice
in the real world.



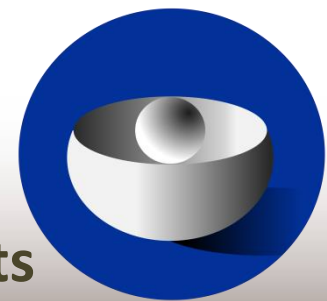
**Format of collaboration
to be piloted with a group of GPs
and how such group
could be established as a pool of EMA experts**



- 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.

So we can be the architects of a “new era”

