Discussion on the EMEA Transparency Policy

Perspectives from Healthcare Professionals

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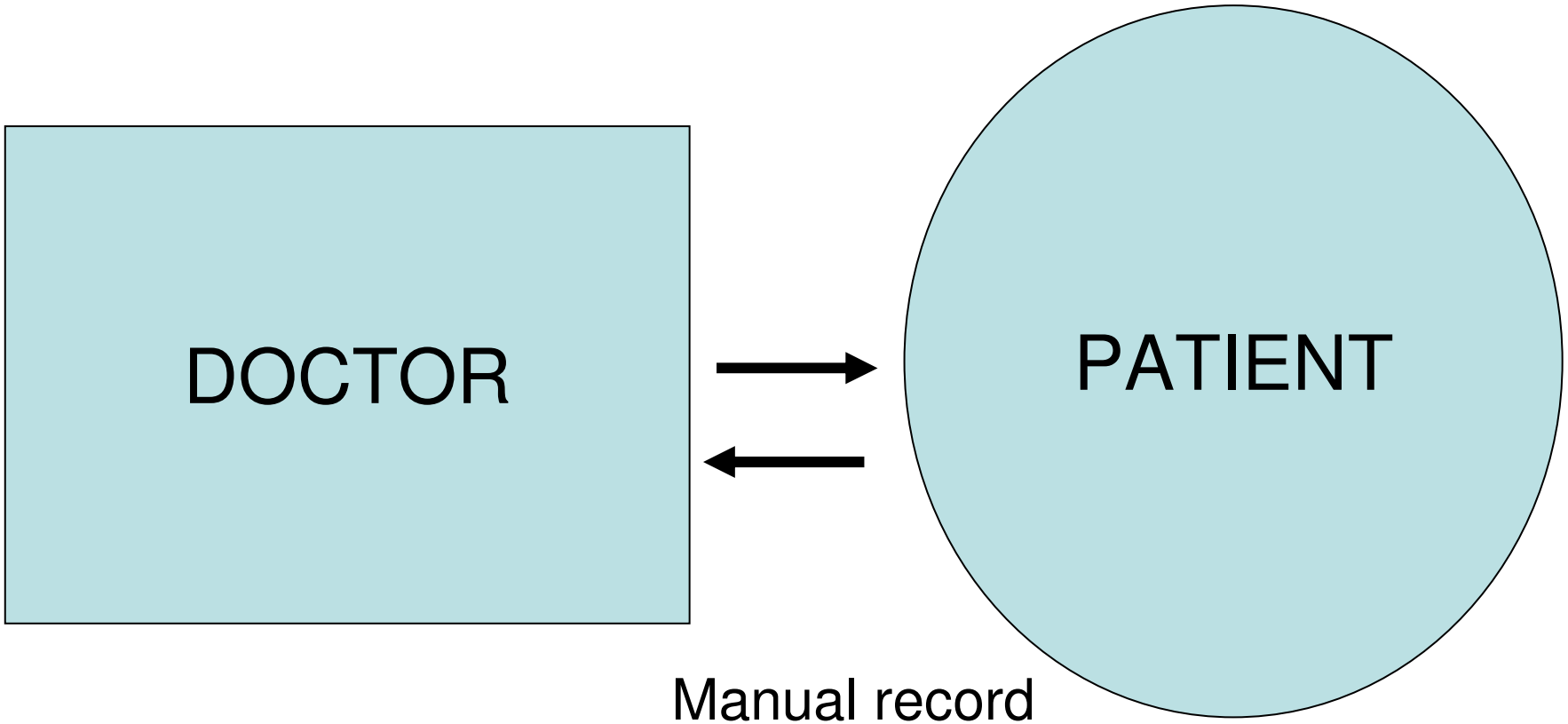
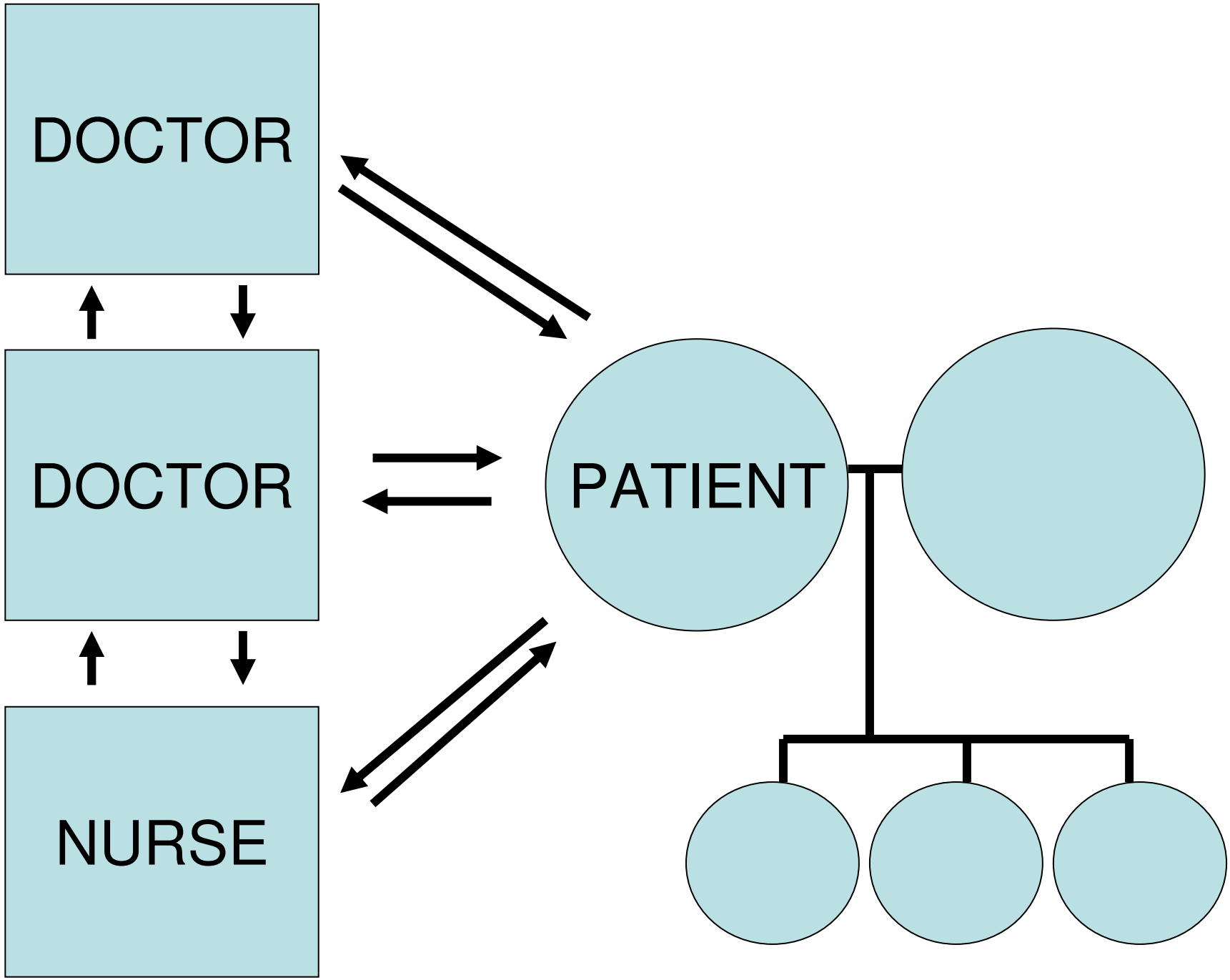
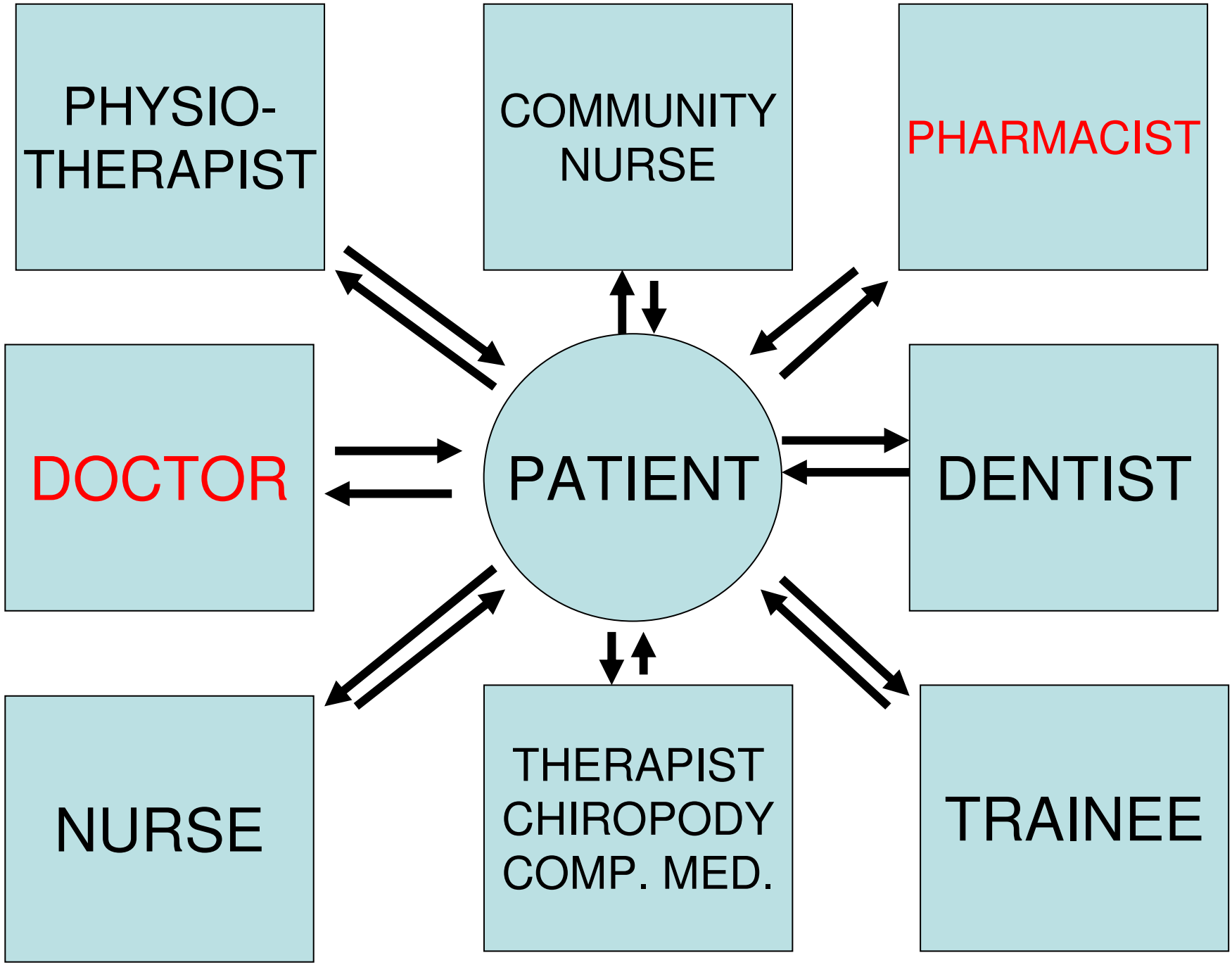


Manual record
Memory
Familiarity
Continuity


DOCTOR
DOCTOR
NURSE
PATIENT


PHYSIO-
THERAPIST
COMMUNITY
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DOCTOR
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DENTIST
NURSE
THERAPIST
CHIROPODY
COMP. MED.
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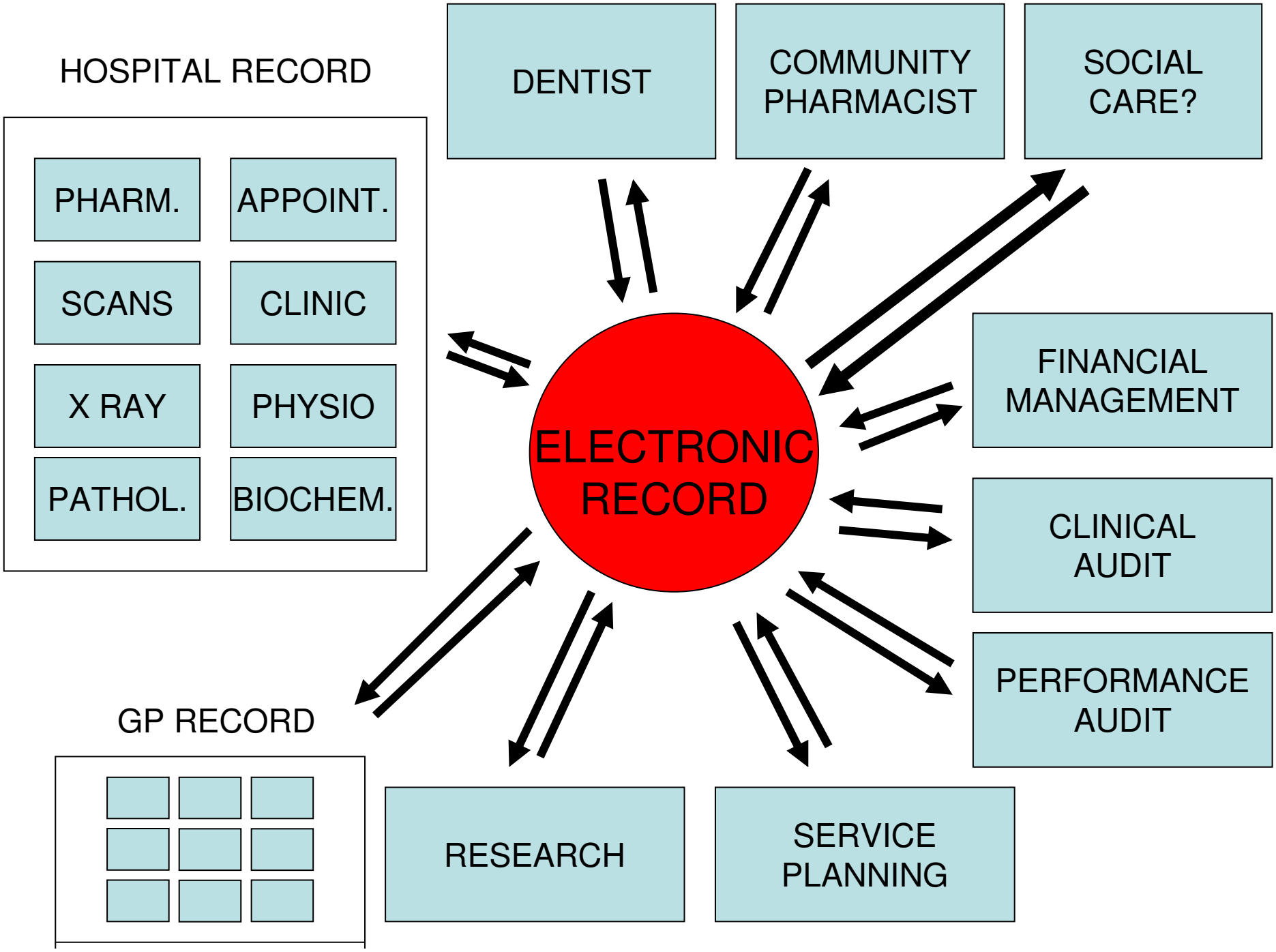
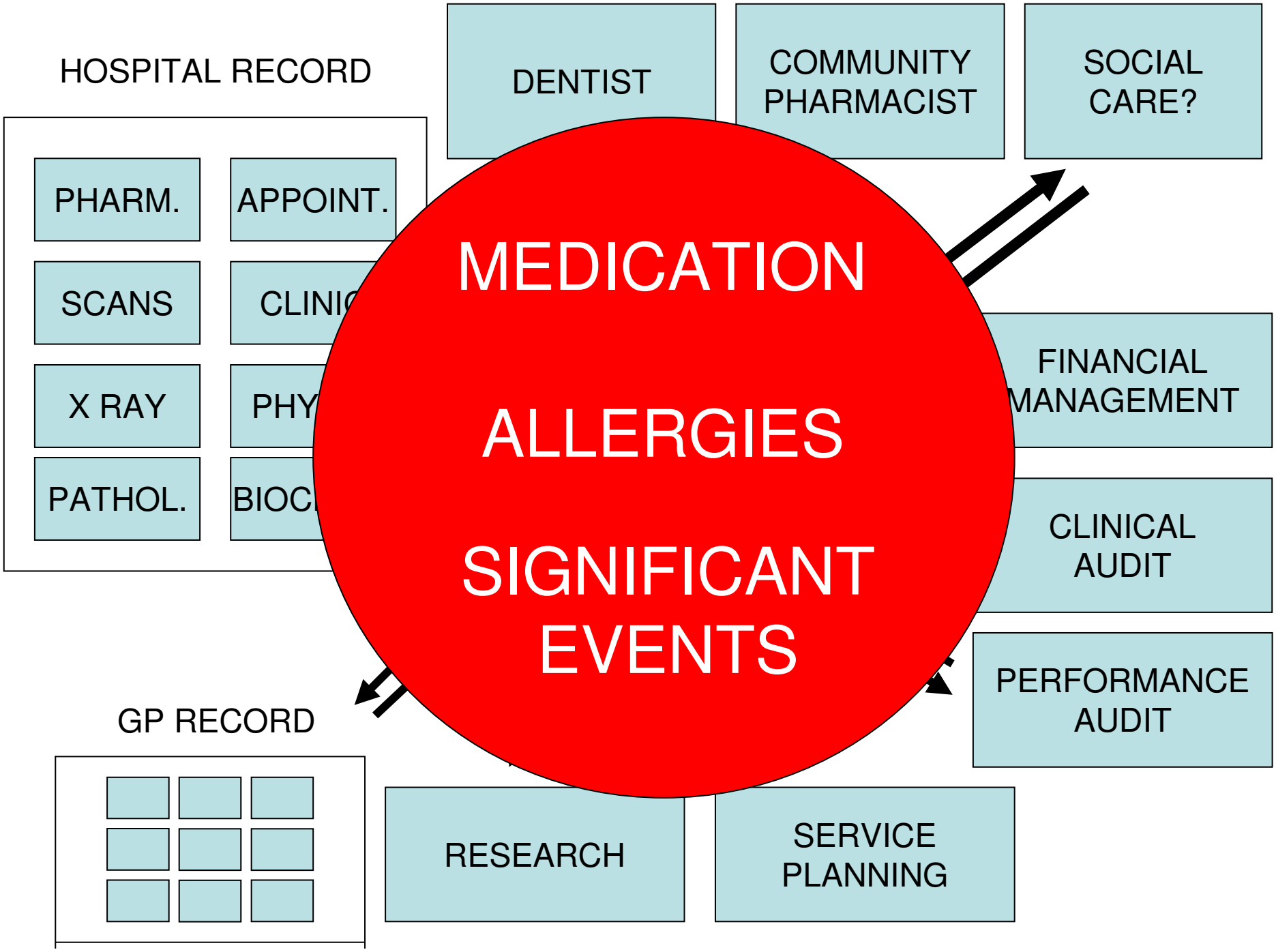
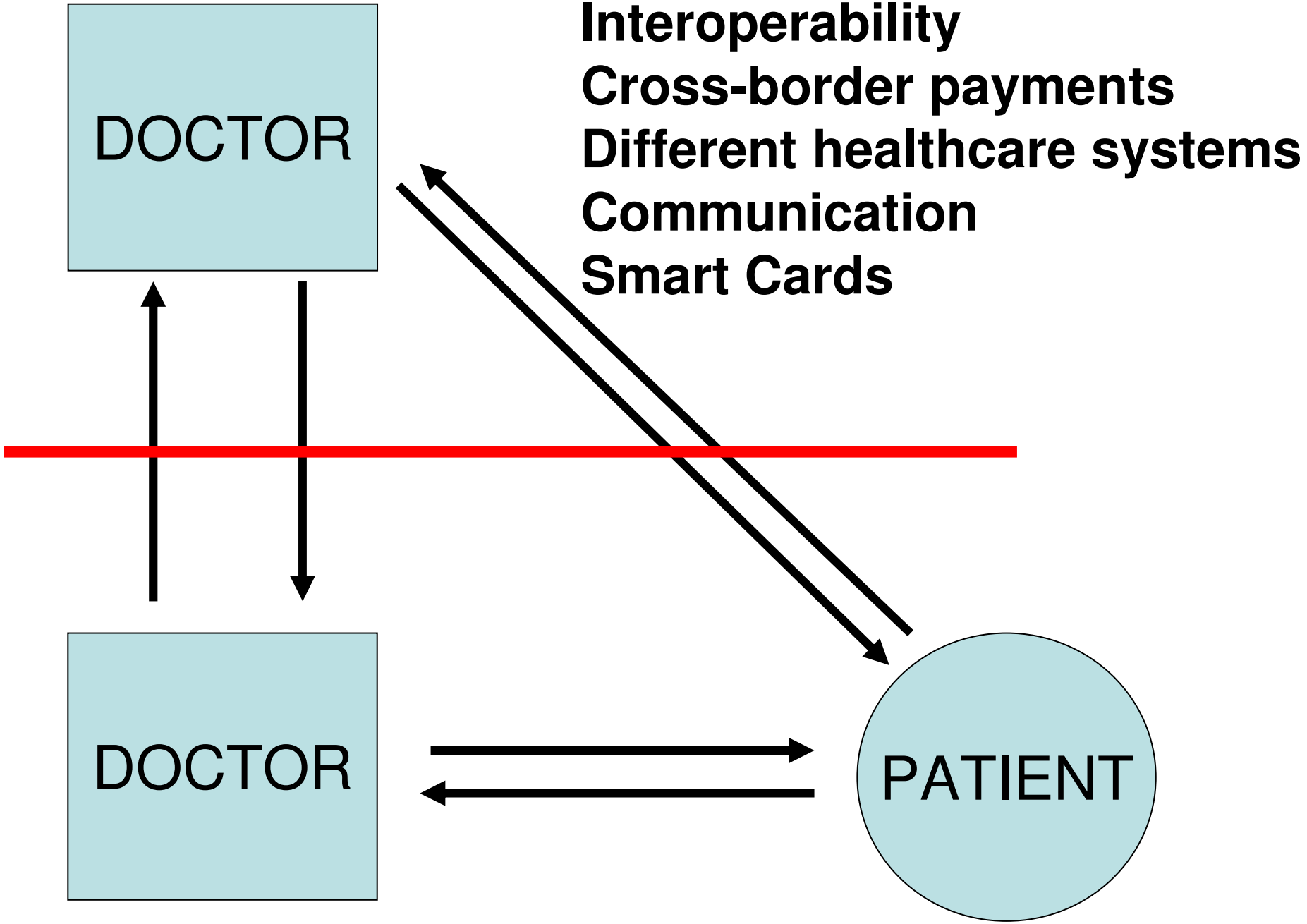

HOSPITAL RECORD
PHARM.
APPOINT.
SCANS
CLINIC
X RAY
PHYSIO
PATHOL.
BIOCHEM.
DENTIST
COMMUNITY PHARMACIST
SOCIAL CARE?
ELECTRONIC RECORD
FINANCIAL MANAGEMENT
CLINICAL AUDIT
PERFORMANCE AUDIT
GP RECORD
RESEARCH
SERVICE PLANNING


HOSPITAL RECORD
PHARM.
APPOINT.
SCANS
CLINIC
X RAY
PHY
PATHOL.
BIOC
DENTIST
COMMUNITY PHARMACIST
SOCIAL CARE?
MEDICATION
ALLERGIES
SIGNIFICANT EVENTS
FINANCIAL MANAGEMENT
CLINICAL AUDIT
PERFORMANCE AUDIT
GP RECORD
RESEARCH
SERVICE PLANNING

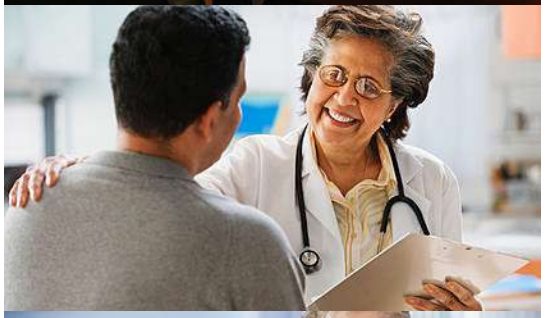

DOCTOR
Interoperability
Cross-border payments
Different healthcare systems
Communication
Smart Cards
DOCTOR
PATIENT

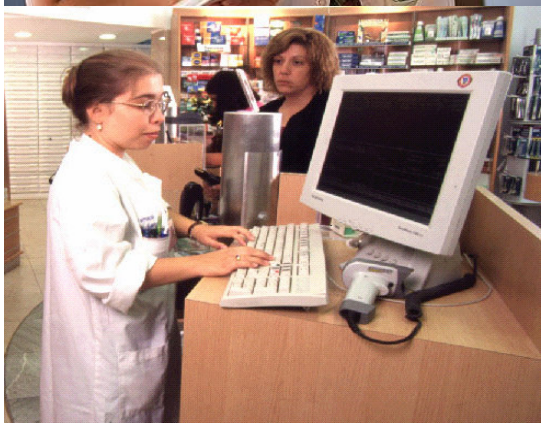
What matters to HCPs?

- Does the information contribute to patient safety?
- How useful will the information provided by EMEA be for health professionals to use it when considering a treatment option?
- Is the information provided relevant for a clinical decision?
- Is the information provided in a way which is meaningful to patients?
- Is it easy to access?

Co-ordination within the Healthcare team

- The more information the health care team members have and can share about the patient, the better they can develop a plan of care tailored to him/her. The members of the team need to know:
  - the patient's medical history
  - any allergies and sensitivities
  - Medication taken, including OTC
  - "Complementary" medication
  - Compliance and attitiude





- Health care professionals need to have easy access to information on:
  - generic and brand names
  - active ingredients
  - indications and contraindications
  - instructions
  - benefit/risk
  - warnings and precautions
  - interactions – with food, dietary supplements, other medicines
  - side effects/adverse reactions
  - expiration dates

Patient safety

- Clear identification and labelling
- Patient identification
- Communication:
  - Prescriber/pharmacist
- Warnings:
  - Standard warnings
  - Interactions
- The “literate” patient
- Clear prescribing and dispensing data
  - Electronic prescribing
  - Legibility!

Are you satisfied with the current level of transparency?

- Yes, but:
  - Clearly can be improved
  - Visibility v transparency
  - How to improve awareness of EMEA's role?
  - Website development
  - Articles in journals
  - Cross-reference from NMA regulatory bodies

Expectations on non-product related issues:

Do you think that additional specific transparency measures should be considered (for instance on the drafting of Guidelines, EMEA Committees' Monthly Reports etc)?

- Medicinal products before authorisation:
  - There is no information on what medicines are being evaluated before an opinion from the CHMP is provided
  - EMEA could make available a list of all applications received (depending on commercial confidentiality?)

- Medicinal products after authorisation:
  - The new pharmacovigilance provisions foresee that more information is made available by companies with regards risk assessment plans and periodic safety reports. Will these be made available to HCP?
  - Strengthen patient reporting

Do you think that specific transparency measures should be considered for emerging issues (for instance safety issues, quality defects etc) irrespective of the status of the authorisation of the medicinal product?

- Yes:
- It is important for HCPs to understand how guidelines are developed to allow more input in its development, and to how decisions are taken and what is the impact

With regards to EMEA interaction with its stakeholders, do you have any particular suggestions in order to improve such interaction?

- The trend developed in the past 3 years should be continued and further developed. The involvement of stakeholders in workshops such as this one to discuss the developemnt of EMEA's policies is very welcomed