# PCWP meeting with all eligible patient & consumer organisations
# 26 Nov 2015

## Swedish Medicines Agency proposals for patient engagement

Lena Ring

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# Our vision

# A leading force in collaboration for better health

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# Never forget the people.

**All of our debates and discussions have meaning only when they improve the health of people and relieve their suffering.**

*WHO Director-General reminds health officials: never forget the people*
*Dr Margaret Chan – Director General for Communicable Diseases*
*Address to the Sixty-fourth World Health Assembly Geneva, Switzerland, 16 May 2011*

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# Brief CV Lena Ring

- PhD 1999– HRQL focus
- Director of Studies/Researcher PRO
- Bioethics /Researcher PRO
- RCSI Dublin /Post-doc PRO
- Director of Studies/Researcher PRO
- AZ – PRO Scientist/PRO Skills lead + UU Associate Prof.
- MPA – researcher + UU Professor in Health-related QoL assessments in Health Care

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# Many interested parties – broad social responsibility


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# Previous Patients' Council

- 2009-2011
- 12 patient organisations and 4 annual meetings
- Aim: exchange of infromation and increase openess
- Fizzled out
- Expressed need for patient and consumer involvement

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# New road to be taken – the one less traveled?

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# Design methods

- Partnerships
- Co-creation with patient and consumers – the journey

Innovation

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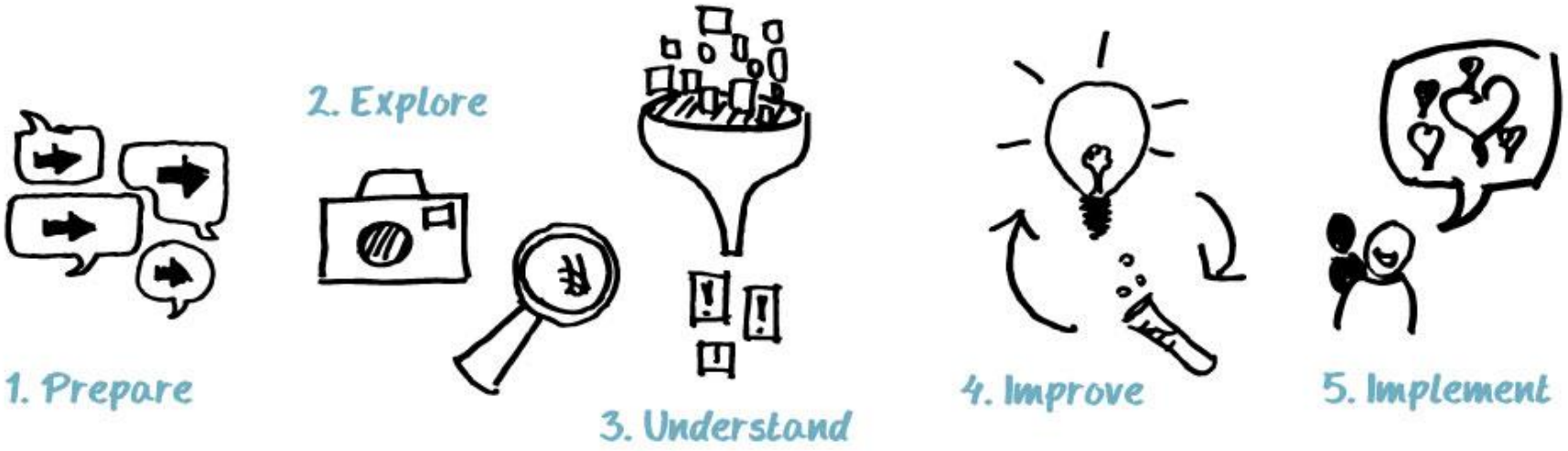
http://experiolab.se/en/

# The EXPERIO Lab design process

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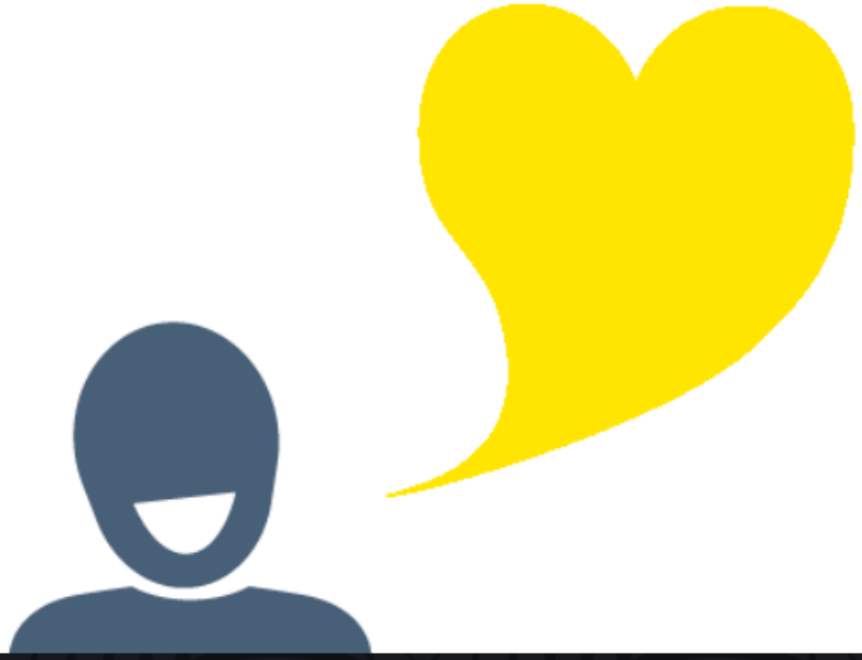
http://experiolab.se/en/

EXPERIO LAB

# Our philosophy

**Curiosity** and empathy for people in their everyday lives. **Courage to dream** of a better future. **Co-creation** to make it happen.

Read more...



Experio Lab Social media Our Partner

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# The PRIO project - The Swedish government's investment within the area of mental ill-health

- Overall aim: to improve the lives of persons with mental ill-health.
- Develop and test a model for patient and relatives engagement in mental ill-health.

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# The PRIO project - The Swedish government's investment within the area of mental ill-health

- Prioritised groups are children, adolescents and young adults as well as persons with extensive or complex psychiatric problems.
- Through PRIO, the government ultimately **aims to prevent mental ill-health** and to **improve the health services and care** for persons with this condition.
- The project runs until 2016.

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# Network to strengthen the collaboration with patient/user organisations and agencies

- *National Partnership for Mental Health (NPMH or NSPH) - a network of organizations for patients, users and next of kin within the psychiatric field.*
- *National Board of Health and Welfare*
- *The Swedish Agency for Health Technology Assessment and Assessment of Social Services - SBU*
- *Public Health Agency of Sweden*
- *Medical Products Agency*

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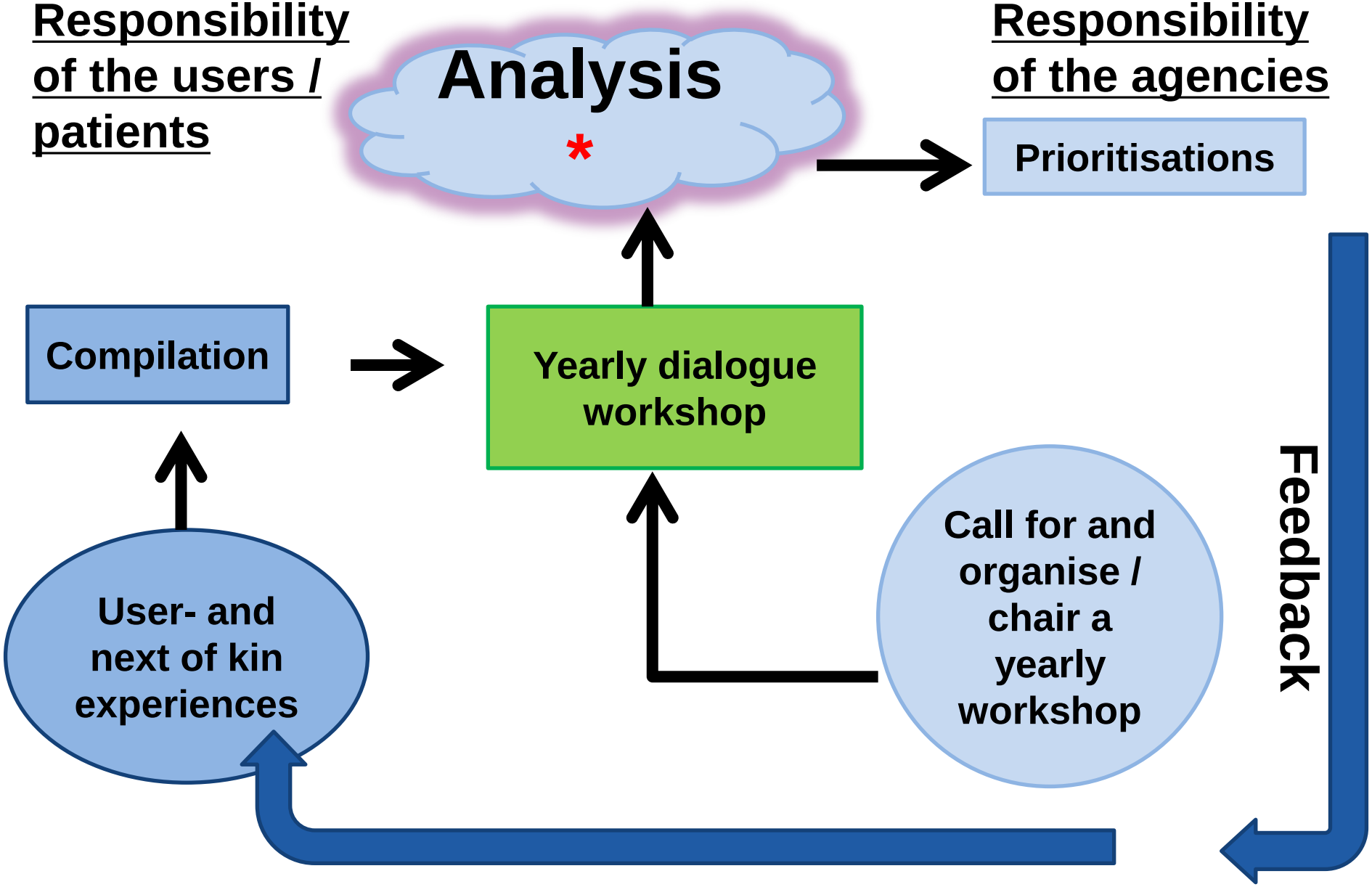


* The analysis is done by the agencies together with the user/patient organisations


Open the door to patient & consumer engagement…

# BACK-UP SLIDES

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ISOQOL

International Society for Quality of Life Research

*Dedicated to the promotion of excellence in the science of health-related quality of life.*

**ISOQOL**

**23rd Annual Conference**

**19-22 October 2016**

**COPENHAGEN**

**DENMARK**

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# ISOQOL Patient Engagment SIG and Task Force


- Patient Engagment World Cafe → QLR paper
  - SIG started in Miami 2013
  - Challenge: how much patient involvment and how?
  - 2015 Task Force
  - Design methods



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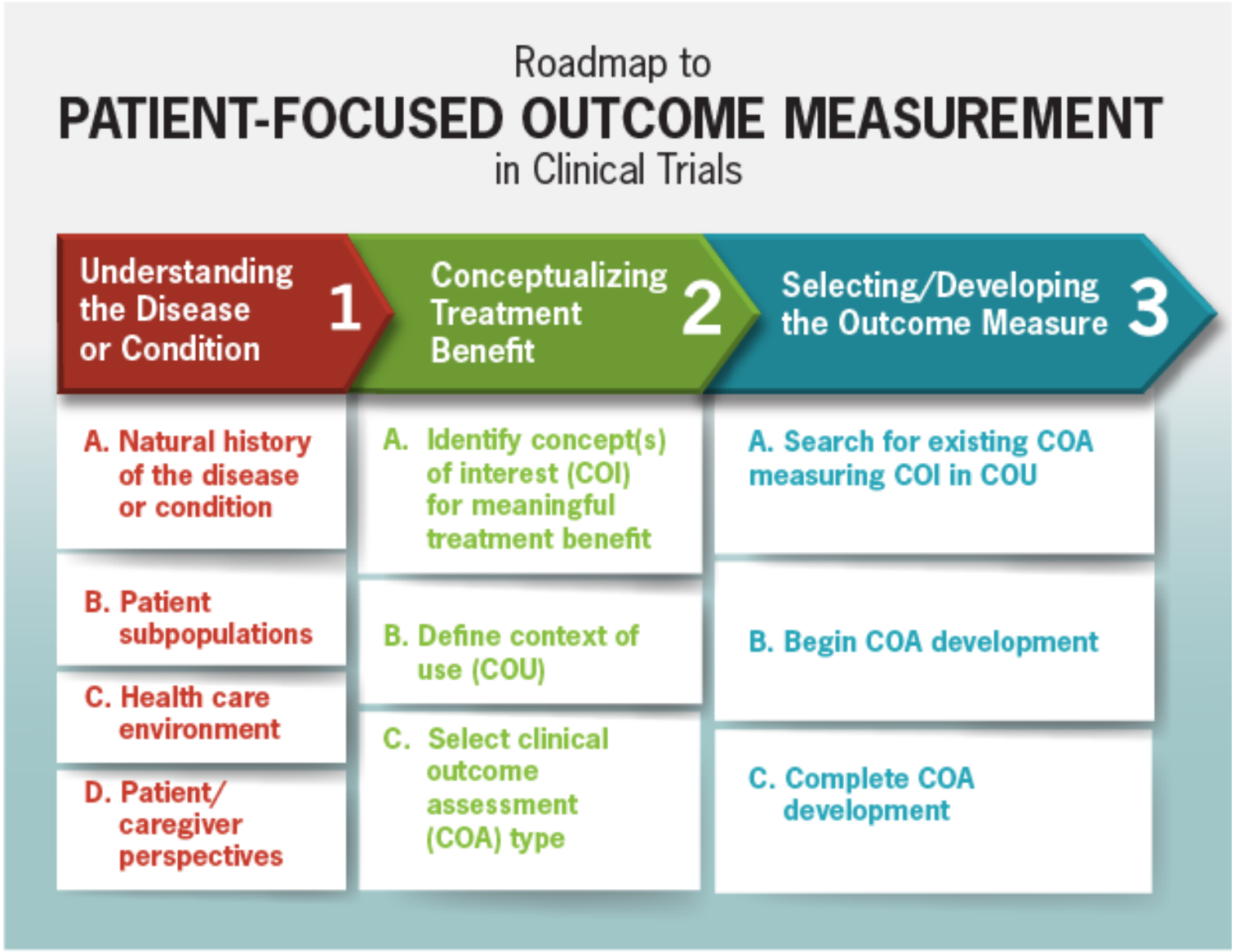


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# Roadmap to **PATIENT-FOCUSED OUTCOME MEASUREMENT** in Clinical Trials

## 1 Understanding the Disease or Condition

**Natural history of the disease or condition**
- Onset/Duration/Resolution
- Diagnosis
- Pathophysiology
- Range of manifestations

**Patient subpopulations**
- By severity
- By onset
- By comorbidities
- By phenotype

**Health care environment**
- Treatment alternatives
- Clinical care standards
- Health care system perspective

**Patient/caregiver perspectives**
- Definition of treatment benefit
- Benefit-risk tradeoffs
- Impact of disease

## 2 Conceptualizing Treatment Benefit

**A. Identify the *meaningful health aspect* that is the intended benefit to patients in their daily lives**
- Survives (e.g., length of survival)
- Feels (e.g., symptom severity)
- Functions (e.g., walking ability)

**B. Identify the measureable *concept of interest* that represents the meaningful health aspect, which can be:**
- Equivalent to the meaningful health aspect (e.g., patients' self-reported ambulatory activities in daily life) OR
- Distinct from, but related to the meaningful health aspect (e.g., 6-minute walk test)

**C. Define context of use for clinical trials, e.g.:**
- Disease/Condition entry criteria
- Clinical trial design
- Endpoint positioning

**D. Consider appropriate clinical outcome assessment type(s):**
- Patient-Reported Outcome (PRO)
- Observer-Reported Outcome (ObsRO)
- Clinician-Reported Outcome (ClinRO)
- Performance Outcome (motor, sensory, cognition)

## 3 Selecting/Developing the Outcome Measure

**A. Search for existing clinical outcome assessment measuring the concept(s) of interest in the context of use :**
- Measure exists
- Measure exists but needs to be modified
- No measure exists
- Measure under development

**B. Begin clinical outcome assessment development**
- Document content validity (qualitative or mixed methods research)
- Evaluate cross-sectional measurement properties (reliability and construct validity)
- Create user manual
- Consider submitting to FDA for qualification for use in exploratory studies

**C. Complete clinical outcome assessment development:**
- Document longitudinal measurement properties (construct validity, ability to detect change)
- Document guidelines for interpretation of treatment benefit and relationship to claim
- Update user manual
- Submit to FDA for qualification as effectiveness endpoint to support claims

Updated on March 14, 2014

U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Office of New Drugs
**http://www.fda.gov/Drugs**

# Medical Products Agency (MPA)

- A government agency acting under the Ministry of Health and Social Affairs
- Role is to promote human and animal health
- Almost 800 employees, many are pharmacists or physicians
- Headed by the Director General who reports to the government

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# Areas of responsibility

- Ensuring that medicinal products are safe, effective and of good quality, and that they are used beneficially
- Acting to see that cosmetic products are safe and not harmful to the environment
- Ensuring that users of medical devices have access to safe products that are fit for their intended purpose
- Counteracting the misuse of products within the agency's remit. Includes combating and informing about the illegal and dangerous trade in pirate-manufactured medicines on the internet

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# Responsibilites (continues)

- Providing citizens with quality-assured, producer-independent information about medicinal products

- Within the Centre for the Rational Use of Medicines (CBL) coordinate a national medicinal products strategy in collaboration with other agencies/organizations

- Exercise overall responsibility for environmental issues related to our sphere of operations

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# National medicinal products strategy (NLS)
## - A unique form of collaboration

During 2011, the government gave the MPA the task of building a Centre for the Rational Use of Medicines (CBL) secretariat


- Vision: Correct medicinal product treatment for the benefit of both patients and society
- Broad constellation of stakeholders interact around commonly-set goals in the medicinal product field
- Annual action plan with around 30 projects reported to a High Level Group twice a year

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# A leader in cooperation

- MPA is one of the EU's most consulted medicines agencies
- Co-ordinated by the EU's European Medicines Agency (EMA) in London

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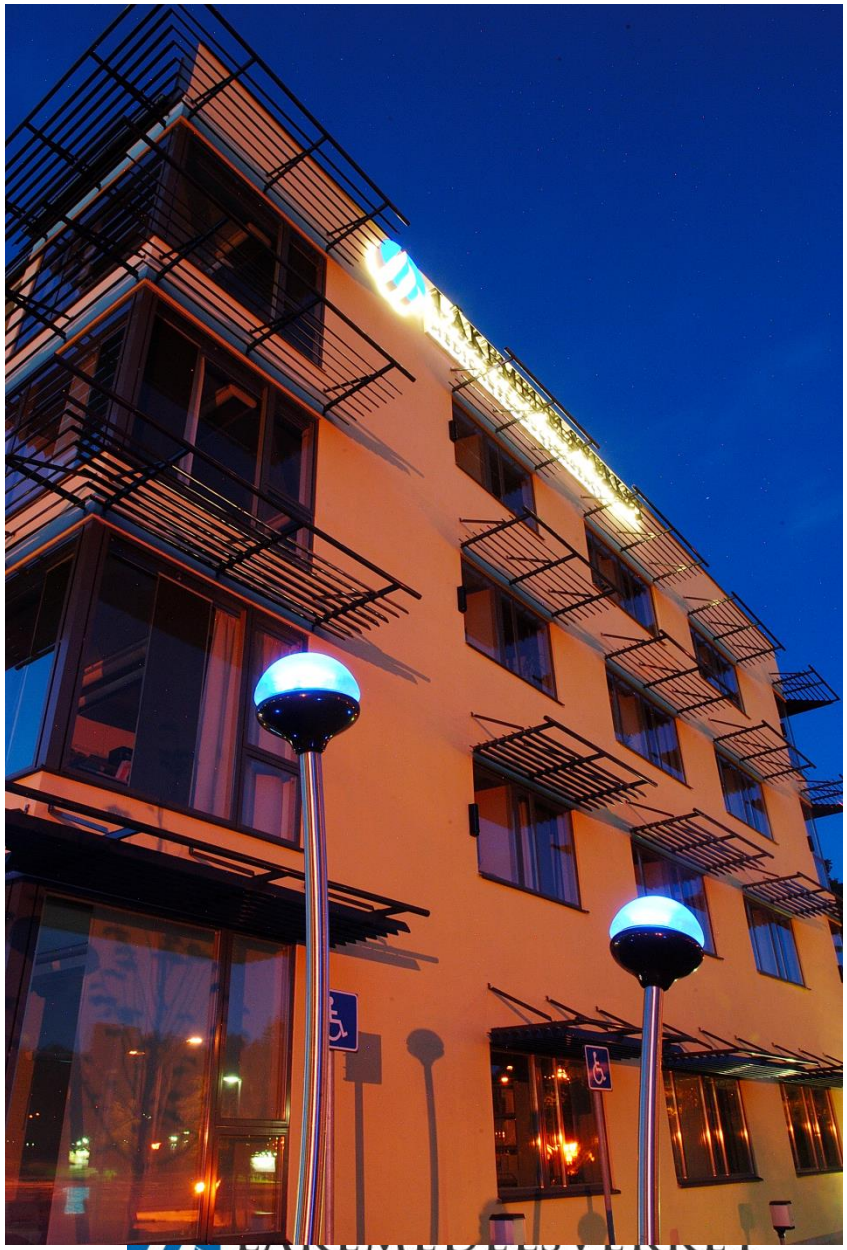

# What does
## the Medical Products Agency do?

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# Evaluate and grant approvals

- Approve medicinal products, including herbal remedies
- Assess and approve clinical trials of medicinal products and medical devices
- Register herbal and homeopathic medicinal products
- Assess the substitution of medicinal products
- Grant licenses and exemptions
- Grant permits to operate pharmacies
- Provide scientific and regulatory advice to companies

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# Follow-up and supervise

- Follow-up the safety and side effects of approved medicinal products
- Check cosmetics, hygiene products and narcotics
- Supervise medical devices
- Inspect pharmaceutical companies, wholesalers, blood centres, dialysis units, etc.
- Supervise pharmacies and retail outlets
- Review medicinal product advertising
- Combat the illegal trading of products within the agency’s areas of responsibility

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# Inform

- Information to the general public via the Medicinal Products Information service (LMU)
- Safety information – e.g. new adverse reactions or other risks, product withdrawals, important non-availability information, and accidents and incidents involving medical devices
- Medicinal product monographs - evaluation of new medicinal products in comparison with previously approved therapies
- Medicinal product recommendations - developed by experts for healthcare professionals and patients

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# Swedish Poisons Information Centre (GIC)

- November 1st, 2009 – responsibility for poisons information was transferred from Apoteket AB (formerly the National Corporation of Pharmacies) to the MPA
- GIC is an independent unit within the MPA section Usage
- GIC informs healthcare professionals and the general public about the risks, symptoms and treatment of various types of acute poisoning. Provides 24/7 telephone support
- Approximately 40 employees at the Karolinska University Hospital in Solna, Stockholm

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# Support to society in general

- Assists when actions or measures related to medicinal products are required
  - Who can prescribe medicinal products and how?
  - Who is to report side effects and how?
  - For preventing the risk of abuse
  - Regarding medicinal products' effect on the environment, etc.
- Is a referral body
- Develops regulations and guidelines

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# Information channels

- Website
  - www.lakemedelsverket.se
- Personal contacts
  - E-mail: registrator@mpa.se
  - Telephone: +46 (0)18 – 174600
- Publications
- Newsletters
- Massmedia
- Courses, seminars


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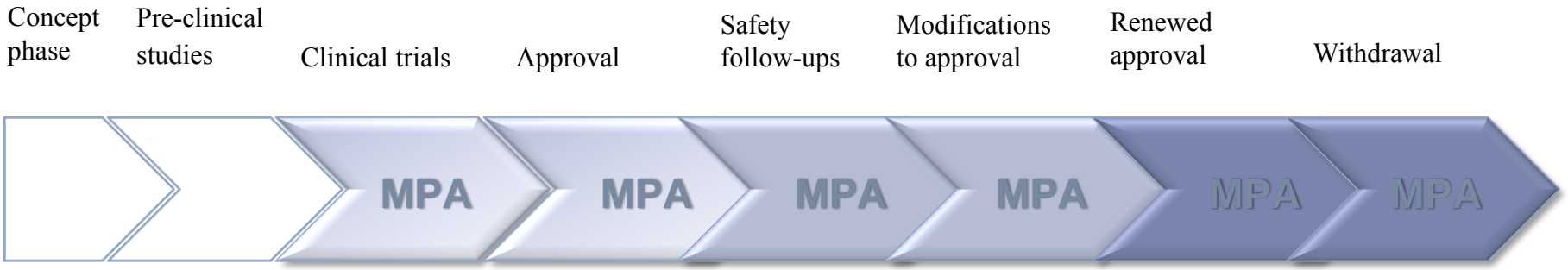
# How is a medicinal product approved?

# Life-Cycle of a medicinal product

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# Several approval procedures

Authorisation to sell a medicinal product in one or more EU countries

- Centralised procedure (approval throughout the EU)
- Mutual recognition procedure (2 to 30 countries)
- Decentralised procedure (2 to 30 countries)

Authorisation to sell a medicinal product in a specific country

- That country’s national procedure

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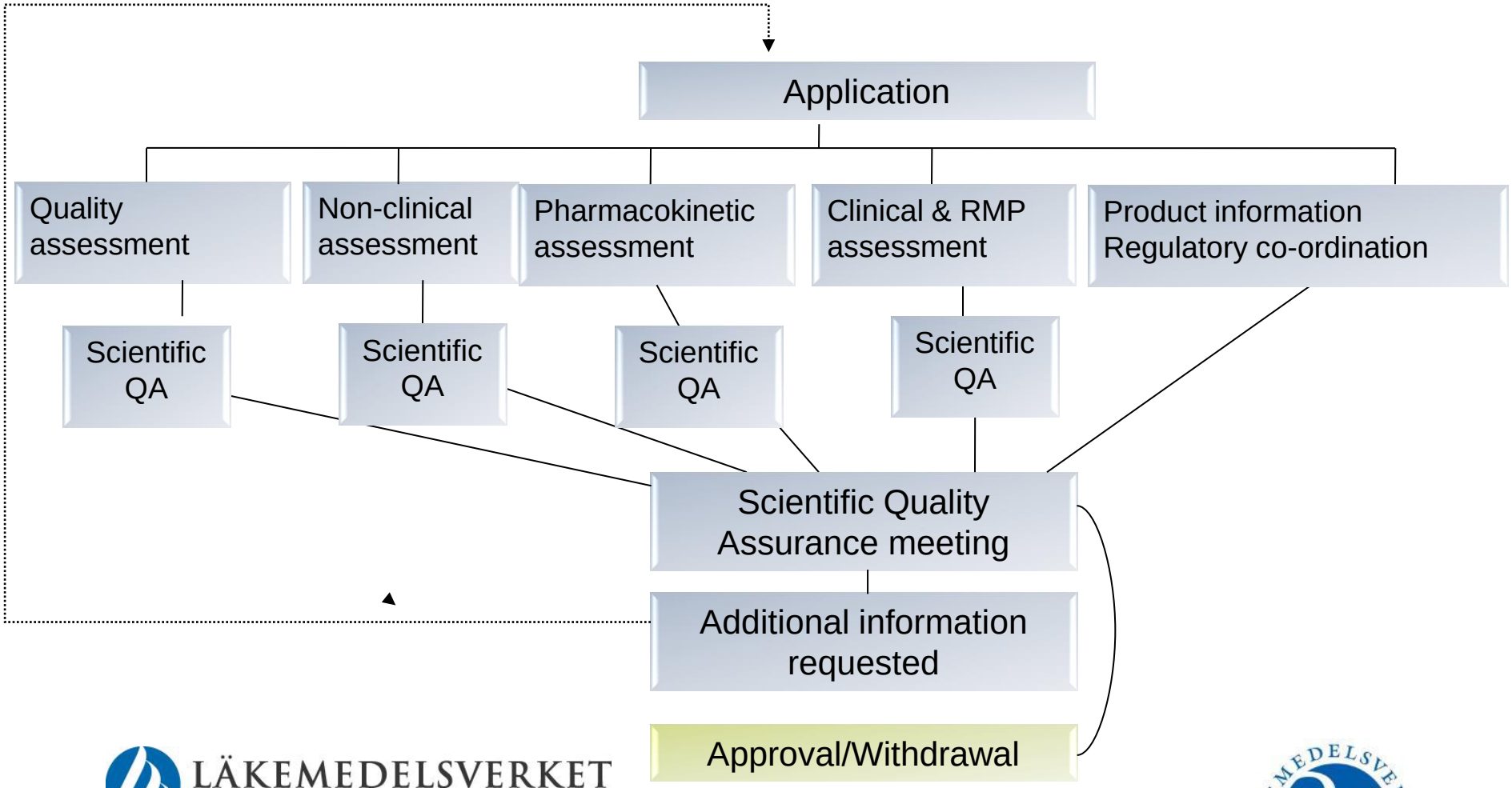
# Application for approval of a medicinal product – case flow at the MPA

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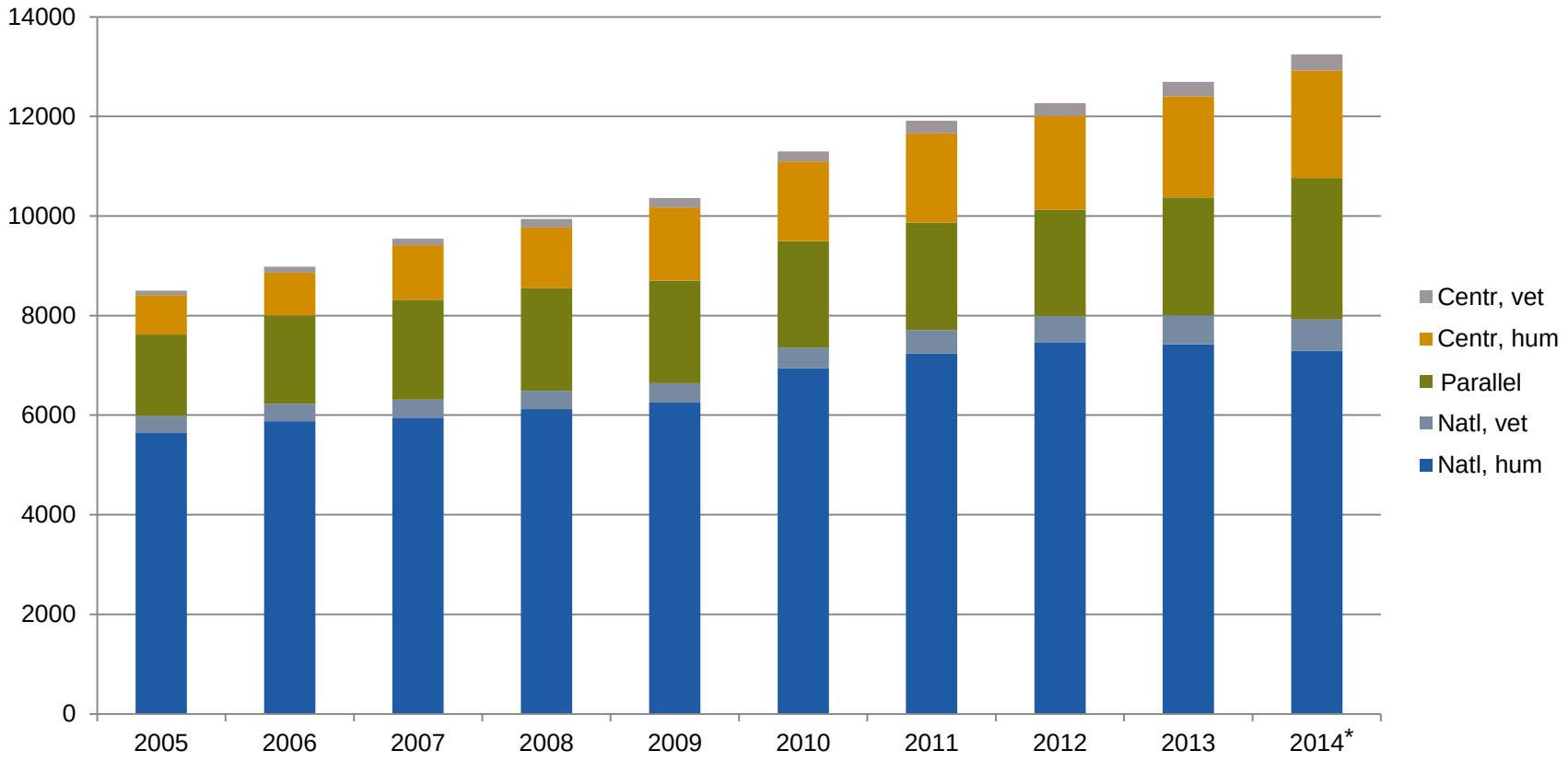
# Authorised medicinal products




** An increase of ca 550 authorised medical products during 2014.*

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