Sundhedsstyrelsen
Danish Health and Medicines Authority

Referat af mødet d. 16 april 2015
i rådet for lægemiddelovervågning

Tilstede: Ib Valsborg, Jens Peter Balling, Kim Dalhoff, Marianne Lisby, Rita Offersen, Mette Holst og Sine Jensen.

Fra Sundhedsstyrelsen deltog: Henrik G. Jensen, Helle Harder og Doris Stenver.

Fraværende: Annemarie Hellebek, Birthe Søndergaard, Michael Dupont og Jesper Hallas.

1) **Velkomst og referat fra sidste møde**
   Ingen bemærkninger til referatet fra sidste møde.

2) **Eventuelle ændringer i habilitetserklæringerne**
   Sker der ændringer i jeres habilitetsforhold, skal I huske at meddele det til sekretariatet. Der var ingen ændringer i medlemmernes habilitetsforhold.

3) **Meddelelser fra formanden**
   Til mødet i dag er der modtaget afbud fra Annemarie Hellebek, Birthe Søndergaard og Michael Dupont.

4) **Opsamling og evt. bemærkninger til materiale udsendt til orientering siden sidste møde:**
   - ✓ Information om materiale vedrørende HPV- i forbindelse med udsendelse på TV 2 24. marts 2015
   - ✓ Information om bivirkninger ved MFR 3. marts 2015
   - ✓ Information om HPV i forbindelse med artikel i Politiken 5. februar 2015
   - ✓ Information vedrørende Off-label rapport fra Sundhedsstyrelsen 30. januar 2015

   Off-label rapporten blev sendt ud i starten af januar. Der kommer en opfølgning på den på et senere møde.

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Programmet i TV2 ”de vaccinerede piger” har givet anledning til flere indberetninger. Og der har i tiden efter programmet været en del spørgsmål herunder også spørgsmål fra Folketinget. Sine spurgte ind til erfaringer fra andre lande. Det blev oplyst, at lignende drøftelser var i flere andre lande, men at vaccinen fortsat blev anvendt i hele Europa og anvendt i USA og anbefalet af WHO.

5) Meddelelser fra Sundhedsstyrelsen

a. Status HPV – herunder satspulje og opfølgning på tv-udsendelse.

Bilag - kronik fra Politiken den 26. marts 2015 af læge Louise Brinth, Frederiksberg Hospital.

Indledningsvis understregede Sundhedsstyrelsen, at man har et rigtig godt samarbejde med Louise Brinth og Synkopecenteret ved Frederiksberg Hospital.

Danske Regioner har meddelt, at de 1. juni er klar med et behandlingstilbud til pigerne. 1. juni vil der være en indgang i hver region til piger med mulige bivirkninger efter HPV. Praksiskonsulenter, som de praktiserende læger kan rådføre sig med i tvivlsspørgsmål, vil også være klar 1. juni.

Den 5. maj er ministeren kaldt i samråd. Samme dag er der også en lukket eksperthøring, med fordele og ulemper ved alle vacciner i børnevaccinationsprogrammet på dagsorden.

TV2´s udsendelse ”de vaccinerede piger” kom desværre til også at dreje sig om 4 manglende mails Der er igangsat en fornyet signalanalyse, hvor vi ser bredere på symptomerne omkring POTS. Vi ser både på data fra egen database og fra WHO´s database.

Der blev spurgt til om PRAC er bekendt med dataene fra JAPAN, og det kunne Doris bekræfte at de er, og PRAC vurderede december 2014, at man hverken kunne afkræfte eller bekræfte en sammenhæng mellem vaccinen og POTS/CRPS. I Japan har de valgt at tage vaccinen ud af børnevaccinationsprogrammet, men det er stadig muligt at købe den i Japan.

Der blev spurgt til, om der ligger noget forskning på vaccinerede og ikke-vaccinerede piger i forhold til diagnosen POTS. Helle kunne oplyse, at da POTS er en ny diagnose, er der ikke mange data i Landspatientregisteret, men vi er i gang med at kigge på de diagnosekoder, som ligger omkring POTS for at se om de kunne være relevante.

Der blev spurgt til om Sundhedsstyrelsen har set på Jesper Mehlsens udtalelse om en sammenhæng mellem mulige bivirkninger og sportsaktive piger, og hvordan vi vurderer den mulige sammenhæng. Vi har kigget det tilgængelige materiale igennem, som der er på nuværende tidspunkt, og der er ikke videnskabelig evidens for udtalelsen.

Danske Regioner og Sundhedsstyrelsen har sammen taget initiativ til at arrangere et møde med de fem hospitalsindgange og praksiskonsulenterne den 19. maj på Fyn.

Formanden foreslog, at Rådet inviterer relevante interessenter til et bredt sammensat møde, hvor problematikken omkring HPV-vaccination bliver belyst.

Henrik og Ib arbejdere videre på rammerne for sådan et arrangement.

b. Handlingsplan III v/Helle Harder

I forbindelse med vores kampagne til de praktiserende læger, har vi fået lov til at deltage i SOL-kurserne, som er en del af alle specialeuddannelserne. I samarbejde med bivirkningsmanageren fra Bispebjerg Hospital har vi 45 min. hver 14. dag, til at fortælle hvad bivirkningsindberetningerne bruges til. Vi har valgt at fokusere på at praktiske eksempler på hvordan vi bruger indberetningerne til højnelse af patientsikkerheden.

På næste møde i Kvalitetsforum, den 30. april, skal vi snakke om regionernes udfordringer med, at de ikke har adgang til batchnumrene, når de skal indberette.

Jens Peter orienterede om, at Direktivet vedrørende forfalskede lægemidler, introducerer sikkerhedsforanstaltninger, der vil gøre det muligt at kontrollere lægemidlets ægthed og identificere individuelle pakninger, ligesom det vil være muligt at kontrollere, om den ydre emballage er blevet brudt.

Som nævnt tidligere har vi en specialestuderende som kigger på vores Follow up procedure. Hun fremlægger sine resultater på næste møde i kvalitetsforum. Som nævnt på et tidligere møde har vi lavet nye regler for hvad der kan søges follow up på.

MHRA er i gang med at lave en bivirknings applikation, så DAPs bliver bedre og mere interaktive. Den regner vi med at gennemføre i Danmark i løbet af efteråret 2015.

Der vil blive indkaldt til et ekstra møde efter sommerferien, hvor 3 separate punkter fra handlingsplanen vil blive gennemgået.

I løbet af året får vi lavet en ATC browser til Empirica. Det betyder at bedre vil kunne udnytte vores data og lave bedre søgninger.

6) Oplæg fra Jens Peter Balling og andre relevante medarbejdere fra Lundbeck.

7) Evt. .

Kim Dalhoff opfordrede til at vi orienterede mere om Interaktionsdatabasen, da han til en konference havde

oplevet, at der stadig er mange der ikke kender til den. Sundhedsstyrelsen kunne oplyse om at den bliver en del af den Nationale Sundheds Portal, når den en gang er klar til at gå i luften, og at vi i den forbindelse vil erindre opfordringen – der er bestemt et udækket informationsbehov.

5. maj 2015

Reference Tina Sølberg

ANNIVERSARY PRESENTATION

2015

Lundbeck PROGRESS IN MIND

Agenda

- Lundbeck 100 år Jens Peter Balling (15 Min)
- Intro to PV at Lundbeck Gitte Frello (5 min)
- Post-marketing PV system Janne Kampmann 15 min
- Clinical trial safety Janne Kampmann (5 min)
- Risk Management system Jørgen Matz (20 min)
- QPPV Oversight Janne Kampmann (10 min)


IMAGINE HAVING
TO FIND THE ONE
DEFECTIVE LIGHT BULB
THAT'S WHAT WE LIKE TO DO. EVEN IF
IT TAKES US ANOTHER 100 YEARS.

Lundbeck’s 100th anniversary

Why we are here

The Starfish Story

MISSION, VISION AND VALUES

OUR VISION

is to become a world leader in psychiatry and neurology

OUR MISSION

is to improve the quality of life of people suffering from psychiatric and neurological disorders

OUR VALUES

Imaginative – Dare to be different
Passionate – Never give up
Responsible – Do the right thing

EXECUTIVE MANAGEMENT

HÅKAN BJÖRKLUND

Chairman with extended operational responsibilities

ANDERS GERSEL PEDERSEN

Executive Vice President, Research & Development

ANDERS GÖTZSCHE

Executive Vice President and CFO

Lundbeck today

We are a specialized pharmaceutical company engaged in discovering, developing and commercializing new and innovative treatments for brain diseases

1915	6,000	13.5bn	70%	2nd
founded by Hans Lundbeck in Denmark	employees worldwide	DKK core revenue in 2014 (EUR 1.8bn and USD 2.4bn)	owned by the Lundbeck Foundation	largest pharmaceutical company in Scandinavia and number 42 in the world

SPECIALIST IN BRAIN DISEASE

Lundbeck is a specialist in brain diseases based on leading expertise in neuroscience research

700 million people worldwide are living with brain diseases which cover a number of psychiatric and neurological diseases, including:

Psychiatry
Alcohol dependence
Anxiety
Bipolar disorder
Depression
Schizophrenia

Neurology
Alzheimer's disease
Epilepsy
Huntington's disease
Parkinson's disease
Symptomatic neurogenic orthostatic hypotension

HELPING PEOPLE LIKE RENÉ

Alcohol dependence
Alzheimer's disease
Depression
Epilepsy
Huntington's disease
Parkinson's disease
Psychoses

René, former alcohol dependent, Denmark

Prevalence
*In Europe, it is estimated that approximately **14 million** people are alcohol dependent.*

Alcohol dependence is a brain disease characterized by a pattern of excessive alcohol consumption that could potentially lead to physiological, psychological and social impairment. Excessive drinking is also associated with large costs to society due to accidents, violence, lost productivity and healthcare expenses.

HELPING PEOPLE LIKE RY

Alcohol dependence
Alzheimer's disease
Depression
Epilepsy
Huntington's disease
Parkinson's disease
Psychoses

Ry, Alzheimer's disease patient, Denmark

Prevalence
*There are **38 million** cases of Alzheimer's disease and other dementia worldwide at any given time.*

Alzheimer's disease is the most common form of dementia. Nerve cells in the brain are lost, causing a gradual functional deterioration of the brain. Symptoms in the mild stage are forgetfulness, changes in personality, and confusion. In the severest stage, patients gradually lose the ability to communicate, eat and drink.

HELPING PEOPLE LIKE REBECCA

Alcohol dependence
Alzheimer's disease
Depression
Epilepsy
Huntington's disease
Parkinson's disease
Psychoses

Rebecca, depression patient, Canada

Prevalence
*There are **350 million** cases of depression worldwide at any given time.*

Depression is a common and partly hereditary disease with symptoms such as melancholy, loss of energy, difficulty concentrating and suicidal thoughts. Depression can be effectively treated by different forms of therapy.

HELPING PEOPLE LIKE WENDY

Alcohol dependence
Alzheimer's disease
Depression
Epilepsy
Huntington's disease
Parkinson's disease
Psychoses

Wendy, epilepsy patient, US

Prevalence
*Around **50 million** people worldwide have epilepsy.*

Epilepsy is a chronic neurological disorder characterized by recurrent seizures that can vary from the briefest lapses of attention or muscle jerks to severe and prolonged convulsions.

HELPING PEOPLE LIKE MATT

Alcohol dependence
Alzheimer's disease
Depression
Epilepsy
Huntington's disease
Parkinson's disease
Psychoses

Matt, Huntington's disease patient, US

Prevalence
5 to 7 people per 100,000 *in Western countries have Huntington's disease.*

Huntington's disease is a hereditary neurodegenerative disease that results in uncontrolled movements, emotional disturbances and mental deterioration. The most visible symptom of Huntington's disease is chorea, which is characterized by involuntary, jerky movements.

HELPING PEOPLE LIKE COLLEEN

Alcohol dependence
Alzheimer's disease
Depression
Epilepsy
Huntington's disease
Parkinson's disease
Psychoses

Colleen, Parkinson's disease patient, Scotland

Prevalence
There are five million *cases of Parkinson's disease worldwide at any given time.*

Parkinson's disease is a chronic and progressive brain disease that usually affects people over the age of 60. Typical symptoms are tremors, stiffness, slow movements and impaired balance.

HELPING PEOPLE LIKE JAKOB

Alcohol dependence
Alzheimer's disease
Depression
Epilepsy
Huntington's disease
Parkinson's disease
Psychoses

Jakob, bipolar disorder patient, Denmark

Prevalence

*There are **26 million** cases of schizophrenia worldwide at any given time.*

*There are **30 million** cases of bipolar disorder worldwide at any given time.*

Schizophrenia is a chronic brain disorder characterized by a disruption of thought processes that can cause hallucinations and delusions.

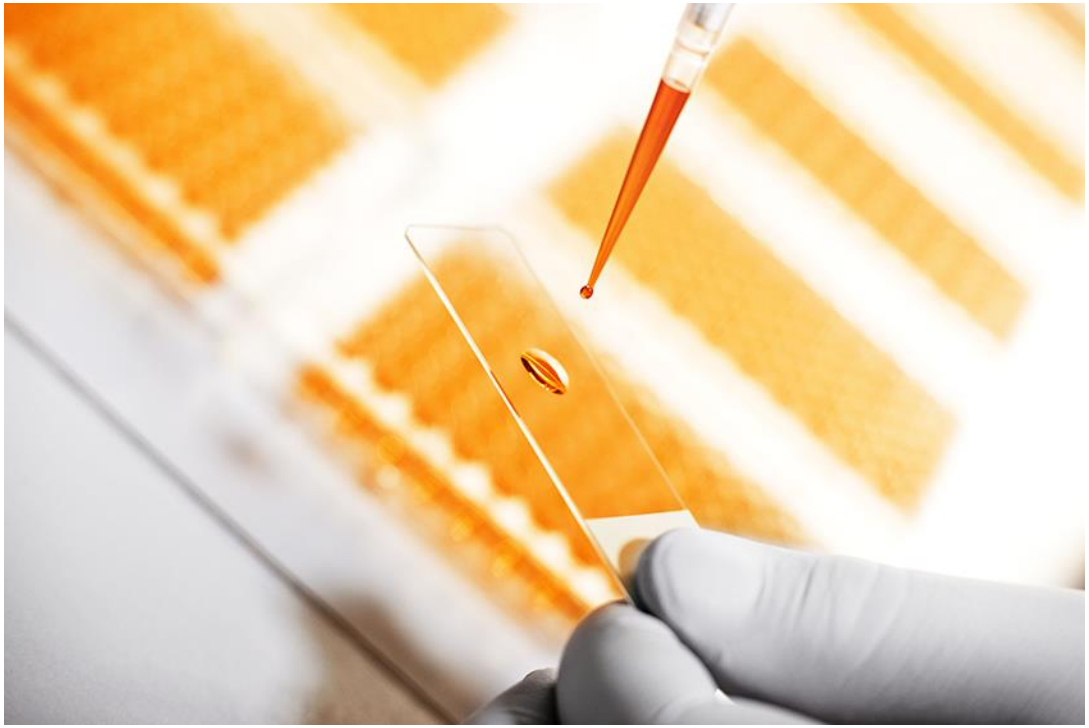
Bipolar disorder is another form of psychosis, where the mood of the patient is affected and can cycle between depression and mania.

DEVELOPMENT OF A NEW PHARMECEUTICAL PRODUCT

No. of molecules / No. of patients

ACTING RESPONSIBLY

Grants Education Environment



Supporting research
The Lundbeck Foundation is the largest shareholder of Lundbeck and owns 70% of the company. The Foundation provides grants for scientific research initiated in Denmark and of the highest international quality in order to make a significant difference to human health and life.

The Foundation annually grants around DKK 400-500 million to support research within medical and natural sciences.

ACTING RESPONSIBLY

Grants Education Environment

Educating doctors and healthcare professionals
At the Lundbeck Institute, healthcare professionals from all over the world are educated in the treatment of brain diseases. Activities are non-product related and all activities build upon objective and evidence-based knowledge.

*Since 1997, more than **100,000** healthcare professionals have benefited from Lundbeck's educational activities.*

ACTING RESPONSIBLY

Grants Education **Environment**

Taking care of employees and the environment

Lundbeck enforces high standards in environmental, health, safety and working conditions throughout the company.

Lundbeck's Code of Conduct is a guide for employees and third parties working on our behalf on how to comply with our business practices and ethical aspirations.

PROGRESS IN MIND

Improved treatment and a better life for people living with brain disease

More than **700 million people** are affected by brain disease worldwide – this is equal to 13% of the global disease burden.

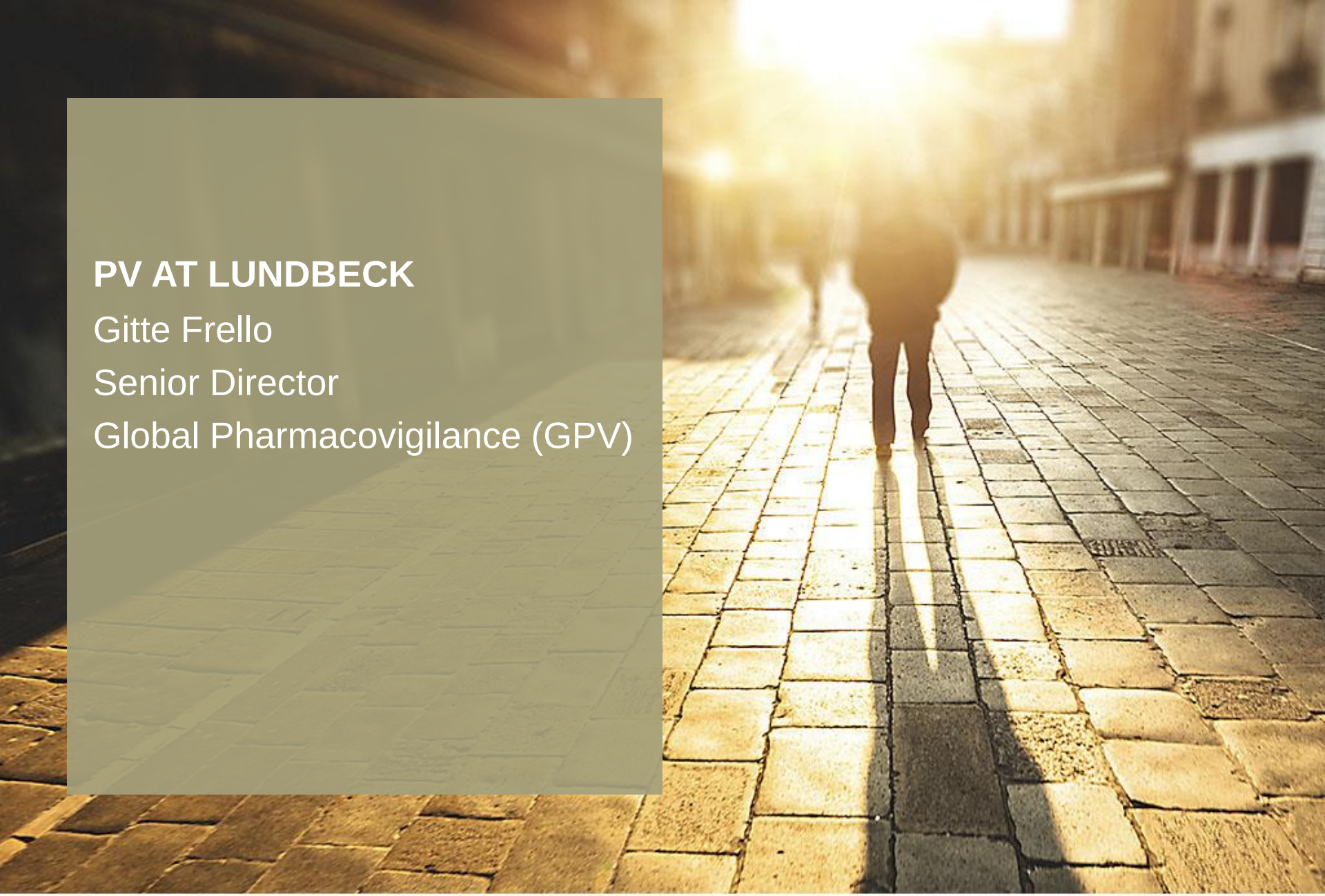
Lundbeck wants to **address brain disease as a global health problem** and calls for a broader global acceptance of the massive economic and societal burden that brain disease represents.

Progress in Mind is Lundbeck's dedication to addressing the global burden of brain disease. Every day, we strive for improved medical treatments and continuous focus on the unmet needs of patients.

Lundbeck

PROGRESS
IN MIND

Learn more on www.lundbeck.com/global/about-us/progress-in-mind



PV AT LUNDBECK

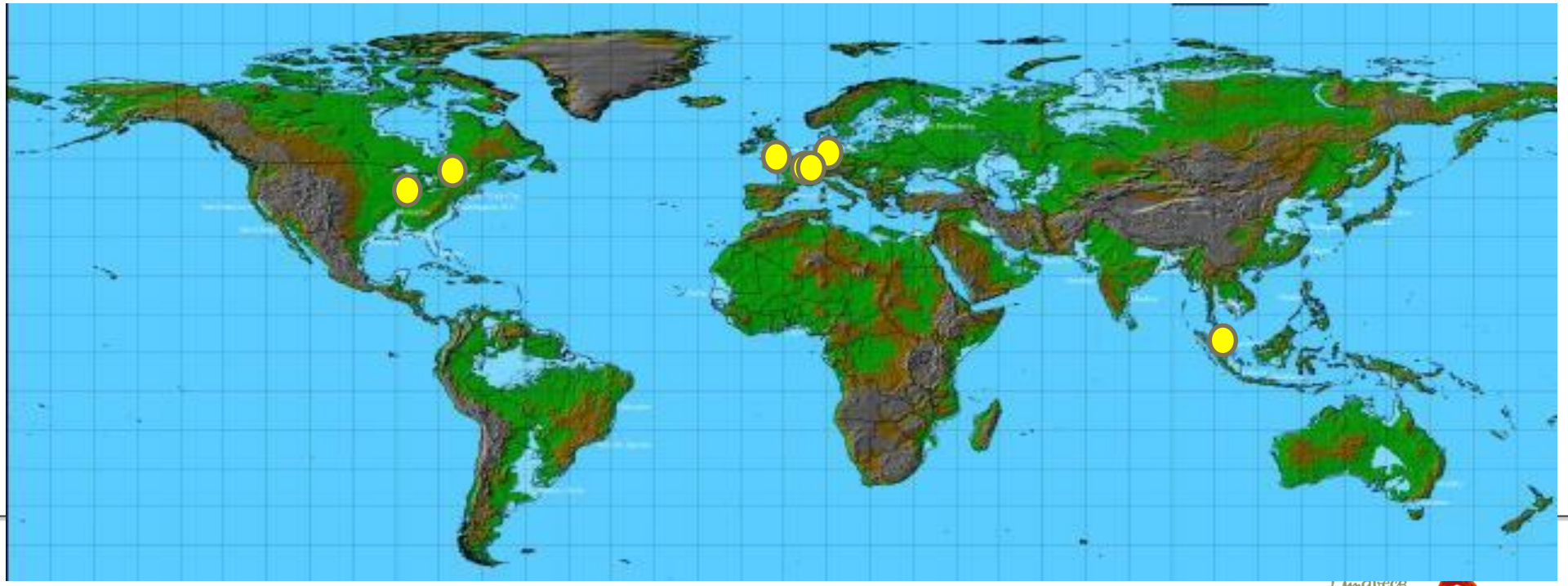
Gitte Frello

Senior Director

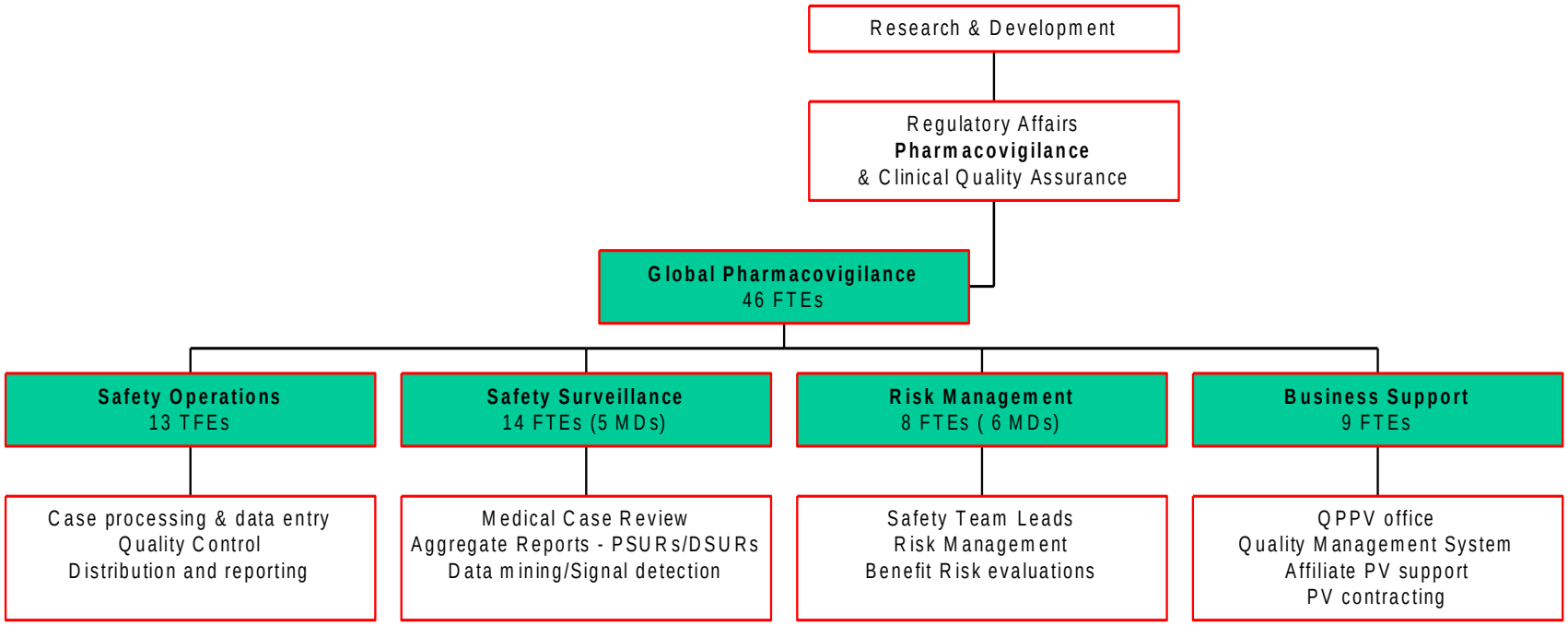
Global Pharmacovigilance (GPV)

Lundbeck Pharmacovigilance organization

- 57 Affiliates and 158 Partners worldwide
  - **22 marketed products in 120 markets**
  - **12000 Adverse Drug Reaction Reports, 1300-1500 complaints**
- 7 Pharmacovigilance centers - North America, Europe and Asia
- 180 staff working with PV globally
  - 47 in Copenhagen, 35 in other PV centers, 100 in affiliates



PV Organization Copenhagen



POST-MARKETING PV SYSTEM

Janne Malene Kampmann

Director & EU QPPV

GPV Safety Surveillance

Post marketing PV system

- ADR Reporting from all sources worldwide (Healthcare professionals, patients, websites (Lu), competent authorities, partners, post-authorisation studies, registries, named patient use)

- Literature surveillance (weekly and monthly)
- Data mining activities (safety database and WHO database)
- Aggregate Reports (PSURS/PBRERs)

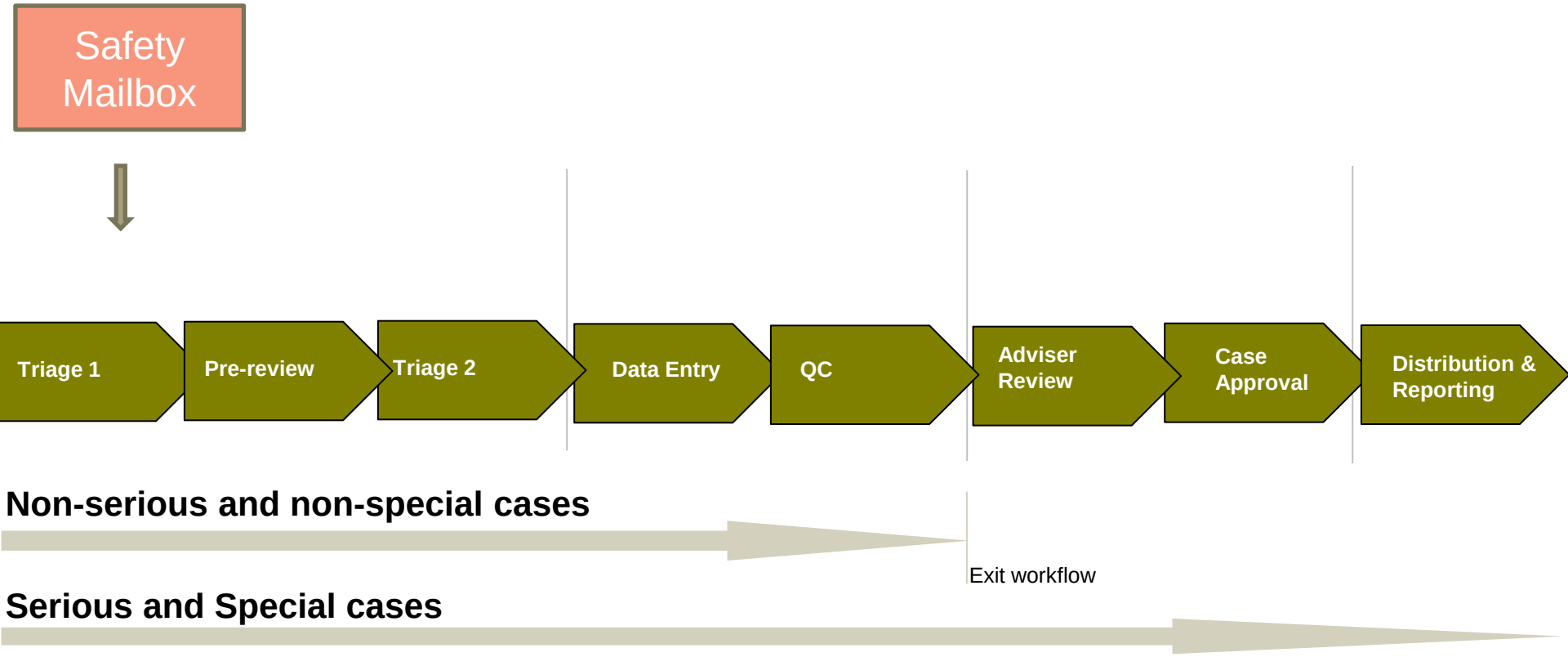
PMS Case handling

- 15 days reporting timeline for serious and 30 days for non-serious ADRs

Incl. Special cases

- Pregnancy and breastfeeding
- Lack of efficacy
- Overdose
- Abuse & misuse
- Off label use
- Medication errors
- Interactions
- Occupational exposure

Case handling Workflow steps



Aggregated reports

Aggregated reports

- Marketed Products
  - Periodic Safety Update Reports (PSURs)
  - Periodic Benefit Risk Evaluation Reports (PBRERs)
  - Frequency - ½ year for first two years then yearly until renewal before 5 years
- Risk Management Plans (RMPs)
  - New registration and onwards

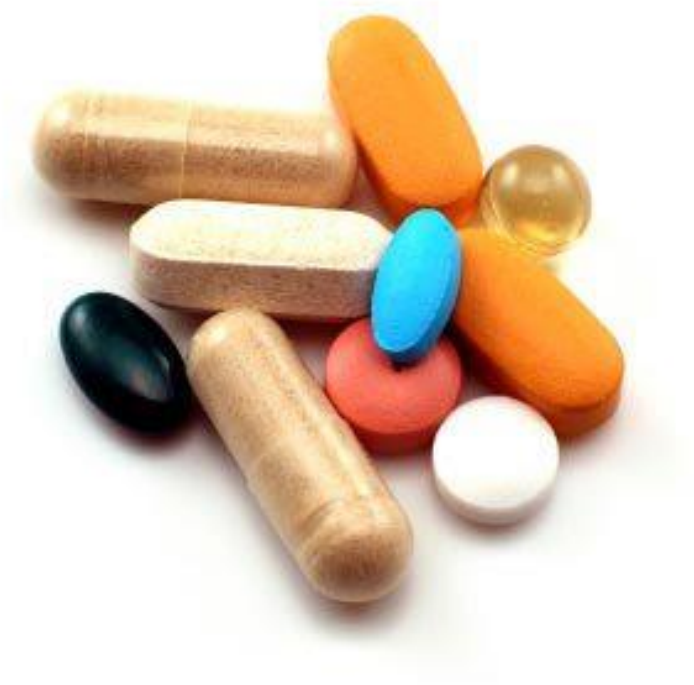
PSUR/PBRER oversight

Produced by	Drug	Country	DLP	Distribution Date to RA	Submission date to CA (DLP + as defined by legislation e.g. 60/70/90)	Period covered (DD-MMM-YYYY to DD-MMM-YYYY)	Frequens	Submitted by (if applicable)
GPV	**Amitriptyline**	EU/EEA	10-jan-15	3-Apr-15	10-Apr-15	11-Jan-2012 to 10-Jan-201	3 yearly	Lundbeck
BMS/Otsuka	**Aripiprazole**	Australia	16-jul-15	7-Sep-15	4-Oct-15	17-Jul-201	1 yearly	Otsuka/Lundbeck
BMS/Otsuka	**Aripiprazole**	EU/EEA	16-jul-15	7-Sep-15	24-Sep-15		yearly	Otsuka/Lundbeck
Merck	**Asenapine**	EU/EEA	12-aug-15	14-Oct-2015	21-Oct-2015		yearly	Merck
LU-DE	**Budipine**	Germany	01-jan-15	25-Mar-15	1-Apr-15		early	Lundbeck Germany
GPV	**Citalopram**	Canada	31-dec-15	23-Mar-16			arly	Lundbeck
GPV-US	**Droxidopa**	US	17-Feb-15					US RA
GPV-US	**Droxidopa**	US	17-Aug-15					US RA
GPV-US	**Droxidopa**	US	17-Nov-15					US RA
GPV	**Escitalopram**	Canada	31-d				y	Lundbeck
GPV	**Flupentixol**	Canada						Lundbeck
Merz	**Memantine**	~~Malaysia~~					1 yearly	
GPV	**Nalmefene**	Is					6 Month	Lundbeck
GPV	**Nalmefene**					Feb-2015	1 yearly	Lundbeck
GPV	Nal					eb-2015 to 24-Aug-2015	6 Month	Lundbeck
Teva						03-Jan-2014 to 02-Jan-2015	1 yearly	Lundbeck
GPV						12-Jul-2014 to 11-Jan-2015	6 Month	Lundbeck
GPV					Sep-15	12-Jan-2015 to 11-Jul-2015	6 Month	Lundbeck
GPV					7-Jun-15	30-Sep-2014 to 29-Mar-2015	6 Month	Lundbeck
GPV					18-Oct-15	30-Sep-2014 to 29-Mar-2015	6 Month	Lundbeck
GPV				1-Dec-15	8-Dec-15	30-Mar-2015 to 29-Sep-2015	1 yearly	Lundbeck
GPV				1-Dec-15	8-Dec-15	30-Mar-2015 to 29-Sep-2015	6 Month	Lundbeck
GPV			29-sep-15	1-Dec-15	18-Apr-16	30-Mar-2015 to 29-Sep-2015	6 Month	Lundbeck
GPV	Z		31-maj-15	2-Aug-15	9-Aug-15	01-Jun-2014 to 31-May-2015	1 yearly	Lundbeck
GPV-US			20-Apr-15	24-Jun-15	29-Jun-15	21-Oct-14 to 20-Apr-15	6 Month	US RA
GPV-US		US	20-Oct-15	24-Dec-15	29-Dec-15	21-Apr-15 to 20-Oct-2015	6 Month	US RA

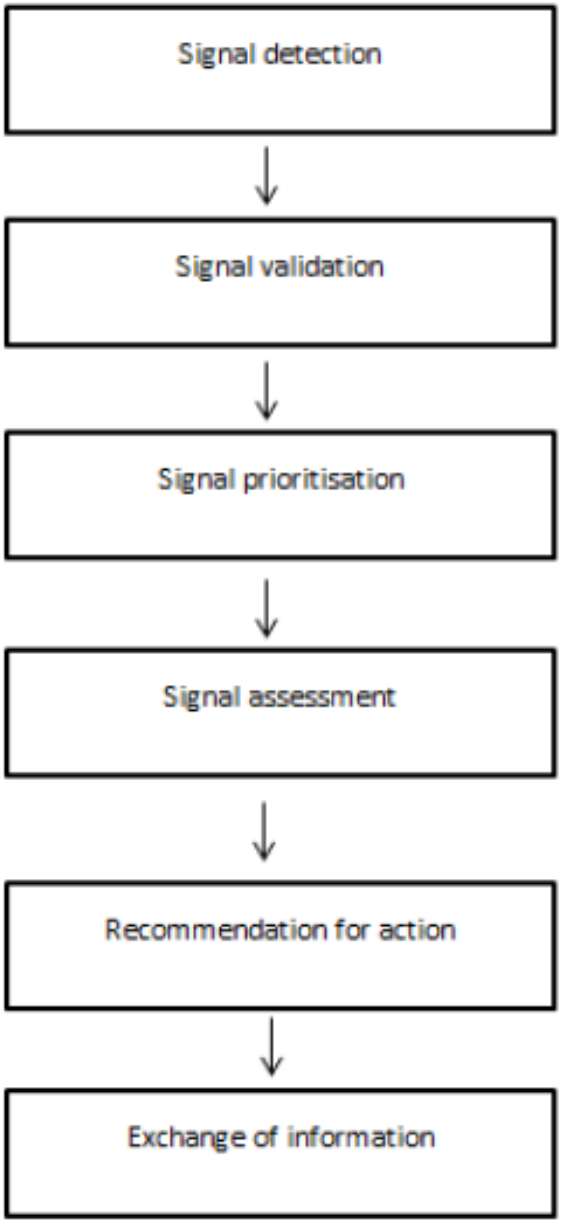
EXAMPLE

Surveillance

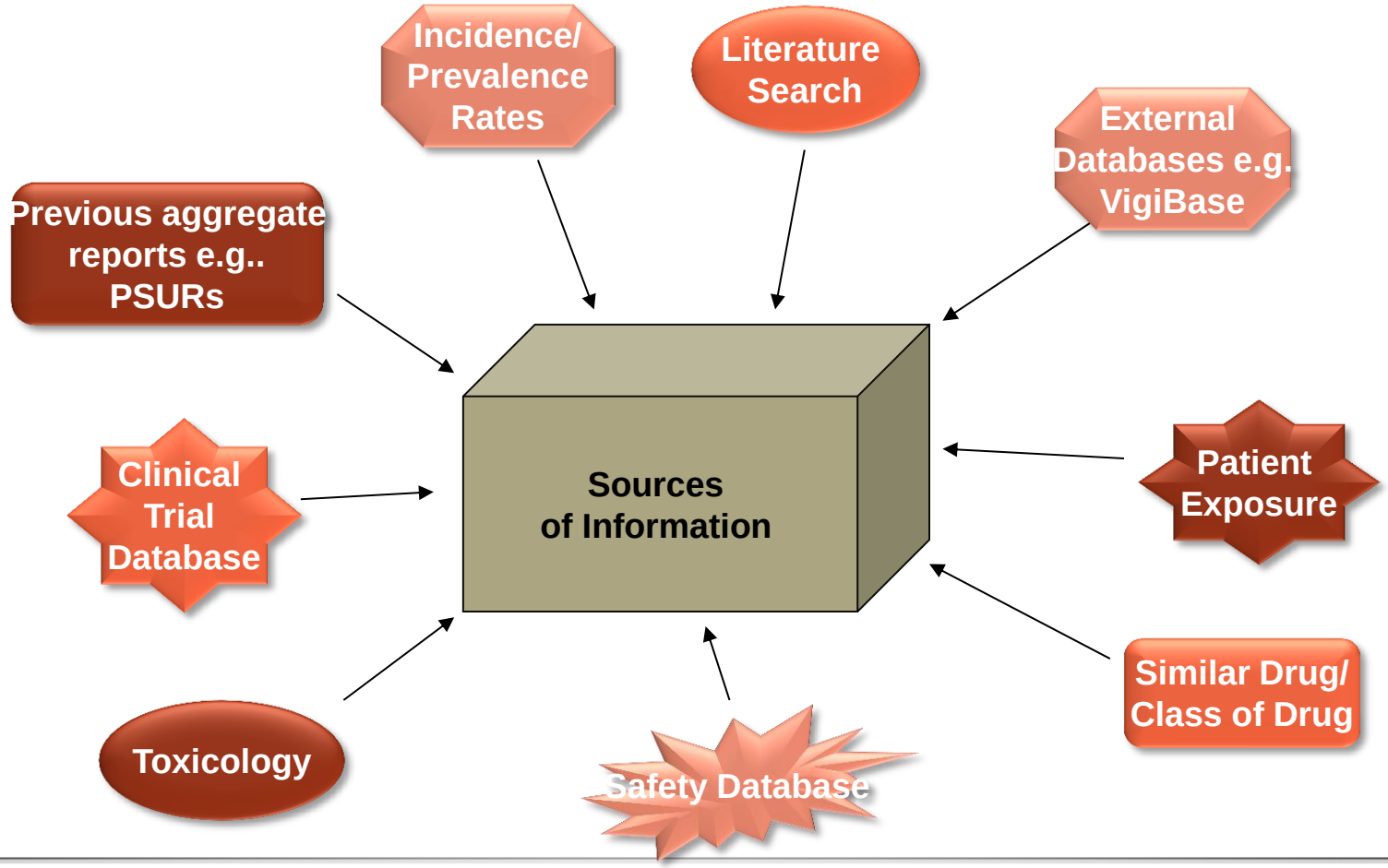
- Literature
  - Weekly and Monthly world wide literature surveillance for articles with active ingredients for Lundbeck products and class effects
- Data Mining/Signal detection
  - Signal detection on Lundbeck Safety database by using an algorithm and external using WHO database



General
Signal management



Assessment of safety signals



Authority requests

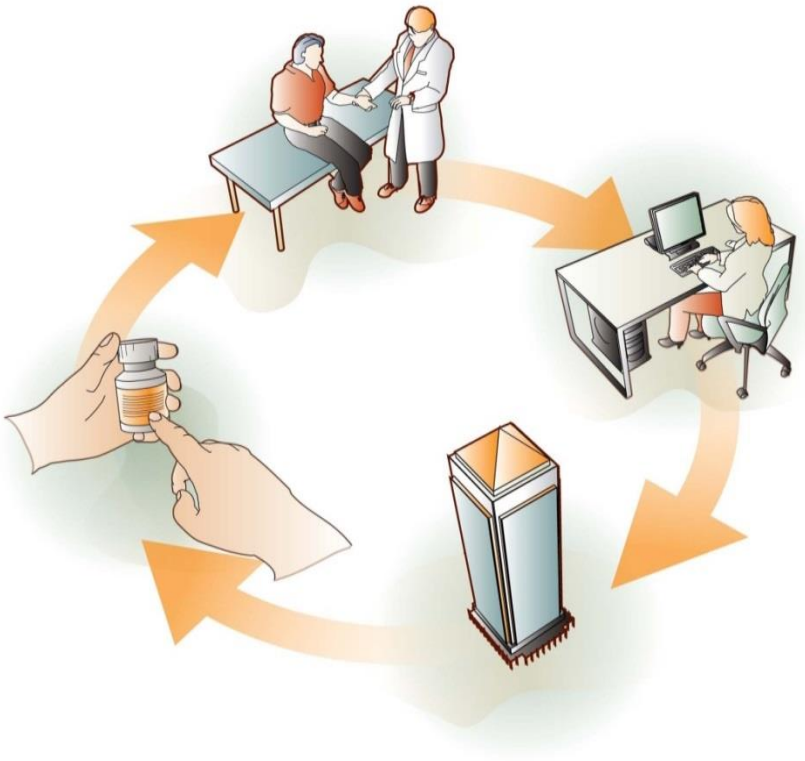
Examples

- Pharmacovigilance Risk Assessment Committee (PRAC) EMA – EU
  - Antipsychotics and acute renal impairment in elderly
  - Memantine (alzheimer) and risk of prostate cancer

CLINICAL TRIAL SAFETY

Janne Malene Kampmann
Director & EU QPPV
GPV Safety Surveillance

Clinical Trial Safety



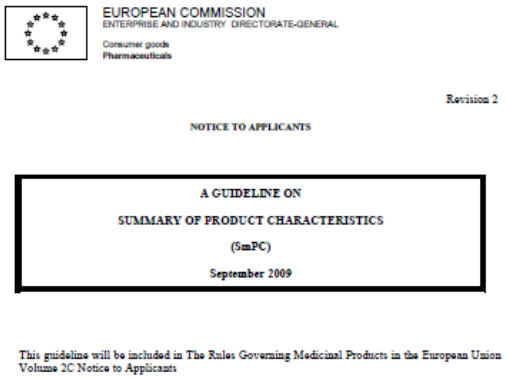
Understanding and preventing adverse events by:

- Monitoring and reporting the use of the drug
- Detecting and assessing any adverse effects
- Assessing frequency, risk, factors, levels of risk
- Assessing risk versus benefit
- Update of Safety Information

Reference documents for safety information

Marketed products

- Summary of Product Characteristics



EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
Consumer goods
Pharmaceuticals

Revision 2

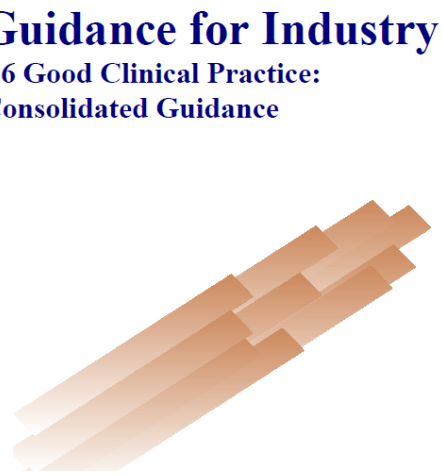
NOTICE TO APPLICANTS

A GUIDELINE ON
SUMMARY OF PRODUCT CHARACTERISTICS
(SmPC)
September 2009

This guideline will be included in The Rules Governing Medicinal Products in the European Union Volume 2C Notice to Applicants

Development projects

- Investigators Brochure
  - ICH E6



Guidance for Industry
E6 Good Clinical Practice:
Consolidated Guidance

Pharmacovigilance in Clinical Trials

Patient/
investigator

AEs

Aggregate
Reports
(DSUR)

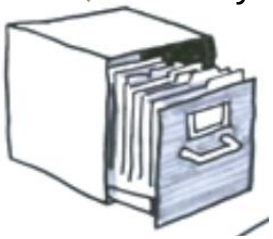
Annually

External Data Monitoring Committees

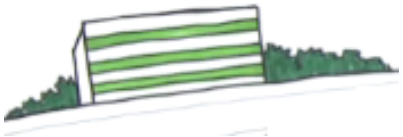
Medical Monitoring & Safety Review

Coding (Adverse events, Medical History and concomittant medication)

Safety database



SUSARs- 7 and 14 days reporting timelines



Health authority

RISK MANAGEMENT SYSTEM

Jørgen Matz
Senior Director
GPV Risk Management

Lundbeck products and projects

- Authorised Products
  - *E.g.* Cipralex®, Selincro®, Brintellix®, Ebixa®, Azilect®, Noritren®, Saroten®

- Development Projects
  - *E.g.* Brexpiprazole, Idalopirdine, IV carbamazepine

Therapeutic safety teams in pharmacovigilance

- Safety Teams organised by products and projects
- Currently 7 product teams and 6 development teams

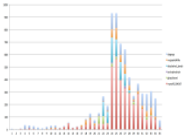
Tasks in therapeutic safety teams

Cases

Reports

Listings

Requests



Activity logs

Litterature

Inputs

outputs

Safety Team

- GPV Risk management
- GPV Safety surveillance
- GPV Safety operations

Memo for QPPV
Evaluate new significant cases
Evaluate signals
Make litterature review
Make aggregated reports
Maintain risk management plans
Surveillance of study activity
Surveillance of post-authorisation commitments
Response to authority requests
Prepare for safety committee meetings

Governance of Benefit-Risk

Safety Team

- GPV

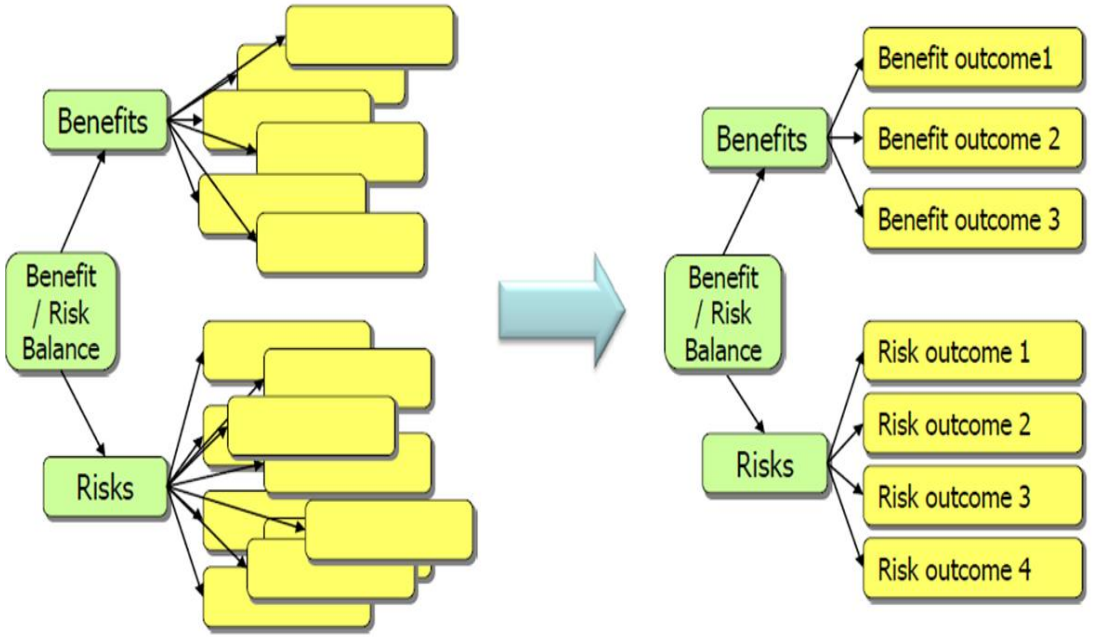
Safety Committee

- GPV (chair)
- Medical expert
- Clinical pharmacology
- Regulatory affairs
- Medical affairs
- Marketing
- Epidemiology
- Toxicology
- Biometrics

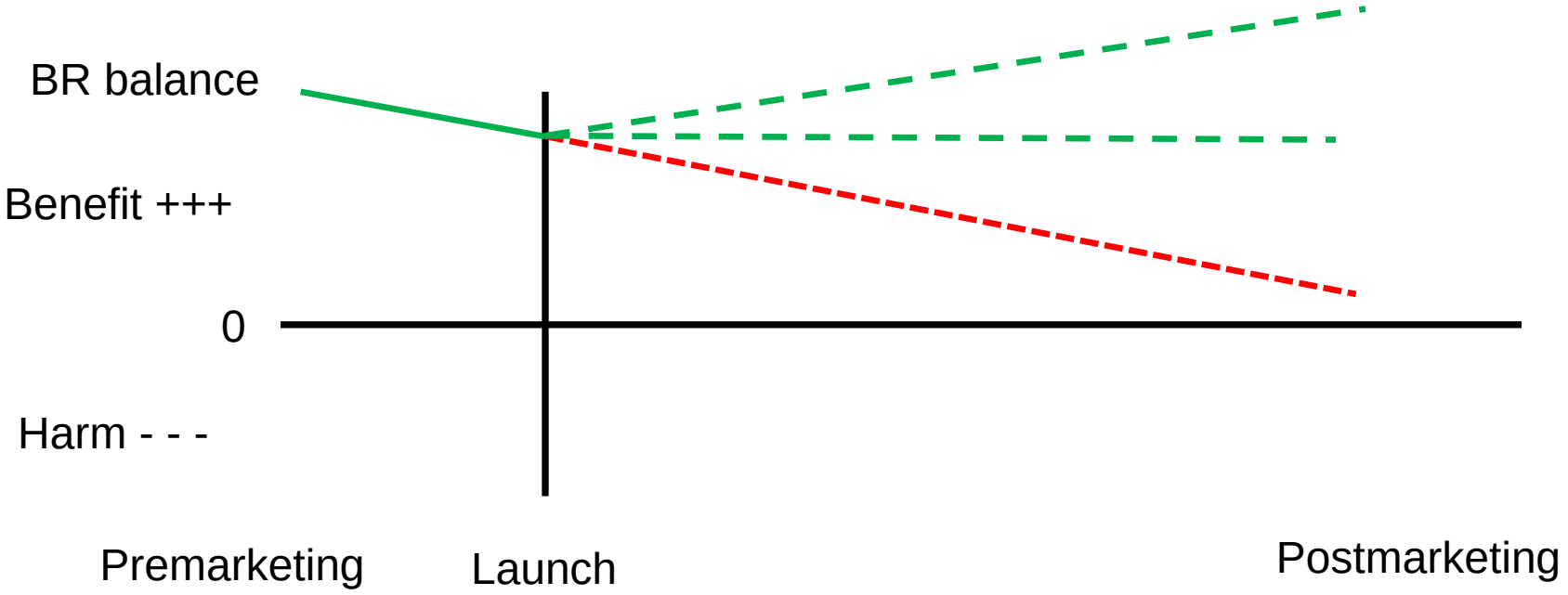
Safety Board

- GPV (chair)
- Executive Vice President R&D
- Vice Presidents of Business Units
- Medical Experts
- QPPV

Benefit-Risk Balance



Assessing the Benefit-Risk Profile



- Benefits and risks do not stay constant after marketing authorisation
- Mitigation: A risk management plan (RMP) is implemented after marketing approval

Source: Bridging the efficacy-effectiveness gap: a regulator's perspective on addressing variability of drug response. *Eichler HG et al.* Nat Rev Drug Discov. 2011 Jul 1;10(7):495-506

Why Risk Management is Important

- Rare adverse events may not be detected in pre-licensure studies
- Clinical trials have limitations. For example, to detect a doubling in an adverse event that occurs at a rate of 1/1000 would require a sample size of 50,000 (two-arm, power=80%, alpha=5%)
- The post-marketing surveillance activities. ***A different benefit-risk profile may emerge as pharmacovigilance reveals further information about safety***

The Risk Management Plan

~200-400 pages + appendices

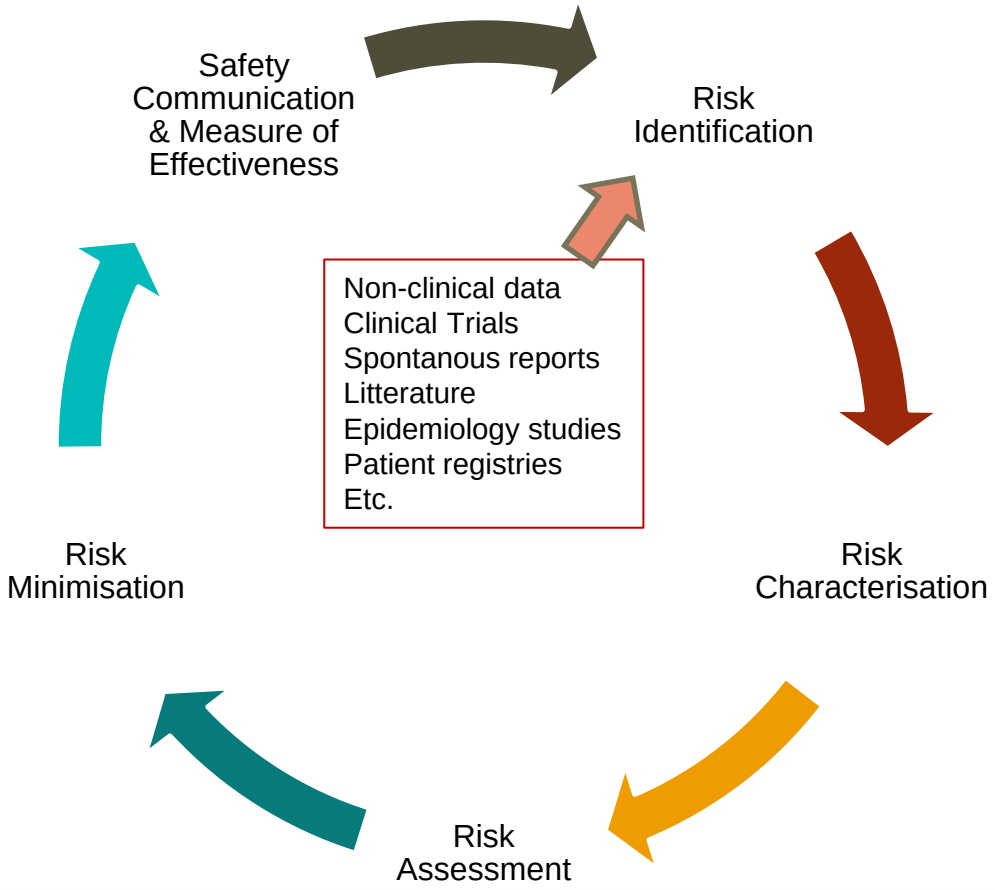
- Product specification
  - Identified risks
  - Potential risks
  - Missing information
- Epidemiology of target population
- Clinical trial exposure
- Populations not studied
- Post-marketing pharmacovigilance activities
  - PAS studies
- Risk minimisation activities
- Public summary

Post-Authorisation Safety Studies (PASS)

- PAS studies are additional pharmacovigilance activites aimed to further characterise the use and the risk og the medicinal producs
  - ***Drug-utilisation studies***
  - ***Retrospective database register studies***
  - ***Case-control studies***
  - ***Cohort studies***
  - ***Open-label or blinded randomised clinical trials (interventional studies)***
- Objectives of a PASS is often:
  - Assesment of risk in a real-life situation
  - Estimation of incidence/prevalence/odds ratio of a specific risk
  - Broader characterisation of risk in a sub-population

Risk Management Wheel

- Pharmacovigilance continuously performs risk assessments:



QPPV OVERSIGHT

Janne Malene Kampmann

Director & EU QPPV

GPV Safety Surveillance

Qualified Person for Pharmacovigilance (QPPV)

- Establish & maintain/manage the Marketing Authorisation Holders pharmacovigilance system.
- Have an overview of the safety profiles and any emerging safety concerns related to medicinal products, for which the MAH holds the authorisation.
- Act as a single contact point for the Competent Authorities on a 24 hour basis

"It is recognised that the important role of the QPPV may impose extensive tasks…..may therefore delegate …."

QPPV Oversight

In terms of structure and performance

- Quality Control / Quality Assurance procedures
- SOPs
- Database operations
- Contractual arrangements
- Compliance data (quality, completeness, timeliness)
- Audit & inspection reports
- Training of personnel

QPPV oversight

In terms of what is going on …globally

- Products marketed in Europe
- Licensing agreements in place
- What is happening with the system
- Compliance of the system
- Signals being identified and evaluated
- Post Authorisation Safety Studies (PASS) being conducted
- Safety questions being asked by the regulatory authorities (globally)
- Risk Management Plans in place
- Audit & Inspections

QPPV office

- Keeping track of compliance with
  - Submission of individual cases (ICSRs) to Authorities & Partners
  - Submission of aggregated reports (PSURs, PBRERs, DSURs)
  - Literature surveillance
  - Signal detection

- Actions from audits and inspections

- Pharmacovigilance System Master File (PSMF)

- QPPV overview → Monthly Report