



Patients and HCPs involvement in regulatory decisions

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Joint PCWP/HCPWP meeting

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Scope of the presentation

- **HCP involvement**
 - The national scientific committee
 - Treatment guidelines
- **Patient/consumer involvement**
 - Patient- and consumer committee
 - The Narcolepsy example
 - In registries
- **Challenges and future plans**

HCPs within the MPA

But first – in house competence – MPA assessors

- **Approximately 45 medical doctors, covering most specialities and 75 pharmacists**

The national scientific committee

- **gives feedback from healthcare – perspective valuable for increased quality at MPA**
- **is a channel for information to Swedish healthcare**
- **contributes with scientific input into MPA decisions and recommendations**
 - regular meetings – ad hoc individual consultation
- **is important for increased national visibility**
- **members ambassadors for the MPA**

Challenges and future plans

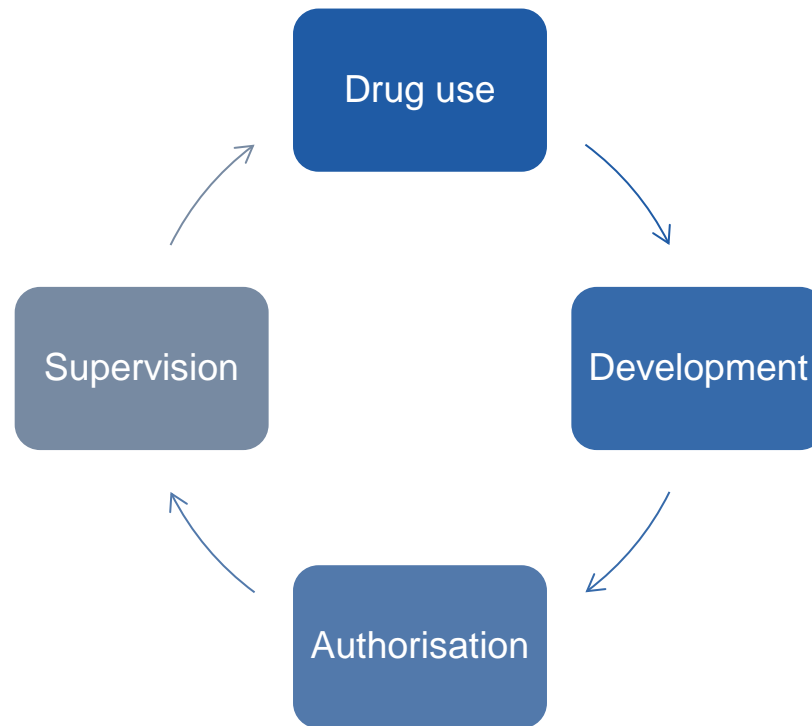
- **conflicts of interests**
 - SE is a small country, in some areas few experts
- **many and short deadlines in the EU system**
- **change from "communication" to "involvement"**

Workshops

Treatment guidelines

- **First workshop for treatment guideline in 1981**
- **1993-2004 in cooperation with Norway**
- **Guidelines for human medicinal products ~ 6/year.
veterinarian ~ 1/year**
- **Choice of topic:**
 - Input from County councils Drug Advisory Committees, Specialist organisations, MPA
 - Consideration: new important drugs, new knowledge, e.g pharmacovigilance, prevalence of illness
- **Cooperation with other health authorities, (e.g The Swedish Council on Health Technology Assessment and National board of Health and Welfare)**

Treatment guidelines



Treatment guideline - workshop procedure

Preparatory work at MPA

- Experts – selection and invitation
- Manuscripts
- Communication plan

Expert meeting

- Presentation of the manuscripts and current state of knowledge
- Discussion - teamwork – consensus

After work at MPA

- Compiling recommendation, e-mail correspondence with expert group
- Check and quality assurance

Publication

- "Information from Läkemedelsverket" – the MPA bulletin
- Web site publication
- Other channels

Expert meetings/ treatment guidelines during 2014

- Acne
- Hepatitis C
- Asthma/COPD
- Sexually transmitted diseases

and within a national strategy to increase knowledge on medicines and their use in children

- Insomnia
- Treatment and prevention of thrombosis

Patient/consumer committee

- **First committee meeting in 2009**
- **Aim – two way communication, information and transparency**
- **4 meetings/year**

Patient/consumer committee

Challenge in 2012 – decreasing number of attendants at the meetings lead to a survey

Reasons expressed:

- **One way communication**
- **The agenda not interesting enough**
- **Long journey to meetings**
- **Members own illness**

Future plans – Invitation to dialogue – How can we do better? meeting plans in progress for early fall 2014

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Patient/consumer involvement

The Narcolepsy example

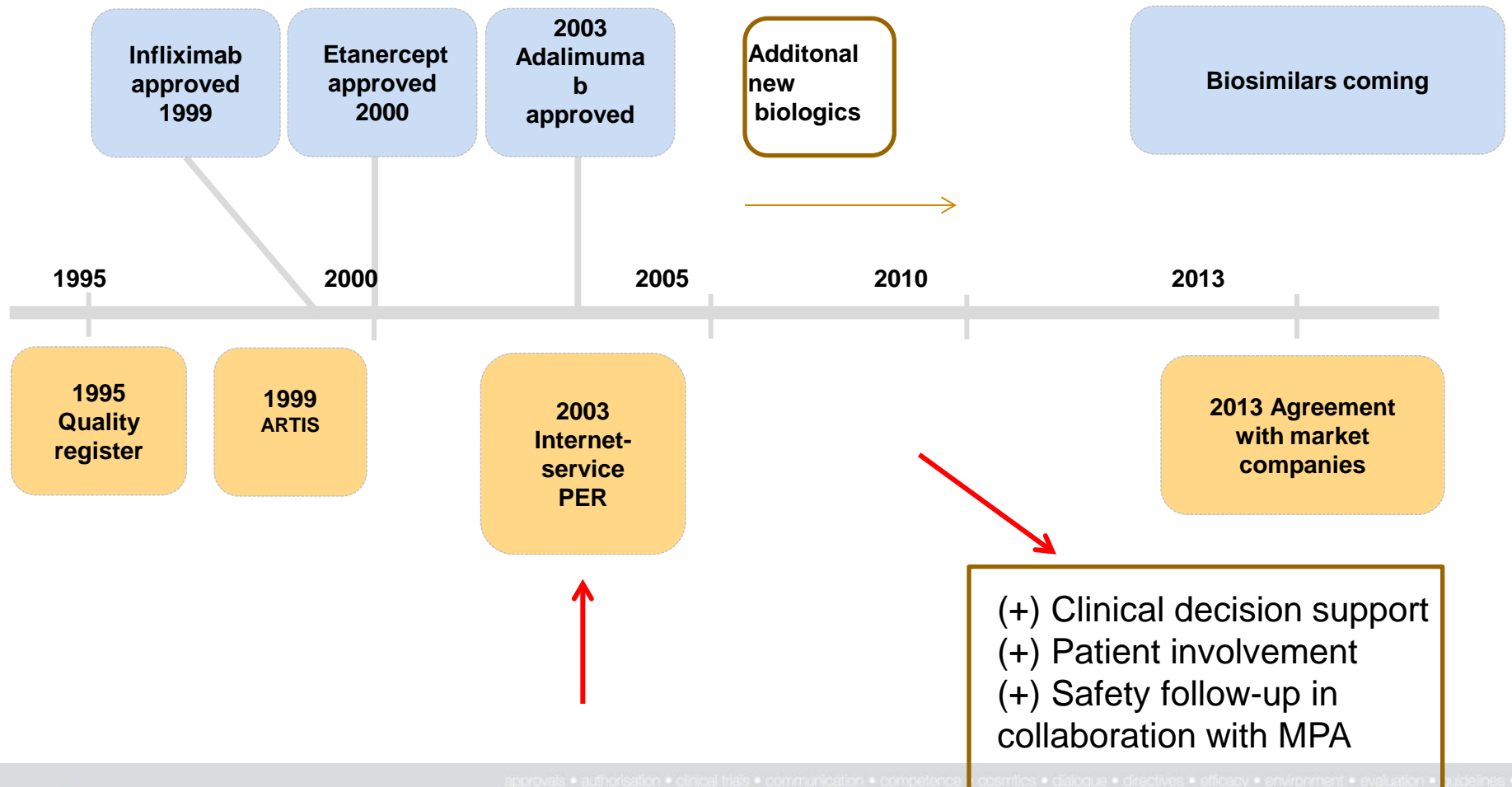
Intense and mutually rewarding interaction from 2010 and onwards

Parents association – narcolepsy in relation to vaccination with Pandemrix

- involvement in communication and research activities**
- several F2F-meetings**

Patient organisation – patient representative participated in the expert group which developed treatment guideline for narcolepsy in 2013

The Swedish Rheumatology Quality and Biologics Register – 1995 and onwards



Quality registries and patient involvement *"Nothing about us without us"*



- Patient reported outcomes (PROs) and side effects directly into registries
- Patients actively participating in decision-making
- Well-informed by use of internet
- Patient organisations influencing the research agenda

RA-register – clinical data

Patient			Nytt besök Översikt Skriv ut översikt Visa graf Felrapport Min Sida									
Personnummer			År	2008	2008	2008	2008	2008	2008	2008	2008	2008
Namn			Dag Månad	28-Jan	28-Mar	24-Apr	26-May	27-May	03-Jul	22-Aug	12-Nov	03-Dec
PAL			Håkan Eriksson									
PAS												
Tillhörighet			Solna									
TA-patient			Nej									
Diagnos			ICD 10									
RA Seropos			M05.9									
Sjukdomsdebut			2006-01-11									
Patientdata			Årskontroll	2008	2008	2008	2008	2008	2008	2008	2008	2008
Tidigare medicinering			Månads-Kontroll	1	3	4	5	5	6	8	11	11
Kriterier			MK-grupp		3	3	6	6	6	9	12	12
HAQ - Funktionsnedsättning			Arbetsförmåga	20/	20/	20/	20/	120/	120/	120/	120/	40/40
EQ-5D			Smärta	50	56	46	3	8			34	40
Arbetsförmåga			Sjukdomskänsla	50	73	78	5	8	100	8	78	49
Gångtid (TWT)			SR	50	34	21	24	56	10	7	12	55
Timed Stand Test (TST)			CRP	50	62	16	32	32	10	6	34	65
Grippit			Läkarbedömning	Måttlig	Hög	Låg		Måttlig			Ingen	
Uppföljda läkemedel			EQ5D								-0.513	1
Biverkningar			RA									
Komorbiditet			Funktionsneds. - HAQ	1	1,13	1,63	2,5	1,88	0,88	0,13	2,63	2
Händelseboken			Svullna leder (28)	5	9	5	2	7		28	3	0
			Ömma leder (28)	5	7	6	3	7		28	12	0
			TIRA									
			Trombocyter			99	34	12				
			DAS28	5.32	5.81	5.22	3.66	5.15		5.92	5.26	3.49
			DAS28CRP	4.95	5.8	5.07	3.65	4.55		6.22	5.76	3.15
			NSAID		COX2		COX2				COX1	COX1
			KORT		PRE		PRE				PRE	PRE
			KORT dos		5/1d		5/1d				45/1d	45/1d
			DMARD 1		MTX		MTX				MTX	MTX
			DMARD 1 dos		20/1v		20/7d				15/1d	15/1d
			DMARD 2									
			DMARD 2 dos									
			DMARD 3									
			DMARD 3 dos									
			DMARD 4									
			DMARD 4 dos									
			Uppföljd månad		0	0	1	0	1	2	5	6
			Uppföljt läkemedel		ENB	ENB	ENB	REM	REM	REM	REM	REM
			Läkemedelsdos		50/1v	50/1v	50/1v	200mg/1·	200mg/1·	200mg/1·	200mg/1·	200mg/14d
			III									
			« Första besöket »									
			Senaste besöket »									