EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

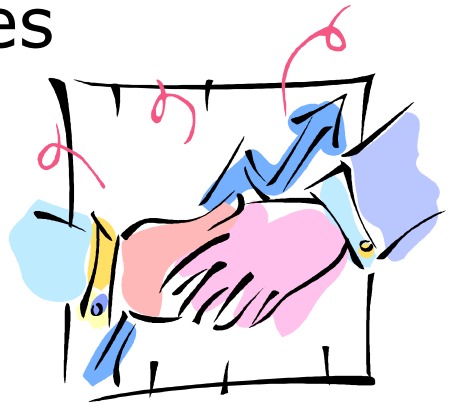
Report to the European Commission – Article 50

Benefits and Infringements

Presented by: Agnes Saint Raymond, Human Medicines Special Areas
Human Medicines Development and Evaluation Unit

Sources of information

- Thanks to Member States
- Thanks to National Patent Offices
- Thanks to Nathalie Seigneuret



Article 50(1)

"On the basis of a report from the Agency, and at least on an annual basis, the Commission shall make public a list of the companies and of the products that have benefited from any of the rewards and incentives in this Regulation and the companies that have failed to comply with any of the obligations in this Regulation. The Member States shall provide this information to the Agency."

Information received

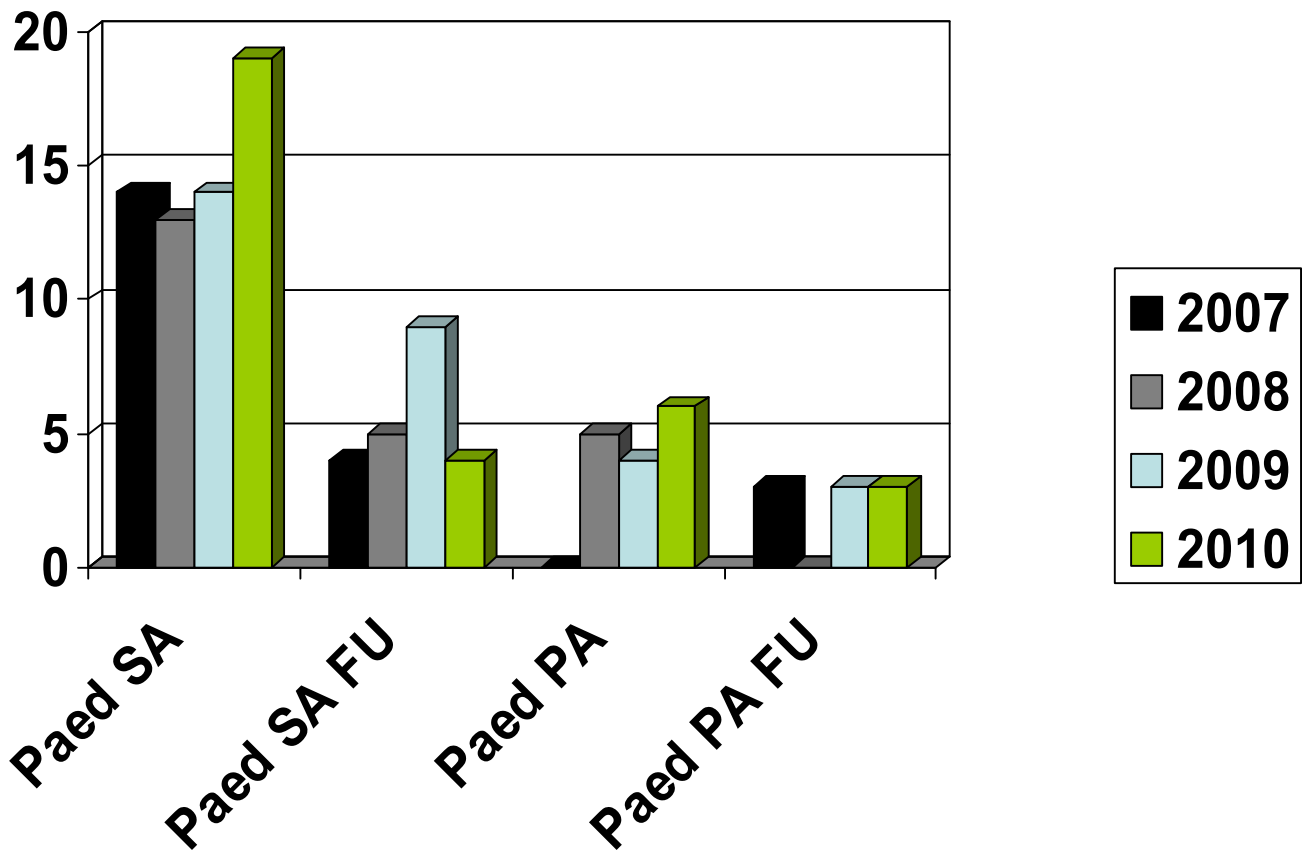
- 19 Member States (plus 1 after report was finalised)
- EEA-EFTA not included as Regulation not included (yet) in the Protocol, but expected in 2011
- 26 National Patent Offices
- Staff from EMA (PTLs, paediatric section, regulatory affairs)

Benefits

- **Scientific Advice**
- **PIPs and Waivers**
- **Compliance statements**
- **SPC extension**
- Marketing Authorisation and SmPC
- Price-Reimbursement benefits
- **Research incentives**
- Paediatric clinical trials
- Marketing authorisation procedures
- Articles 45-46

Scientific Advice (paediatric only)

	SA +PA	Paed %
2007	281	*7.5*
2008	320	*7.2*
2009	388	*7.7*
2010	400	*8*



Scientific advice (paediatric with adult)

	SA	SA FU	PA	PA FU
2009	16	8	8	3
2010	25	6	12	5

PIPs and Waivers in 2010

327 validated applications

- 86% of article 7 applications (n=280)
- 13% of article 8 applications (n=43)
- 1% of article 30 (PUMA, n=4)

10 pre-submission T-conferences

18 applicants (5.5%) were SMEs

115 applications for allergens (new German law)

PIPs and Waivers in 2010

Positive outcome in 84% of cases

260 opinions (253 positive on PIP or Waivers)

Condition Waiver list increased and reviewed

Modifications increasing (110 applications, 103 positive)

Submission of PIP/Waiver applications

Based on Date of 'completion of adult PK studies' by applicant

132 applications with a date (n=280 article 7)

91/132 (69%) later than the date (65/88 PIP, 26/44 W)

Median 19 months (22 for PIPs) range: 0-161 mo

Justifications (if provided) not assessed in 2010

Publication of company names if Decision and delay>6 months (29 applications) in 2010

Compliance statements in 2010

9 compliance opinions by PDCO

2 compliance statements for centrally-approved products

4 compliance statements for article 29 procedures

SPC extension granted in 2010 (*pending)*

- Cancidas (caspofungin) in 6+*7* MS (7 in 2009)
- Cozaar (losartan) in 1+*1* MS (10 in 2009)
- Arimidex (anastrozole) in 12+*1* MS
- Diovan (valsartan) in 10+*3* MS
- Orencia (abatacept) in 7+*5* MS
- Zometa (zoledronic acid) in 11+*7* MS
- Sortis (atorvastatin) in 0+*2* MS
- Xalatan (latanoprost) in 0+*3* MS

SPC extension and other Rewards

Maximum of 13 MS in which SPC extension granted

Extensions pending

In some MS, no SPC or SPC refused

No orphan extension so far

No data exclusivity for PUMA so far

EU Framework Programme 7 funding

3 projects funded

- HIP trial in neonates: dopamine and adrenaline in hypotension (5.6 m€)
- DEEP: PK and PD of deferiprone in children 2-10 years (5.2 m€)
- TINN2: PK and PD of azithromycin for *Ureaplasma* in BronchoPulmonary Dysplasia in neonates (5 m€)

Conclusions

- Reporting by both EMA and Member States needs to be organised (to become less resource intensive) and exhaustive
- Impact of Regulation (information, research and availability of medicines) is showing
- Late submission of PIPs and Waivers
- SPC difficult to obtain when requirements are in place
- More SmPC changes needed after art 45-46 submissions
- Benefits for children