



ÚSTREDNÝ KONTROLNÝ
A SKÚŠOBNÝ ÚSTAV POĽNOHOSPODÁRSKY
V BRATISLAVE

Regulation 1107/2009

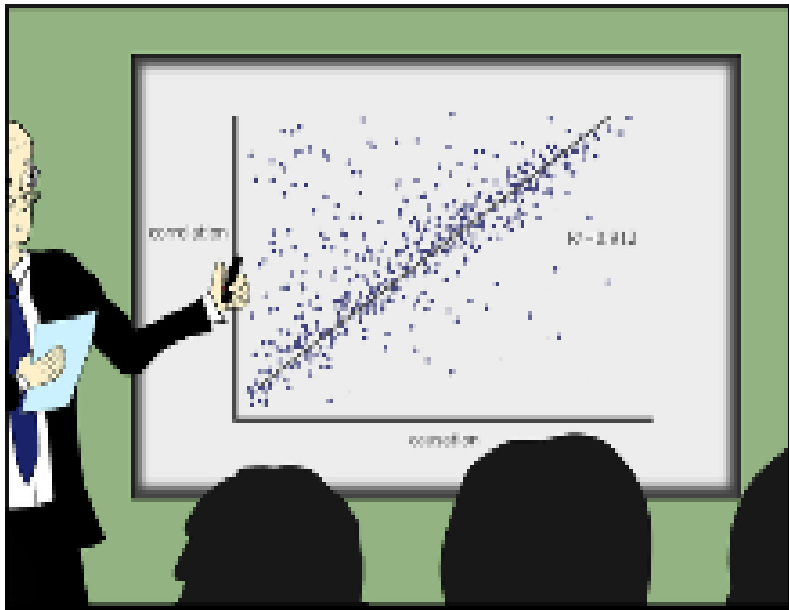
Current issues and challenges

Peter Kiklica, Mgr.
24.10.2017
CEUREG – Country
presentation



Regulation 1107/2009 in Slovakia

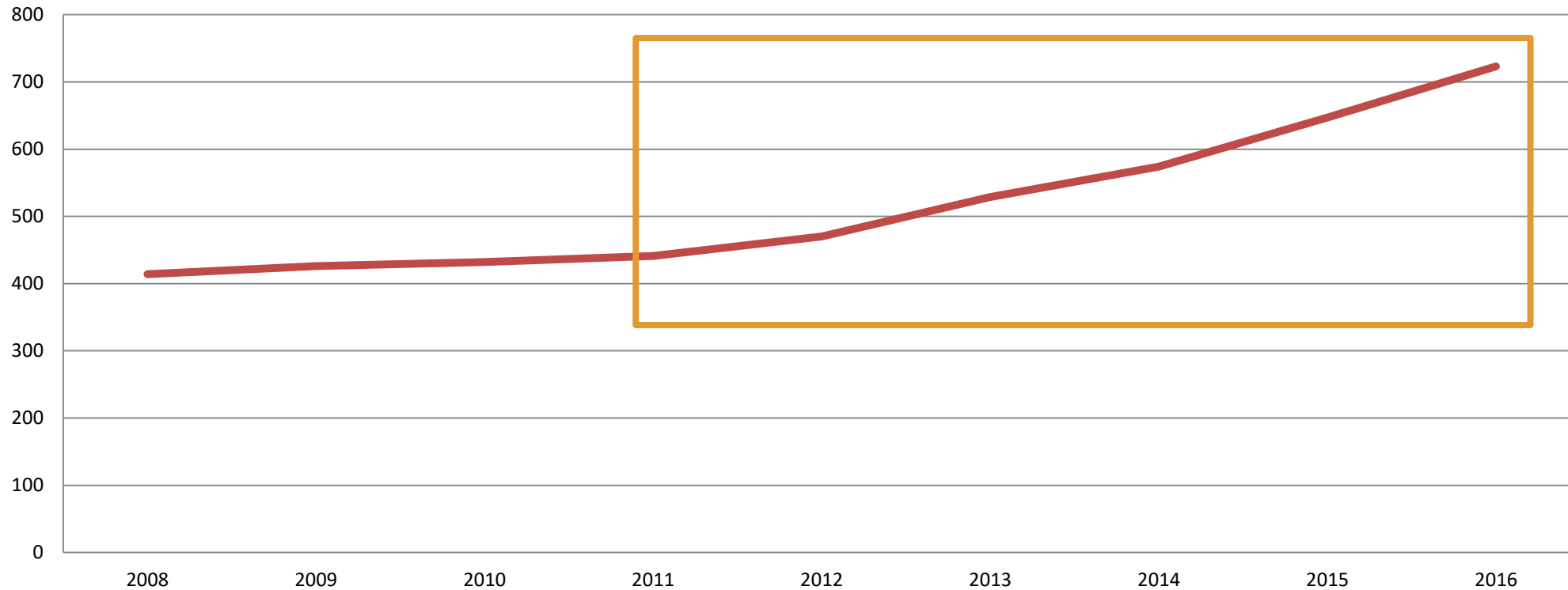
- few statistical data - good picture on data after the Regulation came into force in June 2011
- issues connected with Art. 43 – Renewal of PPP





Authorised products

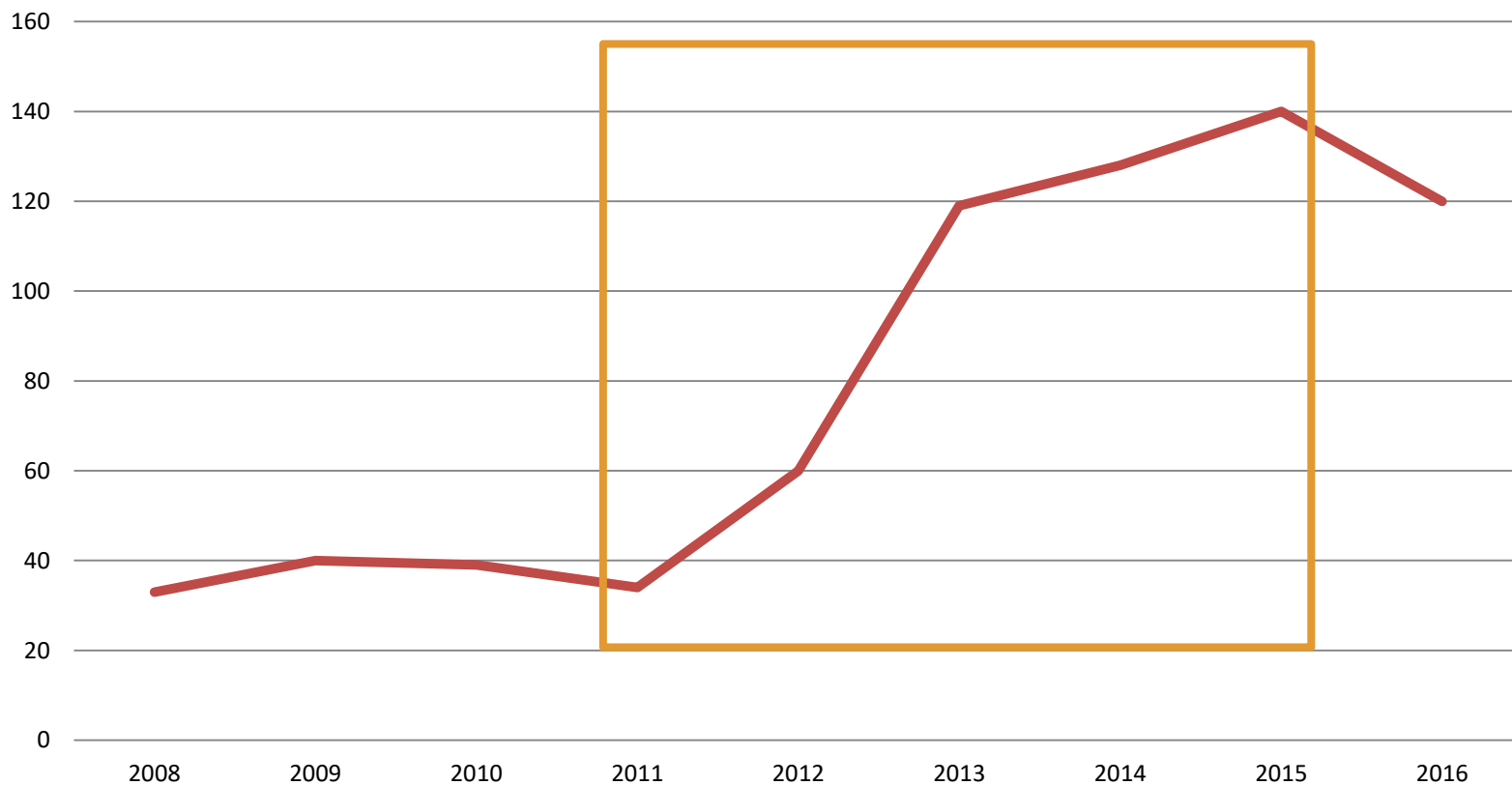
Number of Products



- before 2011 – around 400 products
- after 2011 – increasing tendency + 50 - 60 products per year
- actives – around 225
- what does the future bring - many actives are being withdrawn



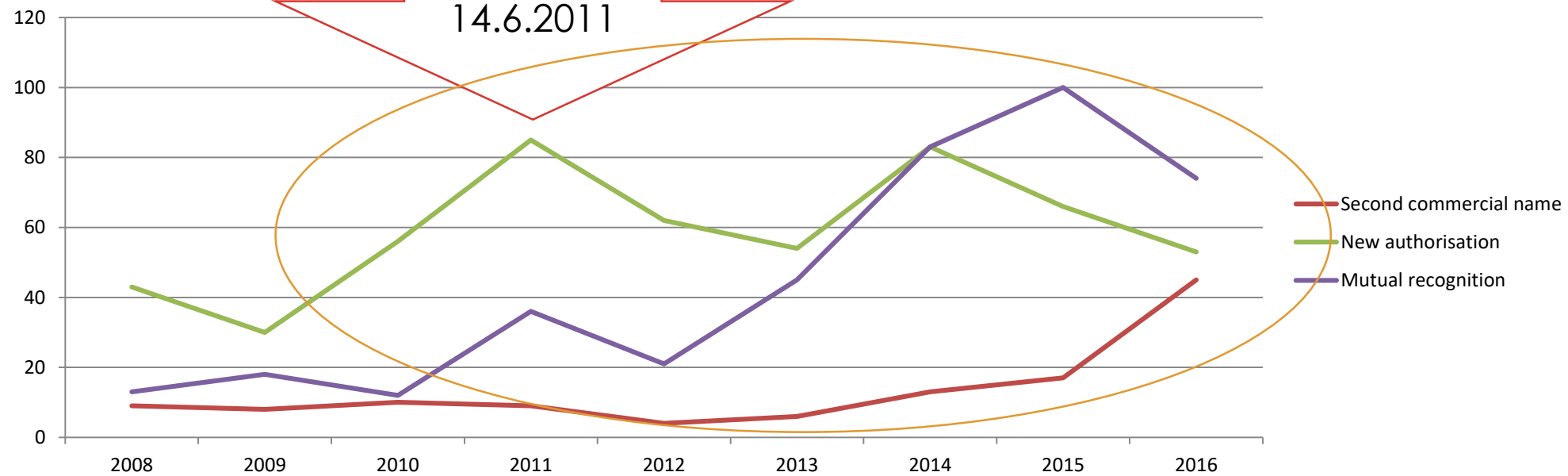
Number of parallel trade products



- between 2011 – 2015 – significant increasing tendency



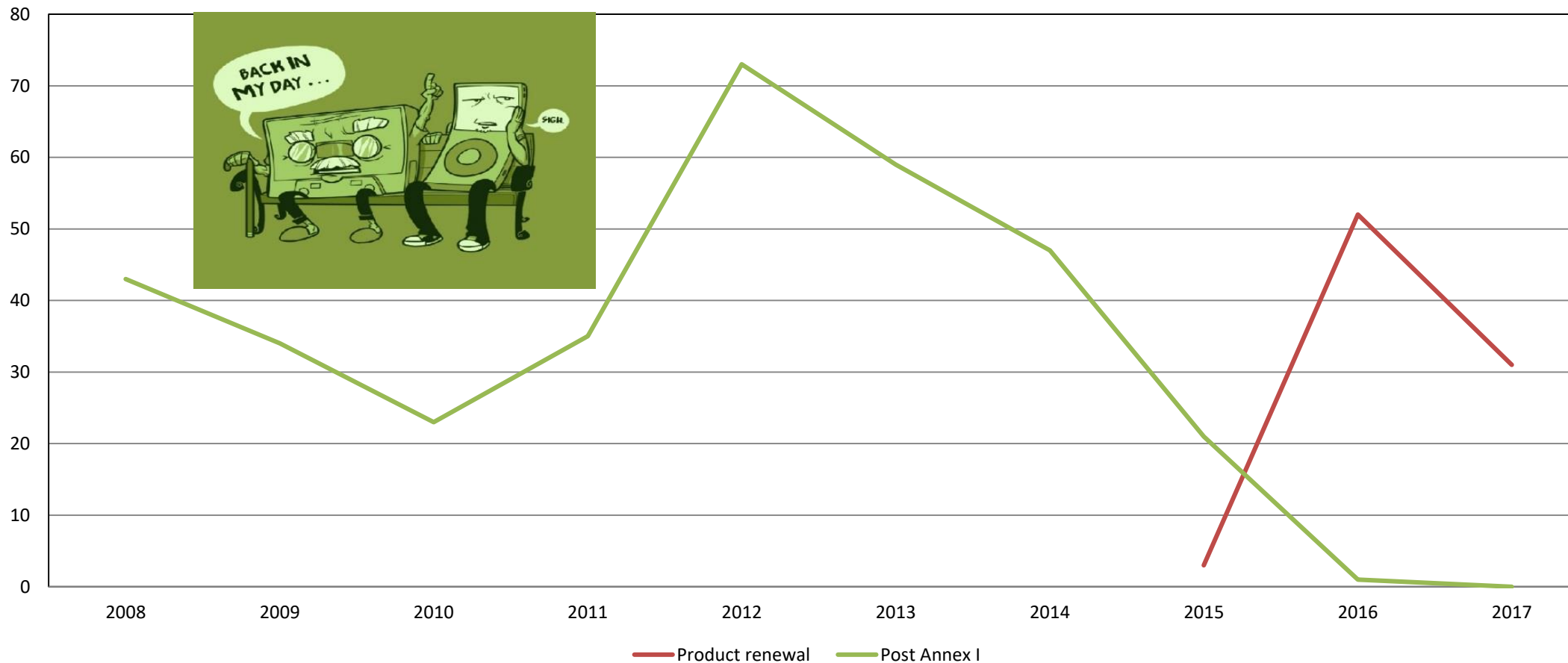
Number of applications



- In 2011 – higher number of authorisation before Regulation 1107/2009
- Mutual recognition – good tool how to authorise the product
- Σ = the higher number of authorised products.



Post Annex I vs. Products renewal applications

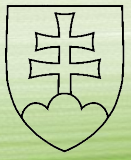


old well known system vs. new system



Renewal of Products

- 90 applications
- 8 as zRMS – starting in 4Q 2017 – not much experience – 2 pre-submission meetings
- 5 applications identified with CAT4 studies – communicated with other zRMS with the same active
- applications are assigned with cooperation on CZSC level
- expected much more applications
- allocation of zRMS for products - based on active substance – we appreciate that approach



Issues connected with Art. 43

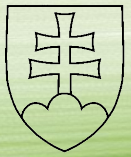
- Minor uses
- New authorisations in the role of cMS
- Blocked applications
 - Mutual recognition
 - Identical products
 - Amendments of authorisations





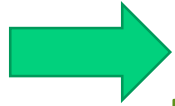
- Very challenging due to different authorisation holders
- Mostly small farmers are holders of decision on minor use
- They are not very familiar with submitting the application and they even don't have access to the data – it is important to set the GAP table
- What would be the better approach - communication with stakeholders is maybe step forward





90 days for cMS decision

procedure of new authorisation



Decision of **zRMS** – new authorisation – old endpoint

Decision of cMS

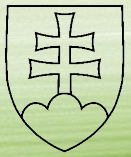
120 days – ideal situation

90 days

30 days before Date of Active Renewal

Date of Active Renewal

Date of Application for renewal of PPP



Blocked mutual recognition

Authorisation
in MSs –
decision
before
renewal

Renewal of active

Application for MR –
submitted after
Renewal of Active

STOP

1 year

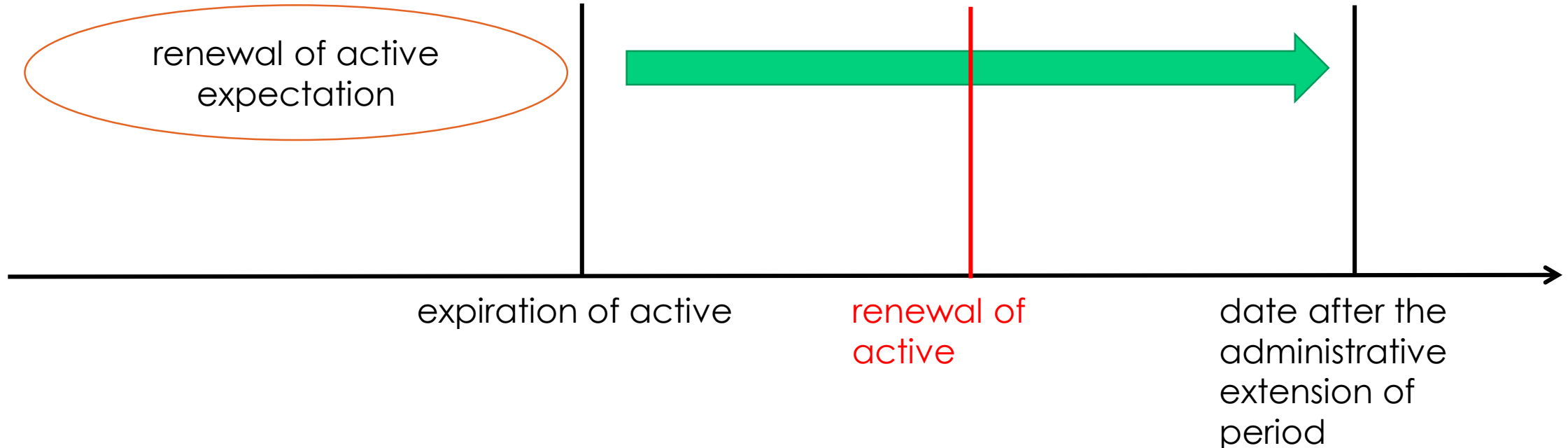
+ 2 years CAT 4

+ zRMS delay



Date of Active Renewal

- tough to plan the applications for renewal of product
- date of renewal of active substance is unpredictable
- complication for both – MS and applicant





Thank you for your attention

