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These slides accompany the explanation of the acquis to Albania and North Macedonia and can only be used for that purpose. Their content is subject to further development of the acquis and interpretation by the Court of Justice of the European Union.

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Explanatory Meeting

Supplementary Protection Certificates (SPC) for medicinal and plant protection products

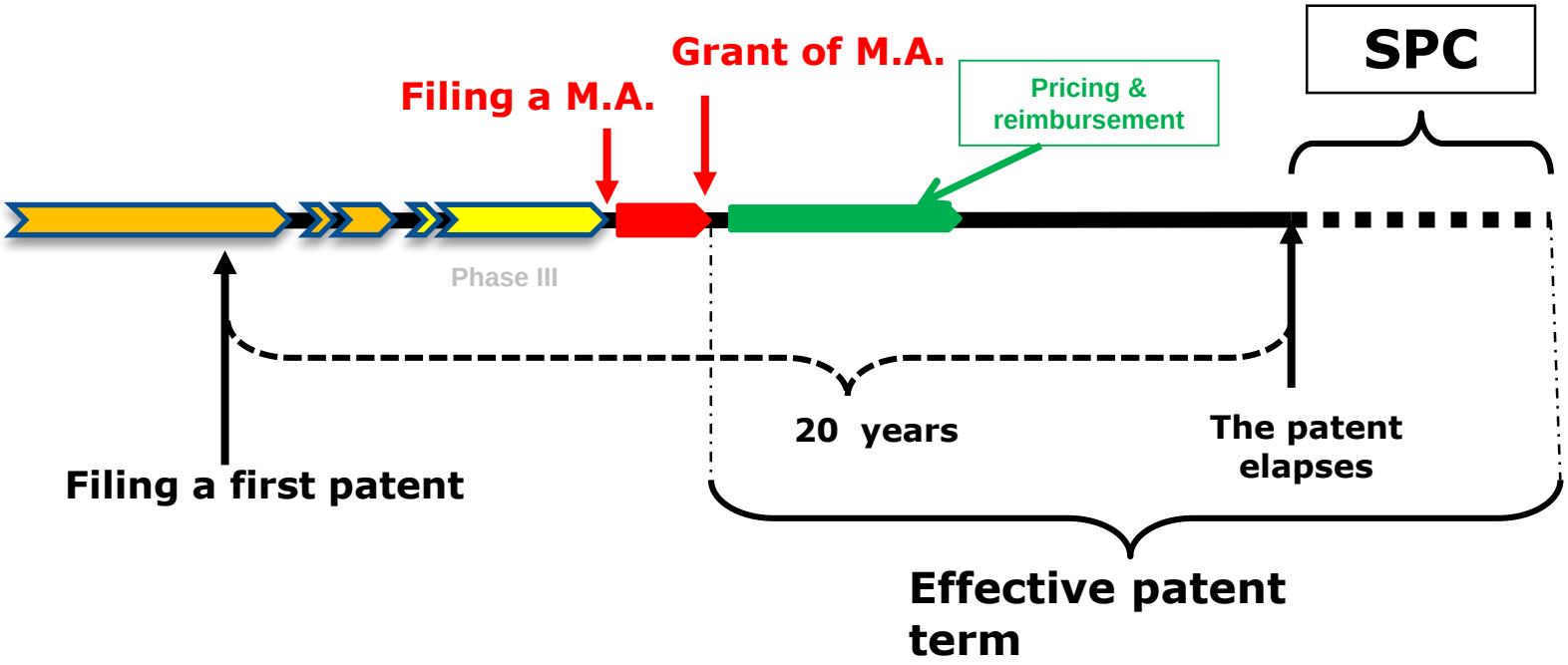
8 February 2019, Brussels

Content of the presentation

1. *Regulation 1768/92 (codified version: Regulation (EC) No 469/2009) and Regulation 1610/96*
2. *Paediatric extensions*
3. *SPC export waiver*

What is a SPC?

- *The SPC extends the protection conferred by the patent beyond its 20-year term for a period of up to 5 years*



- *But, only in respect of a product which has received a M.A. in the particular Member State*
- *It does not extend the term of the patent itself*

SPCs 1610/96 and 469/2009

- *Regulation 1610/96 concerning the creation of a supplementary protection certificate for plant production products*
- *Regulation 469/2009 concerning the creation of a supplementary protection certificate for medicinal products*

Objectives of the SPCs Regulations

- *Improvement in the public health and the production of food*
- *Not to hamper European innovation in the pharma and plant protection sectors*
- *Find a EU-wide uniform solution*
- *Find a balance between the compensation of the results of long and costly research and the public health expenditure*

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Provisions of the SPCs Regulations

- *Scope: a SPC may be granted to any product protected by a patent in a MS and subject to a M.A. (Article 2)*

- *The SPC is granted to the holder of the basic patent (Art 6) (not necessarily the M.A. holder)*

Provisions of the SPC regulations

- *Conditions for obtaining the SPC in each MS (Article 3):*
  - the product is protected by a basic **patent** in force;
  - a valid **[marketing] authorization** to place the product on the market [of the MS where the application is filed] as a medicinal product ....;
  - the product has not already been the subject of a certificate [to prevent undue accumulation of SPCs on the same patent];
  - the authorization referred to in (b) is the **first authorization** ….”

Provisions of Regulations 1768/92 and 1610/96

- *Lodging, publication and grant of the SPC application (Art 7,9,11): in the [Patent Office (Art.9.1)] of each MS. Application within 6 months after the "grant date" of the M.A. (normally)*

- *The granting procedure is a National procedure within the framework established by the Regulation. Every MS Office is free to charge fees (Art 12)*

- *Content of the SPC application (Art 8): mainly applicant's data and proof of fulfilling substantive requirements of Article 3*

- *Subject-matter of protection and effects of the SPC: it extends only to the product covered by the M.A. and for any authorized use of the product as a medicinal product within the limits of the protection conferred by the basic patent (Art 4,5)*

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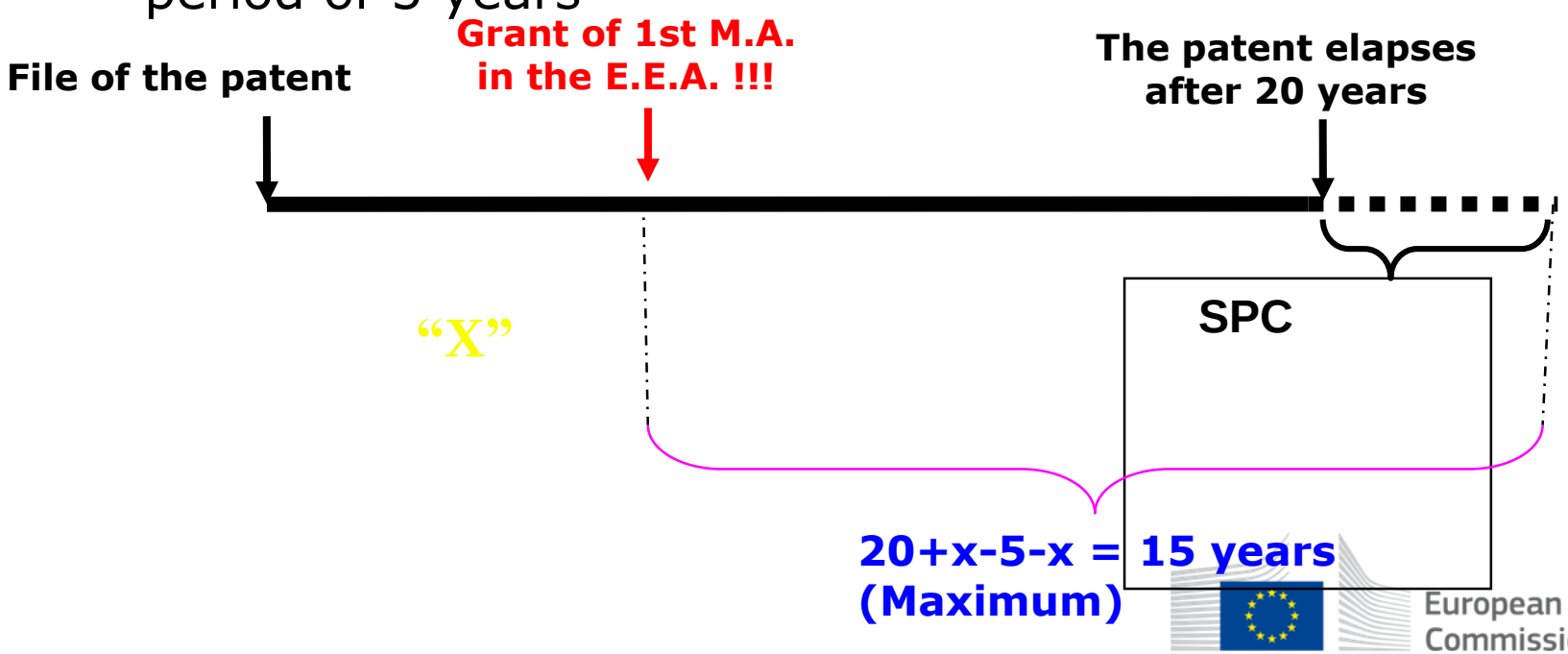
Provisions of Regulations 1768/92 and 1610/96

- *The duration of the SCP cannot exceed 5 years (Art 13)*
  - It takes effect at the end of the lawful term of the patent
  - for a period equal to the period which elapsed between the patent application's date and the date of the first M.A. granted in the E.E.A. reduced by a period of 5 years



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Regulation (EC) No 1901/2006

- *New paediatric-related regulatory obligations in 2007*
- *An additional 6-month extension of the SPC to reward research recommended in a paediatric investigation plan (Art. 13(3))*
- *"Application for an [paediatric-related] extension of the duration" of the SPC (Art. 1(e)) shall be lodged not later than two years before expiry of the SPC (Art. 7.4)*
- *What if the SPC is zero or negative → See C-125/10 (Merck v German Patent Office)*

COM (2018) 317 final

- *To create a limited exception to the SPC by means of a manufacturing waiver for export only*
- *No stockpiling exception*
- *To be apply to regulation 469/2009 only*
- *Making and related acts*
- *Publication by NPOs*
- *Entry into effect of the regulation: to apply only to granted SPCs*

Council discussions

- *Council WG: 18/06/2018, 5/07, 26/07, 07/09, 12/10, 7/11, 28/11 and 08/01/2019*
- *No stockpiling*
- *Definition of makers and products/ medicinal products*
- *Notification*
- *Application in time*

EP discussions

- *Leading committee: JURI (01/19), Associated ENVI and INTA*
- *JURI draft report:*
- *No stockpiling*
- *Clarifying the types of otherwise- infringing related acts*
- *Entry into effect*
- *ENVI and INTA support stockpiling*

- *Thank you for your attention*