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EU SPC System and uSPC: What to be expected?

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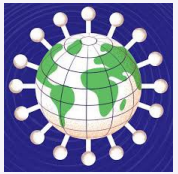
The EU legal context



Pharmaceutical Regulatory Outlook

2020/Nov.
European commission publishes the Pharmaceutical Strategy

2020/Nov.
EC launches a Public consultation on Medicines for children & rare diseases (Paediatrics and Orphan)

2021/Nov.
The European Parliament: gives support to Pharmaceutical Strategy for Europe

2021/Dec.
EC: publication of an online questionnaire about the Pharmaceutical Strategy

2021/April
EC publishes a roadmap/Inception Impact Assessment

2022/April
EC launches a call for evidence to reform the SPC system and proposes a unitary SPC

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2022/Dec.
EC aims at adopting a proposal for a new regulation including a revision of OMP & Paed legislation

Contents

SPC Current Practices

Based on a National or European Patent

Based on a National or Community Market Approval

Granted by the national patent office of each EU Member State

European Regulations No. 469/2009 for medicinal products

Litigate with the competence of the national authorities

Contents

Areas for improvements

More transparency of information

More harmonization

More centralization and Less administrative burden

Less costly and less complex

Greater harmonization of SPC decisions

More legal certainty

Contents

Practioners are in majority in Favor of …

A unitary SCP

A single grant mechanism

A new granting body

No double SPC protection

Practioners are in disagreements about …

Opposition mechanism

Re-opening of the SPC regulation

Appeal instance

Next Steps

As identifed by the European Commsiion

Status quo → No change

Guidelines or « Good Practices »

Legislative changes

Thank you

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