



# MARKET EXCLUSIVITY EXPIRY HAS LIMITED EFFECT ON PRICES OF BRAND-NAME ORPHAN DRUGS

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## Background and importance

- ❑ R&D and market entry for orphan medicinal products (OMPs) are incentivized with a ten-years market exclusivity period as stated in Orphan Regulation (EC) No 141/2000
- ❑ OMP prices often remain high after market exclusivity expiry (MEE), leading to societal debates on the affordability of medicines
- ❑ Transparency on purchase prices of OMPs is lacking due to confidentiality issues
- ❑ Research on actual OMP prices and trends is needed to support policy making

## Aim and objectives

- ❑ Explore trends and price developments in **list prices (LP)** and **purchase prices (PP)** of brand-name OMPs before and after market exclusivity expiry in Western-European countries

## Materials and methods

- ❑ Collection of unweighted annual average LPs and PPs of brand-name OMPs from several university hospitals in Western-European countries
- ❑ Only OMPs for which market exclusivity ended no later than 2019 were included<sup>1</sup>
- ❑ The annual average LP in the year of market exclusivity expiry (MEE=0) in the Netherlands was set as index price (p=100%)
- ❑ Proportions were created to illustrate price trends and to overcome any confidentiality restraints

## Results

- ❑ Participation of 5 university hospitals in 4 countries
  - Netherlands (NL)
  - Denmark (DK)
  - France (FR)
  - Germany (DE) (2)
- ❑ Inclusion of 13 OMPs

Country	MEE+/-2	MEE+/-3	MEE+/-4	Overall LP-PP*100%
NL	-3,82% (sd=5,61)	-4,42% (sd=6,17)	-4,75% (sd=6,35)	-1,99%
DK	-8,75% (sd=12,17)	-8,80% (sd=12,20)	- 8,88% (sd=12,84)	-2,44%
FR	-14,18% (sd=10,55)	-15,30% (sd=10,17)	-15,83% (sd=10,03)	-0,0004%
DE	-11,16% (sd=26,08)	- 10,89% (sd=26,57)	-10,61% (sd=26,84)	-31,75%

Table 1. Average price drops of OMPs per country 2, 3 and 4 years before and after MEE=0 incl. overall average price reduction

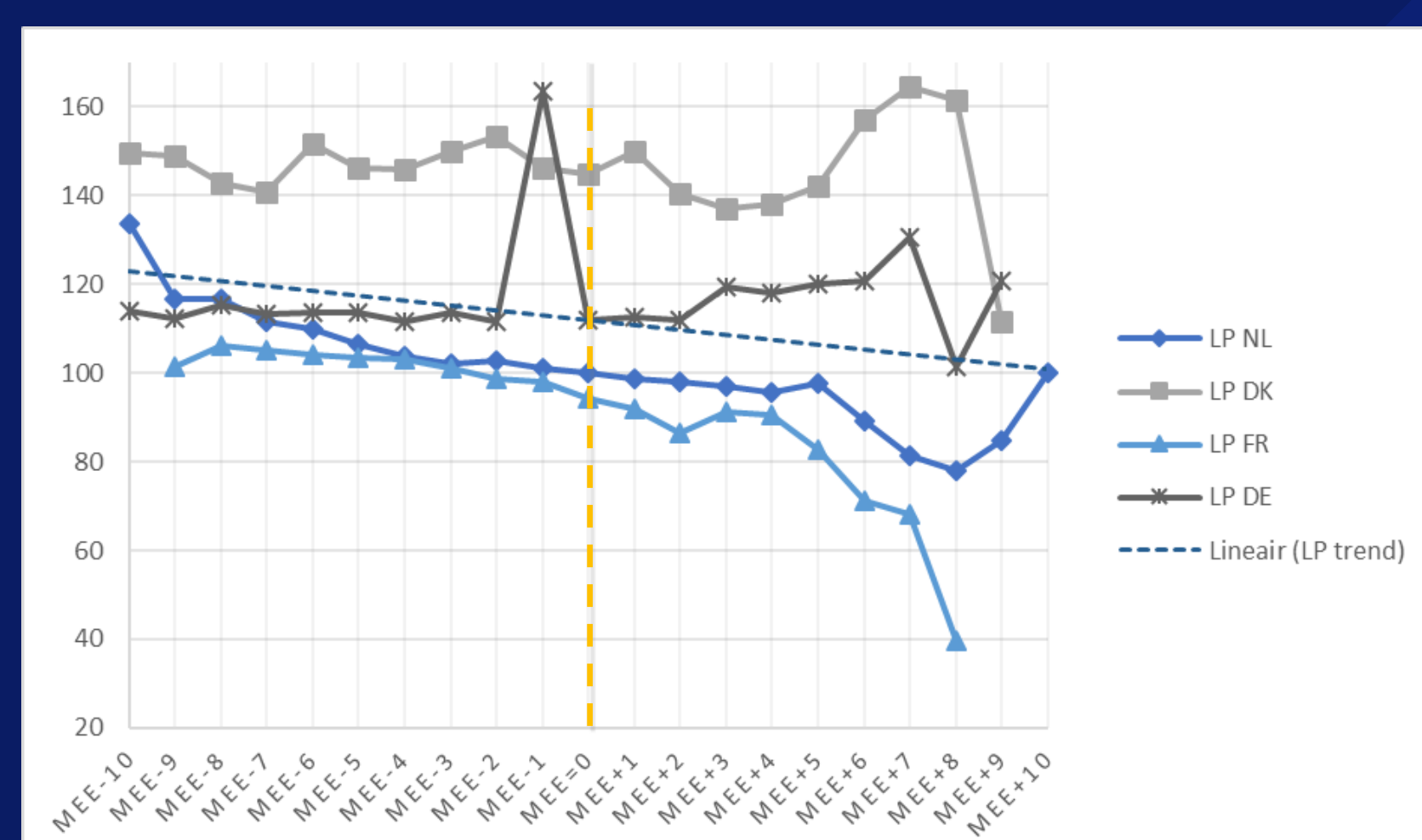


Figure 1. Average annual indexed list prices (LP) per country

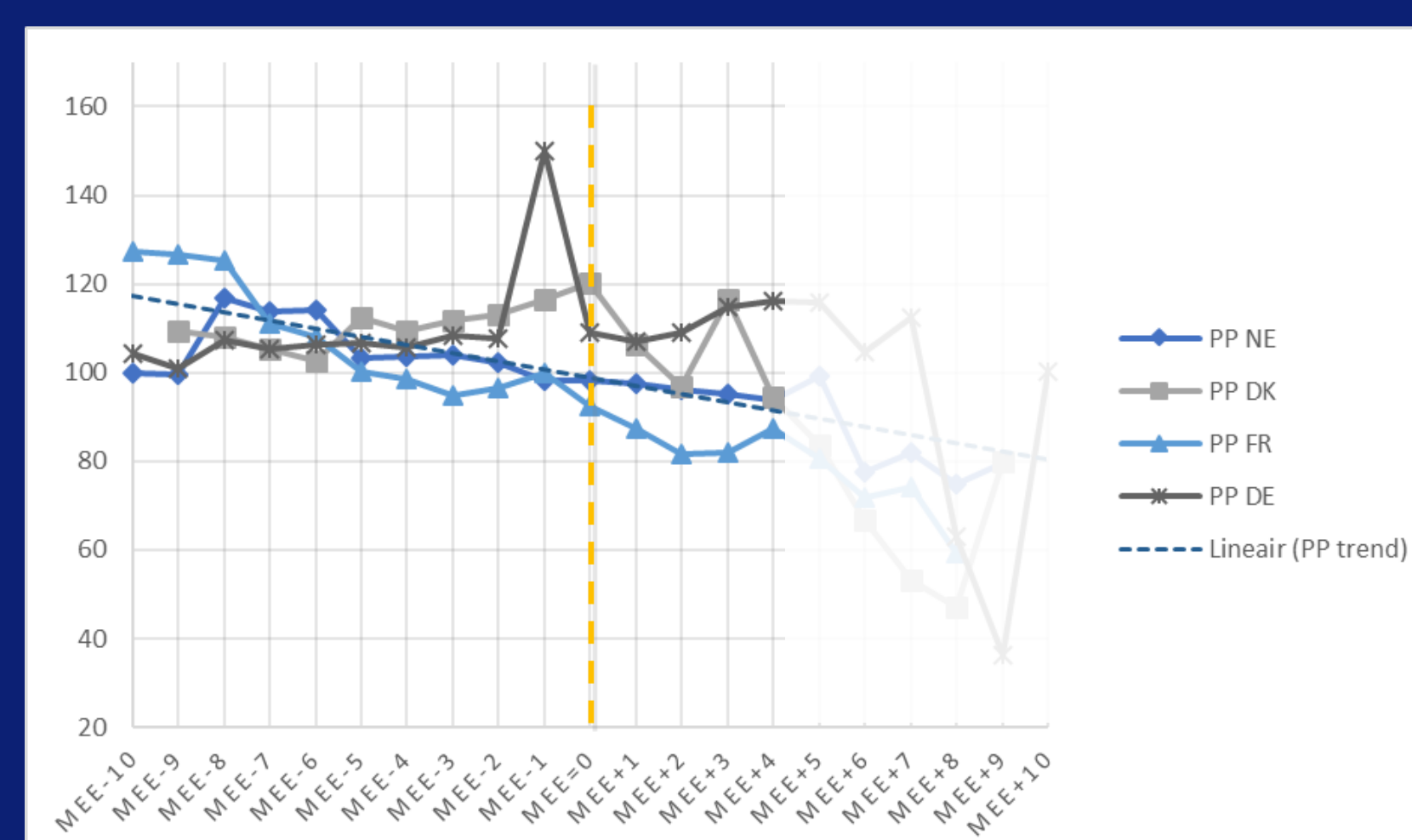


Figure 2. Average annual indexed purchase prices (PP) per country

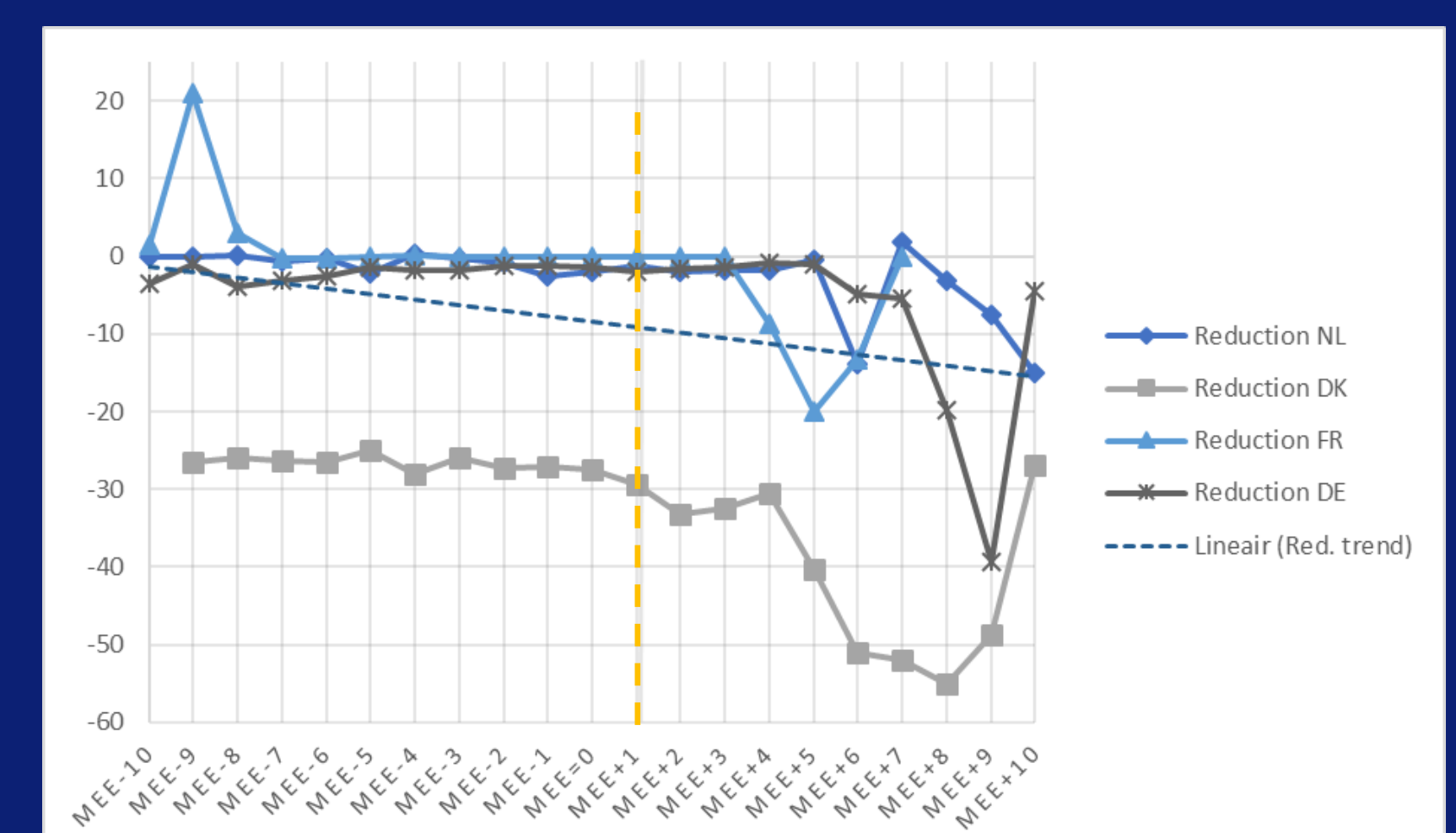


Figure 3. Average annual price differences (LP - PP)\*100% per country

## Conclusion and relevance

- ❑ Overall average PPs drop gradually but limited until MEE+4, but the extent to which prices drop differs per country
- ❑ In the four countries, LPs seem to differ more than the PPs mainly due to a difference in discount
- ❑ Between MEE=0 and MEE+4 the differences between LPs and PPs remain relatively small (after MEE+4 more outliers occur due to lack of data points)
- ❑ Average annual LPs and PPs are the highest in Germany and the lowest in France. Denmark has negotiated the biggest discount

## Acknowledgements

Albane Degraassat Theas, AP-HP, France; Martin Hug, University Hospital of Freiburg, Germany; Morten Houliind & Heidi Letvinka, Copenhagen University Hospital, Denmark; Franziska Behrend, Charité University Hospital Berlin, Germany; Lorenz van der Linden, University Hospital Leuven, Belgium

## References

<sup>1</sup> Dane A, Klein Gebbink A, Kuy van der PHM. (2021). The importance of publishing research protocols for pharmaco-economic studies. Eur J Hosp Pharm

