



European Federation of Pharmaceutical  
Industries and Associations



# Cross-Country Collaborations on pricing and access to medicines

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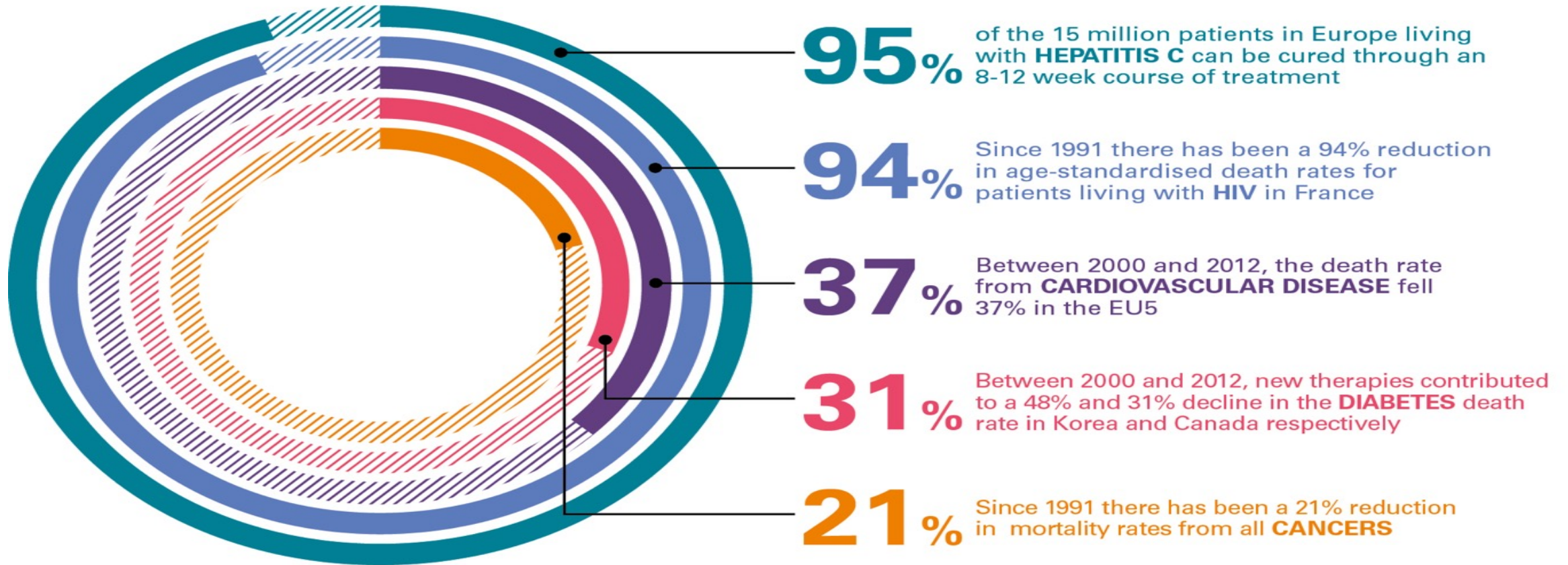
## About EFPIA



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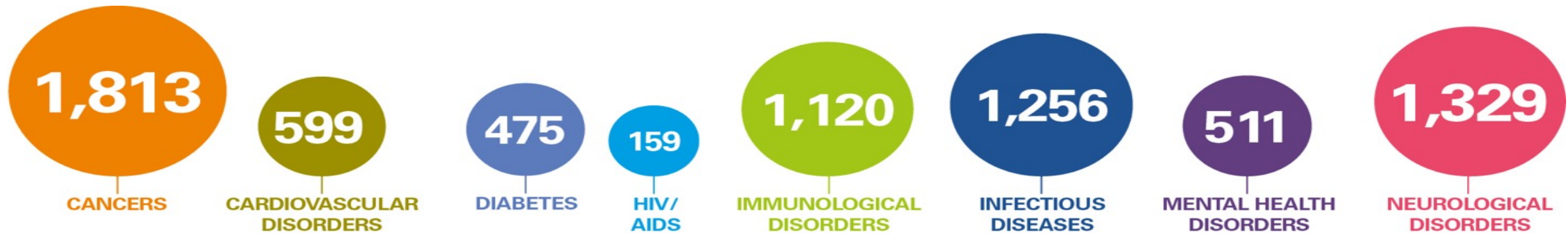
## EUROPE'S HEALTH SUCCESS STORY

Europeans now live over a decade longer than they did just 50 years ago



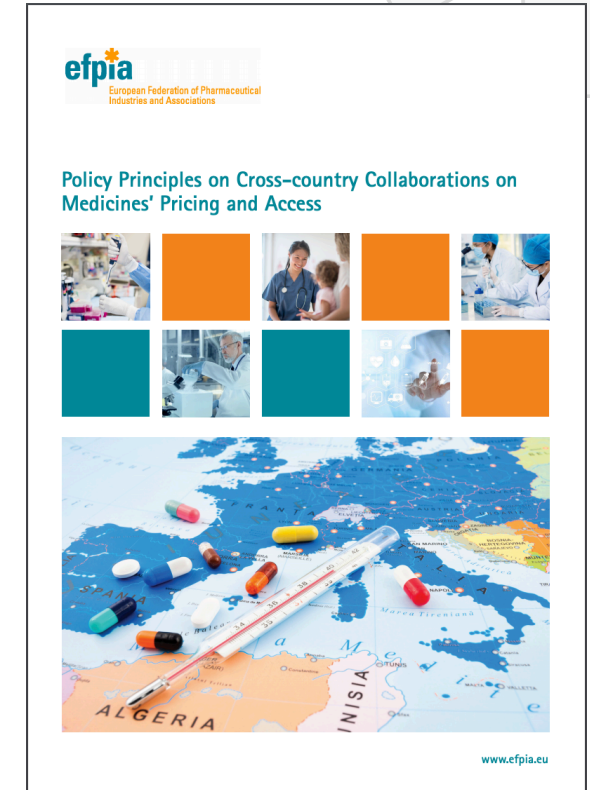
BUT #WEWONTREST

With over **7000 medicines** in development there are many reasons to optimistic about the future of health in Europe



## Five principles for collaboration:

1. Broader & accelerated patient access
2. No extra process burden (replace equivalent steps in countries)
3. For similar/close countries (economic/health/geographic)
4. Voluntary
5. Guaranteed confidentiality





# Overall Industry Assessment

## Potential Opportunities

- Broaden overall access to therapies for patients
- Commercial opportunity by increasing market size and volume
- Harmonisation and streamlining of REA, HTA, pricing negotiations, purchasing and contracting processes – particularly beneficial for smaller companies
- Workload sharing among authorities of participating Member States
- Support for better budgetary forecasts through horizon scanning

## Potential Challenges

- Unclear process:
  - Lack of governance and methodology to initiate, conduct and conclude pilot projects
  - No obligation for participating Member States to adopt the outcomes of joint reports
- Unclear legal basis and framework in particular interactions with current EU (e.g. Transparency directive, public procurement legislation) and national legislations
- Duplication and /or no consideration for existing pan-European initiatives (e.g. EUnetHTA, REA)
- Limited experience of (successful) real-life experience
- Lack of clear impact of horizon scanning activities on budget forecasts
- Risks of distortion in supply, trade and competition if no appropriate conditions for purchasing and contracting (e.g. sound tender criteria)
- Larger Member States increasingly interested in participating to cross-border collaborations
- Breach of confidentiality

## CROSS-COUNTRY COLLABORATIONS ON PRICING AND ACCESS TO MEDICINES

### Questions (process, legal...) and uncertainty for companies



- \* What countries take part?
- \* Who takes the decision? What is the process? (majority, unanimity...)
- \* Efficiency of the process
- \* What is the legal basis and guarantee?
- \* Steps and Timeline?
- \* Transparency across members?
- \* Nature of the Decision
  - \* Agreement? Legally binding? Legal appeal?
  - \* Directly implementable at national level (duplication?), e.g. single price vs price range?  
Across which countries?
- \* Confidentiality of information and data?
- \* Compliance with EU rules, e.g. competition, transparency directive, public procurement

### Wrap-up



- \* Initiatives ran by national authorities (EU is only an observer)...
- \* Various areas of intervention (HTA, joint tendering, joint negotiations, horizon scanning, sharing of information...)
- \* Spontaneous, pragmatic initiatives; Substantial legal/process questions
- \* Industry is in favor of the option that delivers optimal patient access and will preserve financing of innovation in the long run...
- \* Buy-in of companies is necessary for joint negotiations
- \* National authorities seem to have a strong inclination towards economic criterion (price), possibly at the expense of access/innovation





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**Thank you**

