What cancer patients need from the European HTA

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Content of presentation

I. „HTA Initiative" of the Commission

II. ECPC position on:

- **the limits of HTA across the EU**
- **the „HTA Initiative"**
- **the legal aspects of the „HTA Initiative"**

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Timeline of HTA Initiative

September 2016 - the Commission launched the „Strengthening of the EU cooperation on Health Technology Assessment" (HTA Initiative)

October 2016 - January 2017 - public consultation

Since January 2017 - dialogue (face-to-face meetings) with stakeholders

End of 2017 - Impact Assessment on the initiative

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Objectives of HTA Initiative

1. Strengthening Member States their cooperation on HTA

2. A better functioning of the internal market of HTA

3. Contribute to a high level of human health protection (Article 168 TFEU)

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5 Options of HTA Initiative

1. STATUS QUO

- HTA is regulated and organized at national/regional level
- In parallel, a voluntary cooperation mechanism through the Joint Actions and the HTA Network
- The third EUnetHTA Joint Action (2016-2020)
- Voluntary

2. LONG-TERM VOLUNTARY COOPERATION

- The short-term financing of Joint Actions will be replaced by a „long-term mechanism”
- Financed by the EU beyond 2020
- Voluntary

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5 Options of HTA Initiative

3. Cooperation on COMMON TOOLS AND DATA

- Legal framework on common tools and data (tools/IT platforms, how data is collected, shared and used)

- Compulsory

- based on the legal framework the Member States will produce joint REA reports

- Voluntary

- Legislative proposal

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5 Options of HTA Initiative

4. Cooperation on JOINT REA REPORTS

- Rapid Relative Effectiveness Assessment (REA) - focusing on clinical/medical benefits

- Member States jointly produce REA Reports

- Legislative proposal

Two sub-options:

4a. Participation of Member States in the preparation of joint REA reports is voluntary, but Member States that opted in are bound by the results (they cannot replicate it)

4b. Both participation in the joint REA reports and their subsequent uptake are compulsory for all Member States

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5 Options of HTA Initiative

5. Cooperation on JOINT FULL HTA REPORTS

- Full HTA - focusing on economic benefits („value for money")

- Member States jointly produce Full HTA Reports

- Legislative proposal

Two sub-options:

5a. Participation by Member States in the preparation of joint Full HTA reports is voluntary, but Member States that opted in are bound by the results (they cannot duplicate it)

5b. Both participation in the joint Full HTA and their uptake are compulsory for all Member States, as described in option 5b

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European Cancer Patient Coalition

- **Representing more than 400 cancer patient groups in 44 countries**
- **All cancer types – common and rare**
- **Run and governed by patients**

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ECPC Position
- Limits of HTA across the EU -

1. Incredible variety and differences of HTA procedures across the EU

- Very hard to compare different systems to see which is more valuable

- Duplications of work

- Inequalities in access to innovative treatments

2. Lack of transparency of HTA

- Almost impossible for patients to have access to information

- Hard to check legality of the procedures

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ECPC Position
- Limits of HTA across the EU -

3. Unacceptable delays in the HTA process across Member States

- The 180 days limit term provided by Directive 89/105 of 21 December 1989 („transparency directive") is broken by almost each Member State)

- E.g. Transtuzumab (breast cancer): Romania (+2878 days), Slovakia (+3686 days) and Latvia (+4660 days)

4. Patients' involvement in HTA process is very limited

- Survey during 2016 AGM ECPC - none of the approx. 120 participants representing our 408-strong membership was involved in any way in HTA at the national level

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ECPC Position on the 5 Options

1. Options 1 and 2

- **Maintain the current state of fact**
- **Do not cause any noticeable improvements**

2. Option 3

- **A basic option, a „middle" one**
- **There is no guarantee the duplication efforts will be reduced**

3. Options 4 and 5

- **Should be taken in consideration**
- **Provide real added value at the EU level**

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ECPC Position on the 5 Options

4. Option 5b „COMPULSORY - JOINT FULL HTA" represent patients' interests in the most optimal way

5. Establishing an European HTA body similar to EMA should be considered

6. Creating a legal mechanism of patients' involvement in HTA process

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ECPC Position on the 5 Options

7. ECPC understands that option 5b is hard to be achieved for legal reasons:

- pricing and reimbursement is under Member States competence (art. 168 TFEU)

- there is a "link" between „economic evaluation" (as part of full HTA) and pricing and reimbursement

- needs political support to be implemented

8. Option 4b „ „COMPULSORY - JOINT REA" is feasible

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ECPC Position
Legal Aspects of the HTA Initiative

1. Legally, Options 4 and 5 are based on Article 114 TFEU:

- the European Parliament and the Council shall adopt measures for „approximation" („harmonization") of the national laws, regulations or administrative procedures which have as their object the establishment and functioning of the internal market

2. Even though „Public Health" is under Member States competence, Art. 114 TFEU can be used as legal basis for HTA legislation (e.g. Directive 2011/24/EU *on the application of patients' rights in cross-border healthcare*)

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ECPC Position
Legal Aspects of the HTA Initiative

3. ECPC suggested to consider the relevant jurisprudence of Court of Justice of the European Union on using of Article 114 TFEU as legal bases

Three conditions should be accomplished:

- **A real need to harmonize**
- **A favorable internal market purpose**
- **A favorable internal market effect**

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Thank for your attention!

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