The Consumer Voice in Europe

MAKING SURE CONSUMERS ACCESS TREATMENTS THAT WORK AT A FAIR PRICE

BEUC's demands for an EU Regulation on Health Technology Assessment

Contact: Pelle Moos – health@beuc.eu

BUREAU EUROPÉEN DES UNIONS DE CONSOMMATEURS AISBL | DER EUROPÄISCHE VERBRAUCHERVERBAND
Rue d'Arlon 80, B-1040 Brussels • Tel. +32 (0)2 743 15 90 • www.twitter.com/beuc • consumers@beuc.eu • www.beuc.eu
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Why it matters to consumers

When consumers take medicines or use medical devices, they expect them to work. But today, many drugs and medical devices are inefficient and waste consumers' money. Even worse, some treatments are unsafe and might put consumers' health at risk. Health Technology Assessment (HTA) helps governments decide which treatments should be reimbursed and at what price. Therefore, **HTA can ensure that consumers only access and pay for effective treatments.**

Summary

On 31 January 2018, the European Commission published a proposal for a Regulation on Health Technology Assessment (HTA). BEUC supports the need for stronger cooperation on HTA among EU Member States. In this paper, we outline our recommendations for a permanent EU HTA mechanism that truly benefits consumers.

To ensure good governance of the cooperation and achieve results that match consumers' needs we recommend that:

- Member States must lead the HTA process;
- The Regulation should make it mandatory for Member States to use joint clinical assessments, but introduce possibilities to adapt reports to the needs of their national health care systems;
- The Regulation must ensure that the system is independent from economic interests;
- The Regulation must guarantee transparency and public access to documents;
- The Regulation must grant Member States sufficient time to adapt their national HTA procedures to a new EU-wide HTA system.

Furthermore, to secure relevant, high-quality outcomes we insist the Regulation ensures that:

- Manufacturers disclose all relevant data and conduct trials against the best available treatment;
- Orphan medicines, which treat rare diseases, are subject to the same standards as widely-used drugs;
- Medical devices are covered by the Regulation;
- Patients and consumers are involved in the process;
- There exists a clear separation between the decisions of EMA and a new HTA mechanism.

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1. Introduction

Too many drugs or medical devices that consumers use today do not work as they should or as consumers would expect. For example, when Belgian consumer organisation, Test Achats/Test Aankoop evaluated the efficacy of about 6,500 medicines sold in the Belgian market, they found that 11% could not be proven to be efficient and 2% were to be avoided altogether.[1] Unfortunately, this concerns not only medicines that treat mild conditions, such as rhinitis or cough, but also medicines that treat life-threatening diseases like cancer. Moreover, many new drugs do not really make a difference to what already exists on the market. Health care systems nevertheless allocate a considerable amount of public money to reimburse these 'me too' treatments.[2]

Health Technology Assessment (HTA) is an evidence-based, multidisciplinary process that compares the added value of a new health technology - including medicines, medical devices and surgeries - with other existing health technologies and/or the current standard of care.[3] HTA is thus a tool that helps health care systems decide which treatment to reimburse and at what price. As such, **HTA can help ensure that consumers only pay for - and have access to - effective treatments**, while also helping governments prioritise national health care spending among different health technologies.

Today, all EU Member States have started to introduce HTA processes to support their pricing and reimbursement decisions. To strengthen collaboration among European countries and avoid duplication of work, the European Commission (the Commission) on 31 January 2018 proposed a Regulation (2018/0018 (COD)) to set up a permanent EU HTA mechanism.[4]

Overall, **BEUC welcomes the Commission's proposal** which holds the potential to facilitate access to effective medicines for consumers across Europe.[5] Nonetheless, **it is imperative that a new EU HTA mechanism ensures sufficient flexibility for Member States** to adapt the outcome of the cooperation to the needs of their national health care systems.

2. The European Commission's proposal: a good start

While all countries in Europe have HTA bodies in place, their structure, capacity and relevance vary considerably. The proposed Regulation aims at ensuring a more efficient use of resources, while strengthening the quality of HTA processes across the EU. The Commission proposes a permanent HTA mechanism to harmonise the first step of the assessment ('relative effectiveness assessment'), which focuses on clinical data and therefore presents similarities across countries.

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1 Test Santé Magazine n' 132, 2016. The research was conducted by evaluating the efficacy of medicines according to the best scientific evidence.

2 See *e.g.* Links between Pharmaceutical R&D Models and Access to Affordable Medicines, Directorate General for Internal Policies, EU Parliament, October 2016.

3 Boosting cooperation on health technology assessment, European Parliamentary Research Service, March 2018.

4 Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on health technology assessment and amending Directive 2011/24/EU, January 2018.

5 New EU plan to assess medicines' added value will benefit consumers, BEUC press release, January 2018.

In particular, the text proposes a cooperation based on four pillars, namely joint clinical assessments, joint scientific consultations, the identification of emerging health technologies and voluntary cooperation.[6] Member States will lead the assessment process through a Coordination Group, with the support of the Commission throughout the different stages.

The joint clinical assessments are the most important component of the proposal because, after the transitional period of three years, Member States will be obliged to use them in their HTA process at national level. The text however foresees a 'safeguard clause' that allows countries to conduct a national assessment in addition to the joint one, if this is justified by the need to protect public health in that specific country.

BEUC strongly supports enhanced cooperation on HTA among EU Member States because it has the potential to ensure that all consumers across the EU will benefit from innovate and effective medicines. Specifically,

- If assessments are conducted at European level, **countries will reduce the risk of duplicating their work and therefore waste time and money**. In turn, this might also free up resources within their national health budgets.[7]
- **An EU HTA mechanism will help reward only truly innovative health technologies**. As a consequence, this would push companies to develop health technologies with an added value for consumers and patients, as opposed to the current regrettable 'me-too' drugs pattern.
- **A permanent structure is necessary to build long-term trust and capacity**. The EU has invested significant resources in promoting HTA cooperation: the results of the current project-based model, which will end in 2020, have however been limited.

While the Commission's proposal includes many welcome elements, it also suffers from several shortcomings. On 3 October 2018, the European Parliament adopted its position, and delivered a text that would significantly improve the Commission's proposal.[8] The Council is meanwhile still considering the text, with discussions expected to carry on throughout 2019. **BEUC welcomes the Parliament's position,[9] and calls on Member States to expedite their negotiations with a view to reach a Council position**.

In this paper, we outline how the Commission proposal should be further improved to ensure that a future EU HTA mechanism will truly benefits consumers. BEUC urges the co-legislators to take these recommendations into account when finalising the legal text.

3. What governance of the EU HTA system?

3.1. Member States must be in the driving seat

As the HTA process is linked to key national competences, such as pricing and reimbursement decisions, Member States, not the EU, must steer the new mechanism. The Commission's proposal rightly proposes a system where national

[6] Voluntary cooperation would allow Member States to conduct HTA on health technologies that are outside the scope of the Regulation, such as surgeries, non-clinical assessments, *etc*.

[7] European Commission (DG ECFIN- EPC), Joint Report on Health Care and Long-Term Care Systems & Fiscal Sustainability – Volume 1, Institutional Paper 037 | October 2016.

[8] Amendments adopted by the European Parliament on 3 October 2018 on the proposal for a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU.

[9] A better system in the making for testing efficiency of medicines and medical devices in the EU, BEUC press statement, October 2018.

authorities responsible for HTA take decisions through the Coordination Group.[10] Yet, it leaves to the Commission the key task of adopting implementing acts defining the methodology to be used during the assessments.

We insist this provision should be modified to ensure that it will be up to the Coordination Group to define the methodology, in the form of guidelines. This would ensure sufficient flexibility to adapt the guidelines to scientific developments, while securing the permanent involvement of Member States in the process. We therefore welcome the approach of the European Parliament, which assigns the role of drafting rules regarding the methodology to the Coordination group.

In addition, the proposal foresees a mechanism where countries act by consensus or, when necessary, vote by simple majority with one vote per Member State. Given the potential implications of this cooperation for national health care system, we support this proposal as it strikes the right balance in ensuring the representation of dissenting views and the need to advance EU-wide HTA cooperation.

Overall, the Commission should assist the Coordination Group throughout the implementation of the four pillars and ensure the *procedural* requirements are observed by Member States. For example, the Commission should verify that the discussions within the Coordination Group are reported in the final assessment, including the dissenting views.

We thus urge the co-legislators to ensure that the Coordination group will:

- Develop the methodological guidelines for conducting the assessments;
- Elect the chair and the co-chair of the meetings; and,
- Adopt the work programme.

We further support the European Parliament's position that the role of the Commission should be limited to:

- Verifying the correctness of the procedural requirements;
- Publishing the reports when procedural requirements are met; and,
- Assessing and establishing possible Member State opt-out requests.

BEUC demands:

- **The co-legislators must ensure that national authorities take all key decisions through the Coordination Group.**
- **The Coordination Group should strive to reach consensus; when this is not possible, decisions should be taken by simple majority.**
- **The Commission should support the Coordination Group throughout the process and ensure the *procedural* requirements are observed.**

[10] This includes designating the experts that will conduct the assessments, approving the joint reports and the annual work programme and selecting the medicines and medical devices that should undergo the assessment.

3.2. Joint clinical reports: their use should be mandatory but with sufficient flexibilities

The current voluntary system has so far led to limited uptake of joint assessments and duplication of efforts. BEUC therefore supports the mandatory uptake of the EU clinical assessments reports.

Nonetheless, **Member States must have more flexibility to adapt them to their national contexts than foreseen in the Commission proposal**. HTA bodies must likewise be able to add new data to the EU assessment when this is necessary to support their reimbursement decisions. This is crucial as standards of care vary from one system to another and data that might be relevant in a country might be less so in another.[11] While some countries for example might assess the value of a new drug by comparing it with treatment *X*, others will need to compare with treatment *Y*. Therefore, a balance is necessary to prevent the duplication of work, while boosting the mutual trust among Member States necessary to drive the cooperation forward.

Unfortunately, the Commission's proposal entails insufficient flexibility and only grants Member States the possibility to conduct their own clinical assessments in strictly limited circumstances justified by public health reasons.[12] **BEUC insists that the exemption circumstances must be broadened to ensure that national health care standards will not be undermined by the joint assessments**.

In line with the European Parliament's position, we therefore urge the co-legislators to ensure that the final text will allow Member States to:

- Complement EU reports with additional analysis and data that were not part of the joint assessments;
- Take into account clinical evidence that is relevant to their specific national context and that is necessary to their national HTA process;
- Disregard the joint report where they need to compare a new drug with a different treatment;
- Update the EU assessment at a later stage if this is necessary to fulfil the requirements of reimbursement contracts;[13]
- Draw their own conclusions on the added value of the health technology concerned, and therefore freely decide whether to continue the (non-clinical) assessment at national level.

While these conditions are crucial to respect the differences among health care systems, **the Regulation must at the same time prevent abuse of these flexibilities**. Therefore, countries should only be able to opt out from the use of the EU reports *after* they provide a compelling justification to the Commission.

BEUC demands:

- **The co-legislators must ensure that Member States will not replicate the joint clinical assessments conducted at EU level.**
- **However, the new Regulation must guarantee sufficient flexibility for Member States to complement EU joint clinical assessments with additional analysis, where justified.**

[11] This is for example the case with social or epidemiological aspects used by some HTA bodies in their evaluations and that vary a lot between EU countries.
[12] See article 34 of the EU Commission proposal.
[13] This might be the case if a country signs a Managed Entry Agreement with a drug maker, which requires the collection of data after a certain amount of time.

3.3. HTA must be independent from private economic interests

As HTA is crucial to pricing and reimbursement decisions, strong safeguards are needed to ensure that all decisions in the new system are taken on the basis of evidence, without pressure from other interested, economic parties. The Commission's proposal states that members of the Coordination Group shall respect the principle of independence but suggests adopting specific rules through implementing acts.

The European Parliament greatly improved the proposal as it specifies that **members of the Coordination Group must not have any financial interest with the manufacturer submitting the dossier, nor with its possible competitors.** We recommend that this principle is established in the legal text itself, rather than through implementing measures. This would help prevent undue influence in the HTA process and increase the robustness of the system. Moreover, it would avoid the unfortunate situation where, in case of positive assessments, public opinion distrusts the decision and ultimately the credibility of the whole system.

The Regulation must further ensure a clear separation of roles in the scientific advice process: where an expert advises on how to conduct the HTA, that expert should not take part in the final assessment of the same product. **Separating the roles would reinforce the principle that the final assessments are based only on scientific evidence and not biased by the relationship developed between the company and the expert during the development of the scientific advice**. Exceptions to this separation of roles could be foreseen for those situations, where the complexity of a dossier makes it impossible to identify two different experts. However, exceptions should be strictly limited, and justified to and approved by the Coordination Group. BEUC in this respect welcomes the safeguards introduced by the text adopted by the European Parliament.

BEUC demands:

- **The co-legislators should include strict rules on conflict of interest for experts taking part in the HTA assessments. Experts participating in the joint scientific consultations must be different from those expressing their view in the joint scientific assessments.**

In parallel, it is imperative that the new HTA mechanism does not risk regulatory capture. Public funding to finance the new mechanism is therefore the best option and we strongly call on the co-legislators to support the Commission proposal on this point. The European Parliament already followed this approach, as it called on the EU to ensure a stable and permanent public funding of the new mechanism.

However, in case further resources will be necessary in the future, a possible fee-paying mechanism must guarantee robust firewalls. **Strong safeguards will be needed to prevent the HTA mechanism from becoming overly reliant on fees by manufacturers**.

Accordingly, an ideal solution would combine sufficient contributions from the EU budget and Member States with a pool of industry fees. Specifically, the Regulation should oblige manufacturers seeking assessment to pay into a common fund financing the cooperation, therefore avoiding a direct pay-for-service mechanism. This would help sever the link between the manufacturer, the fee and the outcome of the assessment process.

The Regulation should empower the Coordination Group to adopt such a fee structure to ensure that industry contributes proportionally to the future HTA work.

BEUC demands:

- **Public funding is the preferred option to finance the new HTA mechanism. In case this will not be entirely possible, the co-legislators should ensure a proportionate mix of public and private resources. To ensure that, it must prevent a pay-for-service mechanism and instead focus on a common fund.**

3.4. Transparency must be the default option

The new European HTA mechanism will deliver reports that will be crucial to shape pricing and reimbursement decisions for health treatments. Therefore, **transparency must be the cornerstone of the process to make public authorities accountable for their decisions**. This is particularly important when national authorities will decide to refuse a reimbursement, or when they will accept to pay a high cost for it.

Unfortunately, the Commission's proposal does not guarantee that the procedures will be sufficiently transparent throughout the whole process. For example, the text grants the Coordination Group the right to report only an 'anonymised summary information'[14] on the joint scientific consultation ('early dialogue/scientific advice'). These consultations are meetings between HTA experts and the applicant, which take place prior to the submission of a dossier to ensure, for example, that all data are included. As highlighted by the European Ombudsman,[15] such a practice risks creating a perception of bias in the eyes of citizens. Therefore, information discussed during joint scientific consultations must also be publicly available. The publication of this information can be useful also to other companies, to learn which type of data/questions are requested by HTA bodies and reduce the necessity of having these meetings in the future.[16] Where companies believe that some information should remain confidential, it must be clearly justified to the Coordination Group, who should decide whether such concerns are founded or not.[17]

Likewise, while the proposal foresees the publication of joint clinical assessments, it does not specify that comments submitted during the discussions should be public. Patients have the right to know how decisions are taken and to be aware of possible dissenting opinions. BEUC therefore calls on the co-legislators to ensure that such comments are made public. Finally, every time a joint assessment will start, this should be reported in the public database, so that stakeholders are aware of the ongoing process over a product.

Against this background, BEUC welcomes the European Parliament's position which includes measures to ensure the necessary degree of transparency in the process.

[14] See article 14 para 2 of the EU Commission proposal.
[15] Letter from the European Ombudsman to the European Medicines Agency opening strategic inquiry OI/7/2017/KR into pre-submission activities organised by the Agency, July 2017.
[16] In case of recurrent questions, guidelines should be developed for assisting companies in submitting the dossier.
[17] Patient involvement in Health Technology Assessment in Europe - An interim report on EPF survey with HTA Agencies.

BEUC demands:

- **The co-legislators should ensure the highest level of transparency in the process, especially about the publication of joint scientific consultations and reports. Dissenting voices during the process must be reported in the report as well.**

3.5. A longer transition period is needed

Member States will need time to adapt their national systems to a harmonised European HTA mechanism. Therefore, **the Regulation should ensure a stepwise implementation**. We consider that the transitional period of three years proposed by the Commission should be further extended. This would benefit those Member States with less developed HTA capacities; in the transition period, they could join the EU HTA as observers while reinforcing their own national procedures.

We further recommend that a capacity building process is included in the proposal to effectively raise the HTA capacities in those Member States that today have limited experience with and resources for HTA.

Furthermore, after the transitional phase *all* medical products falling within the scope will be assessed. As such, we believe that a longer transition phase will be needed to ensure the success of the new mechanism.

BEUC demands:

- **The co-legislators should extend the transitional period and ensure a stepwise cooperation.**

4. How the new European HTA mechanism needs to work

4.1. Manufacturers must disclose *all* clinical data…

The quality and success of the joint EU assessments will depend on data used during the HTA process. The more clinical data the manufacturer provides, the better and more precise the assessment will be.

The Commission's proposal refers to this aspect but delegates the rules governing data requirements to implementing acts. **BEUC strongly disagrees with this approach and considers this an essential requirement that needs to be clarified in the Regulation itself**. As specified in the text adopted by the European Parliament, the Regulation must in particular oblige the manufacturer to submit *all* available information on the product under assessment. This includes data from all studies in which the technology has been tested and studied, the status of these studies (ongoing, stopped, finished, *etc*.) as well as results from both positive and negative trials.

Today, many assessments consider only positive results, meaning trials where the technology has proven to perform well. Yet, to have a full picture, it is crucial to analyse also those trials that failed the test. Manufacturers should provide the information in a structured way, as defined by the guidelines approved by the Coordination Group.

BEUC demands:

- **The co-legislators should ensure that the manufacturer provides a list of all studies in which the technology has been assessed, in a structured manner and including the status of these studies. Both positive and negative results must be considered in the joint clinical assessment.**

4.2. …And be fined if they fail to do so

As the quality of data is crucial, the new HTA mechanism needs to ensure that manufactures provide all data. As foreseen by the European Parliament, the co-legislators should therefore introduce a penalty mechanism to guarantee that companies provide all relevant data. We further suggest that a possibly to suspend the assessment until all data are provided is introduced. In case of deliberate omissions or unjustified delay, dissuasive fines should be imposed on the manufacturer.

4.3. Comparison with actual medicines, not placebos

As the European Parliament proposed, the Regulation must specify that industry shall – wherever possible – provide studies ('comparative trials') where they compare the new product against the best available treatment.

Today, most trials are conducted against placebo where the value of a new treatment is measured by comparing it to an inactive substance such as sugar or distilled water. Such comparisons provide an insufficient basis for assessment. It might thus lead to situations where several drugs are developed to treat the same disease, but no information is available on which treatment works better than the other.[18]

BEUC demands:

- **The Regulation must oblige the manufacturer to conduct comparative trials against the best available treatment, not placebos.**

4.4. Orphan medicines should receive the same treatment

Patients and consumers should receive the best available treatments. Accordingly, all medicines should be assessed with the same rigour. While the Commission proposal does not include a reference to the methodology to be used in assessments, we consider that the legal text itself must specify that all drugs should be assessed with the same rigorous standards. The European Parliament's position rightfully addresses this point in the Regulation. Unfortunately, the Parliament's position foresees the possibility of having '*tailored approaches'* for assessing orphan drugs.[19] In practice, such an approach would allow the new HTA mechanism to rely on limited data for the assessment of orphan drugs, *i.e.* those used to approve the drug by the European Medicine Agency (EMA).

[18] A disease looking for innovative drugs: The case of pulmonary arterial hypertension, September 2018.
[19] Orphan drugs are medicines that threat rare diseases.

Often, however, the data available to approve orphan drugs is less robust than standard clinical trials data. Evidence from recent studies shows that many drugs approved with this data do not provide additional benefits to patients or come to the market with great uncertainties about their value.[20]

Orphan drugs represent a huge share in the pharmaceutical market, and their number has increased in recent years, placing a dramatic pressure on national health budgets.[21] As the number of orphan drugs is expected to grow in the future,[22] it is crucial to have information about their benefits and, whenever possible, about their added value compared to existing treatments. With this regard, HTA can act as an important gatekeeper: for example, they can limit reimbursements to a limited group of patients but also push the industry to collect more data prior to submitting the dossier.

BEUC demands:

- **The co-legislators should ensure that all drugs will be assessed with the same rigour, with no exceptions for orphan medicines.**

4.5. More medical devices need to be included in the scope of the Regulation

Some medical devices, such as pacemakers or hip implants, have a huge impact on consumers' lives. Their quality is paramount for consumers. We therefore strongly support the Commission's proposal to include medical devices of class IIb and III, which are considered at highest risk[23] and include, for example, anaesthesia machines and pacemakers. We likewise welcome the possibility for the Coordination Group to include assessments of medical devices that respond to unmet medical needs, have potential impact on patients, public health or health care systems, have significant cross-border dimension and major Union-wide added value. We finally recommend that also medical devices which lack clinical evidence with regard to their effectiveness are included.

First, consumers need to be reassured that these products effectively deliver the results they promise. The new Regulation on Medical Devices thus only covers the safety aspect of medical devices, without considering their effectiveness. Second, medical devices have a big impact on health care budgets.[24] Therefore, as for medicines, it is paramount that their price mirrors their value. Thirdly, the proposed HTA Regulation presents an opportunity for EU countries to further develop an assessment methodology for medical devices.[25] Stronger HTA on medical devices means more data on their effectiveness which would help reassure consumers that they pay for medical devices that are worth their money.

[20] Drugs in Oncology: an overview of benefit and refund practices in Europe, Grössmann, Wild, and Mayer, 2016.
[21] Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States, June 2016.
[22] Global Orphan Drugs Market: Industry Analysis & Outlook (2018-2022), July 2018.
[23] Currently all medical devices are classified under class I, IIA, IIB or III, with class III being the highest risk class. See EU Commission website.
[24] Statement supporting the inclusion of a broad scope of medical devices in the proposed Regulation on Health Technology Assessment, European Social Insurance Platform, July 2018.
[25] Through EUnetHTA, countries have already dramatically advanced in this process, to the point that joint appraisal of medical devices has overcome those on medicines.

BEUC demands:

- **BEUC calls on the co-legislators to support the inclusion of medical devices in the scope of the Regulation and recommends that also those medical devices for which authorities lack greater clinical evidence with regard to their effectiveness are included.**

5. The role of stakeholders

5.1. Patients and consumers must have their say

Consumers are the end users of health technology; therefore, the new HTA mechanism should ensure that their views and needs are considered. The Commission's proposal foresees the possibility to consult with patients during some part of the process (for example during the draft of the joint clinical assessments report and the identification of emerging health technology). However, patients are excluded from other tasks and we therefore welcome the European Parliament's proposal on how to extend their role.

As suggested in the Parliament's position, **patient and consumer groups should have the opportunity to provide input during the drafting of the annual work programme**. Such input could help identifying emerging health technologies that are expected to have a major impact on public health or health care systems. Similarly, consumer groups can help identify drugs or medical devices that are already on the market for which new clinical evidence has emerged. Likewise, consumer groups should have the opportunity to contribute to the drafting of the joint clinical assessments, for example in relation to the side effects of a vaccine, a new antibiotic or the functioning of a pacemaker.

While 'patients' are also consumers, BEUC considers that the views of both groups should be considered in the new HTA mechanism, for several reasons:

- The view of consumers matters, both as patients and as taxpayers. In some cases, they pay for medicines, medical devices and surgeries out of their pockets, while they subsidise health care systems through taxes.
- Consumer groups can complement the view of patient organisations as they have a public health perspective and therefore do not represent the interests of a specific-disease group.
- Consumer organisations are in contact with people who have been or will be patients in the future.

BEUC demands:

- **The co-legislators must ensure that patient and consumer organisations are both involved in the EU HTA mechanism, both during the drafting of the work programme and during the joint clinical assessments.**

5.2. HTA decisions must not necessarily mirror those of the EU Medicines Agency

The European Medicine Agency (EMA) and the HTA bodies look at different data and answer different questions. The EMA grants a marketing authorisation when the benefits of a medicine outweighs the harm to patients. In other words, the Agency evaluates the *efficacy.* By contrast, HTA bodies look at how drugs or devices work in practice and to what extent they improve patients' conditions compared to existing treatments. In other words, they assess the *effectiveness*.

Despite these difference in competence, the Commission proposes a system which would encourage EMA and HTA experts to coordinate the consistency of their conclusions.[26] BEUC disagrees with this approach and welcomes the proposal of the European Parliament that would prevent an alignment on the data they consider. HTA bodies have repeatedly highlighted their need to have different evidence than that used by the EMA. Therefore, a clinical alignment would not improve the quality of their assessments.

The Regulation should instead establish a mechanism for ensuring that the joint reports will be made available in time for reimbursement decisions. However, the text must not align the HTA process, and the availability of assessment reports, to the EMA's decision on marketing authorisation. Aligning the two processes would put excessive pressure on the work of the HTA experts and potentially undermine the quality of their assessments.

In addition, we support proposed possibility for the Coordination Group to update assessment reports in cases where a drug is granted conditional authorisation or when new evidence is available. This is important to ensure the reports will be useful for those Member States that assess technologies at a later stage.

BEUC demands:

- **BEUC calls on the co-legislators to ensure a timely delivery of the joint clinical assessment reports, while guaranteeing that the process will be independent from EMA's decisions. A mechanism must be foreseen to ensure the update of the reports.**

6. Conclusion

The current mandate for EU cooperation on HTA expires in 2020. The EU has invested considerable resources to promote cooperation in this area – but an entirely voluntary system no longer appears tenable. The current system has so far led to modest results, with low uptake of joint work.

A stable mechanism to facilitate cooperation among HTA bodies around Europe is needed. This would be particularly beneficial for those Member States that do not have a robust system in place, and therefore either pay a price that is too high or deny the reimbursement at the expense of patients and consumers.

[26] See article 13 point 10 of EC proposal.

A new EU HTA mechanism will only succeed if backed by sufficient human and financial resources. To this end, we call on EU leaders to ensure that appropriate funds are made available under the multi-annual financial framework, while sufficient staff resources within the Commission services must also be guaranteed.

ENDS

BEUC The European Consumer Organisation

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