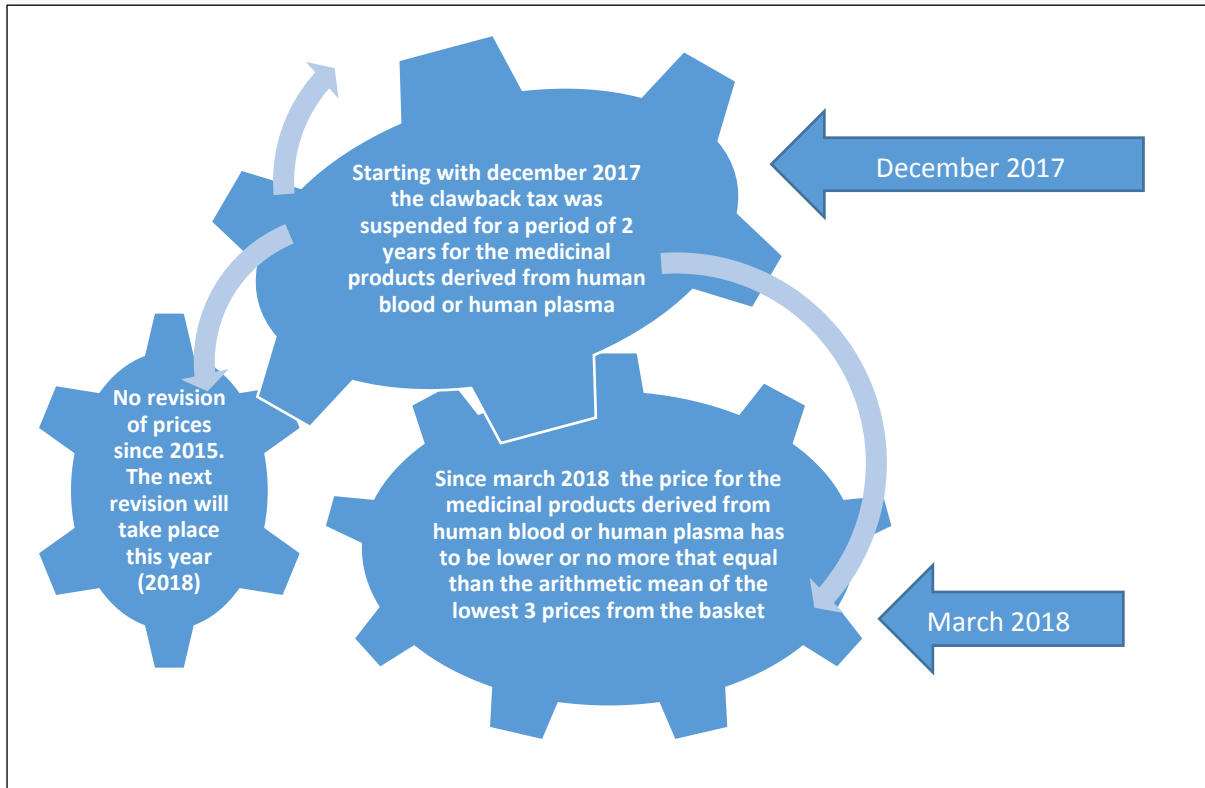


ROMANIA

Recent and planned developments in pharmaceutical policies 2017/2018

Special topic: patient involvement in pricing and reimbursement of medicines

CHANGES IN PRICING



CHANGES IN REIMBURSEMENT

Since January 2018 the methodology for evaluating new INN's in order to be introduced in the reimbursement List has been completed by granting 80 points score (100 max.) for new INN derived from human blood or human plasma used in the treatment of rare diseases where there is no other therapeutic option.

As a consequence of the major immunoglobulin crisis Romania has faced

OTHERS CHANGES

New possibility for the MAH to submit electronically their documentation in order to approve the maximum price thus reducing bureaucracy and foster efficiency.

IT

SPECIAL TOPIC: Patient Involvement in Pricing and Reimbursement of Medicines

HOW? and WHO?

- Formal procedure: Law no. 52/2003 on decisional transparency in public administration **provides for the active participation of citizens** in the administrative decision-making process and in the drafting of normative acts.
- Can send **proposals, suggestions, or opinions** every citizen (patient), legally established organization (patients organizations), NGO etc.

Role & impact

- The public authority concerned (Ministry of Health) is obliged to organize also a public debate in which every citizen or representative of an organization **has the right to make their opinion known**.
- The minutes of these meetings will be **recorded, archived and made public**.
- When the authorities decide to not take into consideration their suggestions/opinions/ or proposals, **are obliged to justify in writing the rejection of the recommendations** formulated and submitted in writing by citizens and their legally constituted associations.
- As public consultation is mandatory then this happens **whenever** a draft has been published in transparency.
- Mostly, the impact of the involvement is **minimal** because of the budgetary constraints faced by the authorities.
- Any person who consider their rights harmed during the public consultation procedure (eg. his participation was denied, absence of an official answer from the authorities etc), **may file a complaint** under the provisions of the Law on administrative litigation no. 554/2004, as amended and supplemented.

HTA

- Regarding HTA, it applies the same procedure as above (no distinction). There is **no direct involvement** of the patients during the assesment procedure.
- Considering that public consultation is 100% transparent then no conflict of interest declaration has to be sign.