TURKEY

Recent and planned developments in pharmaceutical policies 2019

Special topic: patient-based reimbursement decisions

CHANGES IN PRICING

- Euro conversion rate changed to 60% from %70.
- 26,4% price increase applied all medicines.

CHANGES IN REIMBURSEMENT

- No changes since 2018.

OTHERS CHANGES

- Turkey became co-sponsor of Italian Government proposal to World Health Assembly regarding "Improving the transparency of markets for medicines, vaccines, and other health-related products and technologies"
- Strengthening to IT system and electronic database

SPECIAL TOPIC: patient-based reimbursement decisions

- **Who evaluates and takes the reimbursement decision?**
- Turkish Medicines and Medical Devices Agency responsible to take decision for use of medicines which are not yet available in the market. This includes non-authorised medicines and early access programmes. Reimbursement decision taken under ''Medical and Economic Evaluation Commission for Medicines Bringing From Abroad'' (MEEC-MBFA) and commission evaluates submission based on public health need of the product.
- **Under which conditions the reimbursement decisions are made? (reimbursement rates? Are decisions made one time only or do you need to make multiple decisions for the same patient? Is there a time limit?)**
- Social Security Institution (SSI) takes reimbursement decision in inter-ministerial commission. Reimbursement rate define by SSI. There are two separate conditions; a group of product can be used under defined conditions without prior approval of Turkish Medicines and Medical Devices (TMMDA). Rest of the product has to take approval for each patient for defined period (i.e. 3 months) and it has to renew submission for evaluation end of the approval period. Specific use of conditions defined by TMMDA for each product.
- **How does the procedure look like (both out-patient sector, in-patient sector)?**
- There is no specific difference for in-patient or out-patient sector.
- **Under which criteria the procedure will be started usually (e.g medicine is already reimbursed for other indications, medicine does not have marketing authorization in the country, medicine is under evaluation at EMA etc)?**
- There is no such limitation, TMMDA Scientific Commission evaluates all submission with scientific evidences.
- **Which criteria are applied (assessment of clinical efficacy and cost-effectiveness, price negotiation and its fixing possibilities, co-payment mechanisms with the manufacturer)?**
- Permission for usage based on only clinical efficacy and scientific evidence and this permission does not guarantee reimbursement. Social Security Institution evaluates reimbursement submission based on cost-effectiveness, price and current alternative therapies.
- **Besides off-label and direct import use of medicines following options available;**
- Early access programs (Compassionate Use Program): Approximately 35 programs each year.
- Clinical Trials provide early access to innovative therapies. In average 6500 patients accepted to clinical trials programmes between the years 2015-2017.
- Iron, screening tests (such as for cancer), vaccines, tuberculosis medicines, quit tobacco medications, dental health products provides for free from Public Health Institute other Government bodies