Analysis of the Time to Market Access in Bulgaria of New DAA Medicines for Chronic HCV Infection Authorized Under the EMA Specific Procedures for Early Access

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OBJECTIVES

The objective of the study is to evaluate time to market access since marketing authorization of new direct acting antivirals (DAA) for HCV.

BACKGROUND

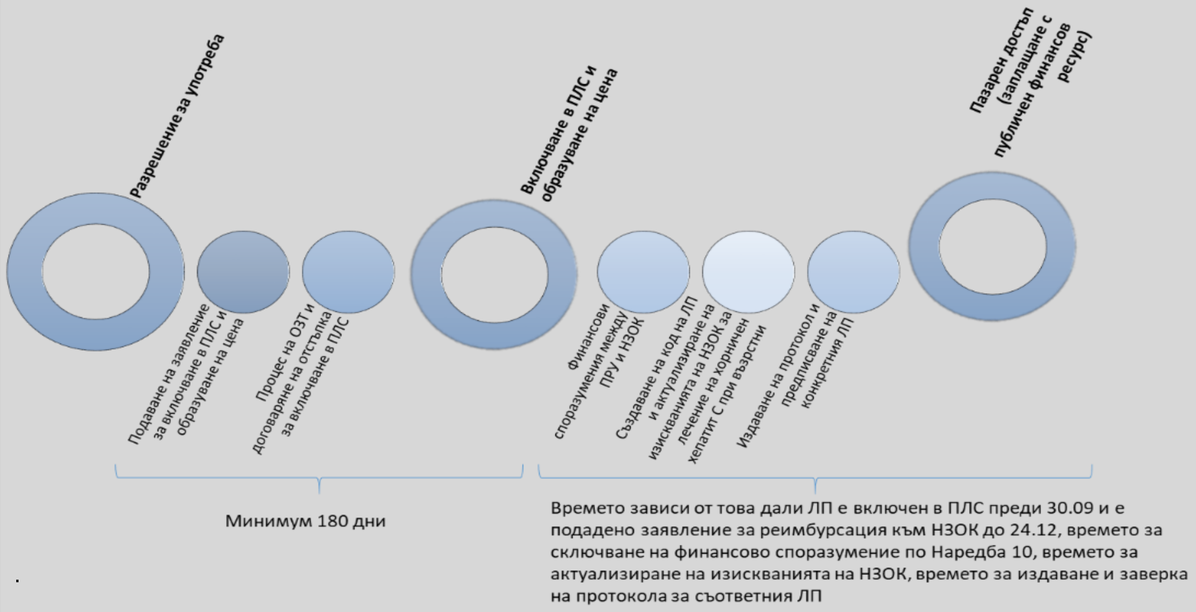
- European medicines agency (EMA) supports early patient access to innovative therapies, especially in areas with unmet medical needs or high social burden (oncology, rare diseases, chronic diseases, etc)
- Patient access to innovative therapies improved significantly with the introduction of several specific procedures - conditional approval, accelerated assessment, approval under exceptional circumstances and compassionate use

METHODS & MATERIALS

- First, we analysed the EMA database for type of specific procedure and date of marketing authorization and the Bulgarian Positive drug list (PDL) for time of inclusion of the new DAAs
- Time to market access was evaluated as the elapsed time from EMA's marketing authorization to inclusion in Bulgaria's Positive Drug List as well as to the actual time of reimbursement by the National Health Insurance Fund Second (NHIF)

RESULTS

- EMA introduced the specific procedures for early access in 2002 and since then has issued 29 conditional approvals, 34 exceptional circumstances and 39 accelerated assessments
- 7 out 8 authorized DAAs for chronic HCV infection are authorized with accelerated assessment.
- All of the medicines are included in PDL as time inclusion in PDL in Bulgaria since marketing authorization in the EU is 1-1.5 years on average in 2014-2016 and 2 years in 2017-2019



RESULTS

Time to reimbursement varies from 6 months to 1 to year since inclusion in PDL

INN/ Trade name	Marketing authorization in EU	Inclusion in PDL	Inclusion of the MP in the criteria of NHIF for therapy initiation	Actual financial coverage by NHIF
SOF/LDV (Harvoni)	16/11/2014	25/11/2015	01.03.2016	Q2 2016
Dasabuvir (Exviera)	13/01/2015	10/11/2015	01.03.2016	Q2 2016
OMB/PTV/r (Viekirax)	13/01/2015	10/11/2015	01.03.2016	Q2 2016
ELB/GRZ (Zepatier)	21/07/2016	22/12/2016	16.01.2017– 15.02.2017 07.03.2017	Q2 2017
SOF/VEL (Epclusa)	05/07/2016	22/12/2017	01.04.2018	Q3 2018
GLE/PIB (Maviret)	25/07/2017	29/11/2018	15.04.2019- 01.10.2019 04.10.2019 01.10.2019- 31.12.2019	Q2 2019
SOF/VEL/VOX (Vosevi)	25/07/2017	10/09/2019	01.01.2020	Q1 2020

DISCUSSION

- The difference in time to market access between the two observed periods may be attributed to the dynamic pharmaceutical legislation in 2016-2019 which experienced a lot of changes in the health technology assessment domain.
- The NHIF database analysis shows that in 2019 the criteria for treatment initiation have been changed 3 times. The possible reason for this frequent change would be that the law on health insurance also underwent some changes in the same year, according to which the prescribing of medicines for treatment of chronic HCV infection could be according to their comparative cost-effectiveness.

CONCLUSIONS

Nevertheless there are mechanisms in place to foster patient access of innovative medicines for unmet medical needs and diseases with high social burden, there are still some barriers to earlier market access attributed to nationally specific pricing and reimbursement practices.

REFERENCES

1. https://encr.eu/registries-network. Accessed on: October 2020
2. Mosle F, Remon J, Mateo J et al. Recommendations for the use of next-generation sequencing (NGS) for patients with metastatic cancer: a report from the ESMO Precision Medicine Working Group. Annals of Oncology 2020; 31(11):1491-1505
3.Leamon J. Incorporation of NCCN guideline information in NGS-based cancer testing panel design. Journal of Clinical Oncology 2017; 35:15_suppl, e13099-313099
4. Rules for inclusion and payment of new medical procedures and medical devices of the National Health Insurance Fund. 2020. Available at: www.nhif.bg. Accessed on: October 2020
5. Phillips KA, Douglas MP. The global market for next-generation sequencing tests continues its torrid pace. J Precis Med 2018