Issue Monitoring

Pharmaceutical Market Progress Report

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High Politics

Romanian Society of Diabetes, Nutrition and Metabolic Diseases debate on World Diabetes Day: The Romanian Society of Diabetes, Nutrition and Metabolic Diseases organized an event in which health authorities, physicians and representatives of patient associations discussed the need for prevention and timely detection of diabetes:

The Minister of Health, Alexandru Rafila, stated that it is not enough for prevention to be carried out only through the communication that comes from the family doctor, as education in schools is necessary.

Andrei Baciu, president of NHIH, announced that, together with Gabriela Radulian, president of SRDNBM, it was agreed to launch a task force that will have the role of facilitating as fair an access to medical services as possible.

Carmen Orban, adviser in the Chancellery of the Prime Minister, spoke about the need to develop a dedicated legislative framework, with defined interventions to counteract the risk of diabetes with strategies to delay chronic complications and with the involvement of all stakeholders in the field, emphasizing the opening of the Prime Minister In this regard.

Diana Loreta Păun, Presidential adviser, emphasized the need for a multidisciplinary and integrative approach, as well as a solid intersectoral commitment to act.

Gabriela Radulian, the president of the Romanian Society of Diabetes, announced the start of a campaign to inform and educate the population on the topic of diabetes, *Diabetes without complications,* through which, starting on November 15, for 10 days, 30 video materials will be broadcasted.

Diabetes awareness campaign at the Palace of Parliament: The Romanian Diabetes Forum coordinated an information and awareness action on November 13, in which members of Parliament and journalists received information about the risks of the condition and the importance of prevention. A similar action was carried out by the organization on November 10, involving media representatives.

The event Marathon in Diabetes: Sănătatea Press Group organized the event *Marathon in Diabetes*, which consisted of 24 hours of live transmission aimed at informing and raising awareness about the issue of diabetes, through shows, debates and press conferences. As part of the campaign, Minister Alexandru Rafila spoke about the need for public prevention policies and emphasized that prevention must start from childhood, through health education in schools.

NIPH press release on World Diabetes Day: The National Institute for Public Health published a press release to present details on the types of diabetes and their causes, emphasize that people with diabetes and health professionals must have access to educational programs, and present the WHO targets for diabetes coverage proposed to be achieved by 2030.

Discussions on the pharmaceutical industry and European legislation: Representatives of national authorities, European decision-makers, and representatives of the pharmaceutical industry discussed inter-institutional and inter-ministerial cooperation for the implementation of a strategy that would create an attractive framework for the pharmaceutical industry in Romania, as part of a Calea Europeană and ARPIM initiative.

Ioana Bianchi, ARPIM Director of External Relations, presented the updates regarding the negotiation process in the European Parliament on the pharmaceutical legislation package and discussed the effects of the changes proposed by the European Commission that will also be felt by patients suffering from a disease rare.

MEP Cristian Bușoi, president of the ITRE Committee highlighted that there will be "attacks" against the pharmaceutical industry in the framework of future negotiations for the revision of pharmaceutical legislation and reiterated the support of the Committee for reflecting the industry's objectives.

Adrian Streinu-Cercel, president of the Senate Health Committee, pleaded for the implementation of a European mechanism to ensure access to orphan medication for everyone at the European level and emphasized the need for a paradigm shift for the pharmaceutical industry.

The Medicines and Medical Devices Policy Directorate at the Ministry of Health presented the main objectives of the Ministry of Health in terms of early access to innovative medication for Romanian patients, respectively a new price policy and sustainable reimbursement and a new methodology for evaluating medical technologies.

The Minister of Economy, Ștefan Radu-Oprea, declared that the pharmaceutical industry will have to be a priority for the Romanian Government in the future and spoke about the creation of inter-ministerial centers for discussions and concrete application on the industry's issues.

The Permanent Representation of Romania to the European Union presented an update of the negotiations at the European level regarding the pharmaceutical legislation and emphasized that Romania's position on the package of changes proposed by the European Commission needs to be sent as quickly as possible.

MEP Nicu Ștefănuță, the coordinator of the Greens in the Public Health Subcommittee in the European Parliament, also invited all interested parties to send their positions regarding the pharmaceutical industry so that the national position is reflected better in the future European Parliament negotiations.

Number of eligible patients for medicines: The National Health Insurance House published the number of eligible patients communicated by the specialized commissions of the Ministry of Health related to medicines for cost-volume/cost-volume-result contracts, updated for November, 2023, with information added for ODEVIXIBATUM and EVEROLIMUS.

Notifications on discontinued medicines and intra-community deliveries: The National Agency for Medicine and Medical Devices published the updated list of permanently or temporarily discontinued medicines on November 17 and the updated version of the notifications of intra-community deliveries received from wholesale distributors for the year 2023 on November 16.

Announcement regarding special needs authorizations: In addition, the National Agency for Medicine and Medical Devices published the list of medicines included in the special needs category on November 17, NIFEDIPINUM, MILRINONUM, and MAGNESII SULFAS.

Legislative Updates

The following legislation was published in the Official Gazette:

[SNHSIF supplement] Government Decision no. 1078/2023, aimed at supplementing the Single National Health Social Insurance Fund budget with RON 1.7 billion to cover the necessary expenses for medical services, medicines, materials and medical devices, including the running of national curative health programs and the provision of reimbursed and free medicines for November 2023, was published in the Official Gazette, Part I, on November 10.

[C2 List of medicines] MoH/NHIH Order no. 3810/1008/2023 containing amendments and additions to the list of trade names and reimbursement prices of medicines that are given to patients included in the national health programs corresponding to the INNs contained in section C2 of sublist C of GD no. 720/2008 for November 2023, was published in the Official Gazette, Part I, no. 1030 on November 13.

[Human Medicines Package] Senate Decision no. 174/2023 on the Human Medicines Package - COM (2023) 192 final, COM (2023) 193 final, according to which the Senate considers that the package on Medicines for human use respects the principle of subsidiarity but does not respect the principle of proportionality and makes a series of recommendations to be sent to the European institutions, was published in the Official Gazette, Part I, no. 1039, on November 16.

Updates on current legislation

[SNHSIF supplement] The Chamber of Deputies adopted the draft bill approving GEO no. 78 /2023, which allows the main authorizing officer of credits for the budget of the National House of Social Health Insurance to distribute the amounts withheld in a proportion of 10%, to be allocated for supplementing transfers from the state budget to the budget of the Single National Health Social Insurance Fund.

[SNHSIF, Framework contract, Immunological medicines] The Chamber of Deputies adopted the draft bill approving GO no. 21/2023 containing provisions related to the method of providing immunological medicines which are to be supported by transfers from the state budget, the deadline for the elaboration of framework contracts, and the legal representative of the marketing authorization holder who is not a Romanian legal entity.

[National Prevention Plan] The Committee for Health issued an admission report for the draft bill approving GO no. 40/2023, which establishes the legal and normative frameworks

necessary for the development of the National Health Promotion and Disease Prevention Plan, applicable for 4 years.

[Diabetes mellitus] The Committee for Health issued an admission report for the draft bill approving GO no. 39/2023, which proposes changes and additions to ensure terminological clarifications of all the terms and conditions under which people's access to medical services for the prevention and early detection of diabetes mellitus will be ensured.

[Clawback, NMVS, Food supplements] The Committee for Health issued an admission report with admitted amendments for the draft bill approving GEO no. 88/2023, containing provisions related to medicines, obtaining data from NMVS, exceptions from the obligation of authorized distributors to pay quarterly contributions for medicines, the establishment of the Electronic Health Information Management System, and provisions regarding food supplements.

New Legislation

[Clawback Q3 2023] The Ministry of Health published in consultation a draft order approving the Q3 of 2023 list that contains the classification of medicines for human use authorized to be placed on the market in Romania supported by the Single National Social Insurance Fund of Health and from the budget of the Ministry of Health, in type I and type II medicines, according to the provisions of GEO no. 77/2011.

Issue Monitoring provides companies and business associations with real time alerts and periodic reports on various policies that are under debate in Parliament, Government or Authorities. The monitoring includes the entire legislative life cycle of draft bills, relevant news in mass media and stakeholders' profiles. For an in-depth monitoring, experts are present at public debates and industry events, providing a detailed synthesis of discussions.