

News, current issues

- **Legislations** come into force between 01/08/2016 and 01/09/2016: Act CLIV of 1997 (01.09.2016); Act XCV of 2005 (01.09.2016); NM Decree No.9/1993. (01.08.2016); Gov.Decree No.43/1999. (01.08.2016,02.08.2016,17.08.2016,01.09.2016); ESzCsM Decree No.32/2004. (01.08.2016); EüM Decree No.31/2010. (01.08.2016)
- **ANNOUNCEMENT [HU]:** "Pharma producers' new payment duties" [link](#)
- **NEWS [HU]:** "20 billion HUF shortage in drug budget" [link](#)
- **NEWS [HU]:** "Healthcare, the biggest battlefield of next 1,5 years" [link](#)
- **NEWS [EN]:** "What do patients know about generic biotech drugs?" [link](#)
- **NEWS [HU]:** "New system of patients' main data file is the basis of healthcare reform" [link](#)
- **NEWS [HU]:** "Use of generic drugs is important for everyone" [link](#)

Macro approach to financing healthcare and medicinal products

Balance of the Health Insurance Fund

| Health Security Fund | 2015. I-XII. | 2016 original appropriation | 2016 | | |
|--|----------------|-----------------------------|----------------|--------------------|----------------|
| | | | I-VII. months | % of appropriation | % of last year |
| Total of Budgetary Expenditures | 1 955,3 | 1 963,7 | 1 160,4 | 101,3% | 103,3% |
| Curative preventive provisions | 960,6 | 982,4 | 561,8 | 98,0% | 102,2% |
| Medicine subsidies | 326,2 | 305,1 | 196,4 | 110,3% | 105,4% |
| Medicine subsidies (pharmacy) | 310,6 | 231,4 | 187,7 | 139,1% | 104,5% |
| Total of Budgetary Revenues | 1 925,4 | 1 963,7 | 1 185,8 | 103,5% | 104,9% |
| Social Security Contributions | 1 223,4 | 1 417,0 | 858,3 | 103,8% | 119,8% |
| Contribution of Pharmaceutical Manufacturers and Wholesalers | 65,3 | 58,0 | 42,2 | 124,8% | 111,1% |
| Balance | -29,9 | 0,0 | 25,5 | | 375,2% |

Billion HUF

In expenditures and revenues of 2016 budget, there is 2,77% increase compared to appropriation of 2015 and 0,43% increase compared to fulfilment of 2015. The central budget contribution is planned to be less with 26,5% than last year fulfilment, and this gap is filled with the 18,2% higher social security contribution (218 billion HUFs). The medicine subsidies plan is lower with 21,2 billion HUFs than last year expenses, but higher with 7 billion HUFs than the last year's original appropriation.

In the first seven months of 2016 the Health Security Fund produced a 2,22% surplus due to the higher social security contributions (+31,69 billion HUFs; +3,8%) and the lower expenditures of curative preventive provisions (-11,23 billion HUFs; -2%). Medicine subsidies shows 10,3% surplus as a result of the medicines' higher turnover particularly that reimbursement based on special permission, and reimbursement of medicines without reference price group.

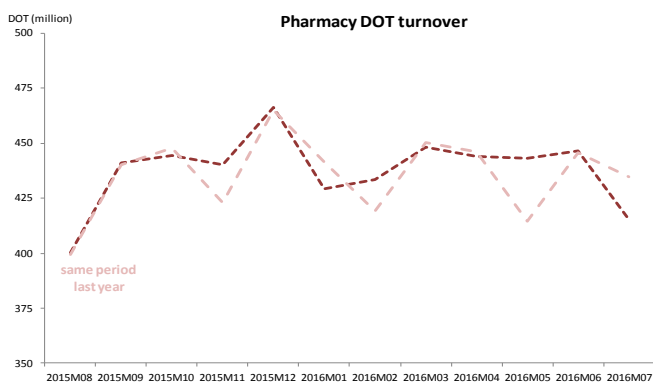
Changes to subsidised medicinal product categories

| Changes in the public drug list | 2016 Apr. | 2016 May | 2016 June | 2016 July | 2016 Aug. | 2016 Sep. | 2016 |
|---------------------------------|-----------|----------|-----------|-----------|-----------|-----------|------|
| Number of new products | 12 | 7 | 17 | 9 | 15 | 47 | 163 |
| Number of new AI | 0 | 0 | 0 | 2 | 0 | 0 | 8 |
| Number of delisted products | 36 | 19 | 1 | 11 | 31 | 6 | 158 |
| Prices | | | | | | | |
| Decrease | 59 | 1 | 0 | 43 | 2 | 3 | 147 |
| Increase | 3 | 0 | 0 | 5 | 0 | 0 | 8 |

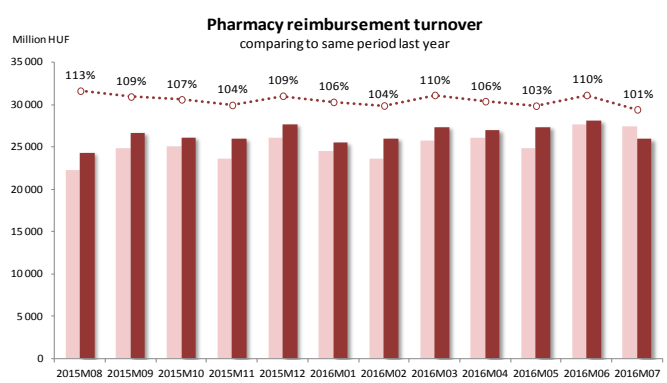
| Changes in the public drug list | 2016 Apr. | 2016 May | 2016 June | 2016 July | 2016 Aug. | 2016 Sep. | 2016 |
|---------------------------------|-----------|----------|-----------|-----------|-----------|-----------|------|
| Reimbursement | | | | | | | |
| Decrease | 155 | 1 | 0 | 53 | 0 | 5 | 261 |
| Increase | 138 | 0 | 0 | 6 | 36 | 0 | 206 |
| Co-payment | | | | | | | |
| Decrease | 200 | 2 | 0 | 52 | 2 | 7 | 340 |
| Increase | 123 | 0 | 0 | 23 | 36 | 1 | 200 |

Source: Healthware analysis based on OEP-PUPHA data

Dynamics of the sales/circulation of prescription-only-medicine



Source: Healthware analysis based on OEP's data



Source: Healthware analysis based on OEP's data

Prescription drugs' DOT turnover in 2015 was 1,04% higher than in 2014, so the trend of drug consumption is still increasing, but in slower rate than in 2014 (2,74%) or 2013 (2,23%); while the reimbursement turnover was higher with 7,44%. The average reimbursement per DOT was higher with 6,34% than the 2014's average. New innovative reimbursement decisions were made in 2014 and 2015 generated 3,1% and 0,65% of annual reimbursement turnover, while only 0,4% of annual DOT turnover.

Drug sales in the first seven months of 2016 was 0,27% higher than the same period last year, while the average reimbursement per DOT increased with 3,58%. The reimbursement turnover was higher with 3,86% for this period compared to last year.

Public turnover data in our Medalyse service

With our service Medalyse for our clients, public turnover data published by NHIF is easily available and it is possible to follow them with time series analysis.

The turnover data – considering the experience of past half year – is published after a shorter period by NHIF, so it is available on the following 16-18th day after the given month.

As contribution, Healthware takes under to upload the data in the information system of Medalyse, if it is possible within 1 workday, therefore our clients are free to reach and analyse the turnover data of NHIF on the 20th day after the given month.

Detailed description about the data published by OEP: [link](#)

Details about Medalyse: [link](#)

Product offering



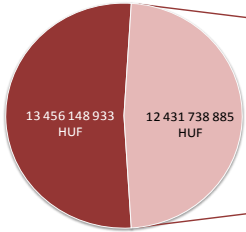
Market data

Marketing authorisation information

| 2015 | EMA | OGYI | 2016 - Q2 | EMA | OGYI | July 2016 | EMA | OGYI |
|------------|-------|-------|------------|-----|------|------------|-----|------|
| New brands | 91 | 190 | New brands | 20 | 57 | New brands | 8 | 16 |
| New SKUs | 1 081 | 2 230 | New SKUs | 161 | 542 | New SKUs | 28 | 115 |

Source: Healthware analysis based on OGYI's and EMA's data

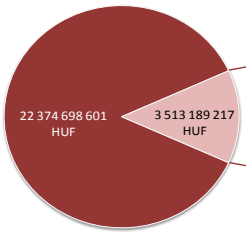
TOP10 DISTRIBUTOR by all reimbursement paid in July 2016



| TOP 10 - DISTRIBUTOR | Reimbursement |
|--|-------------------|
| Novartis Hungária Kft. | 2 482 542 276 HUF |
| SANOFI-AVENTIS Zrt. | 1 734 765 241 HUF |
| EGIS Gyógyszergyár Zrt. | 1 339 960 214 HUF |
| Richter Gedeon Vegyészeti Gyár NyRt. | 1 236 532 319 HUF |
| Pfizer Kft. | 1 116 461 057 HUF |
| TEVA Gyógyszergyár Zrt. | 1 025 872 024 HUF |
| Novo Nordisk Hungária Kft. | 1 007 179 323 HUF |
| Sandoz Hungária Kereskedelmi Kft. | 871 012 094 HUF |
| Janssen-Cilag Gyógyszerkereskedelmi Marketing Szolgáltató Kft. | 816 306 896 HUF |
| Lilly Hungaria Kft. | 801 107 441 HUF |

Source: Healthware analysis based on the sales turnover that pharmacies produced from POM

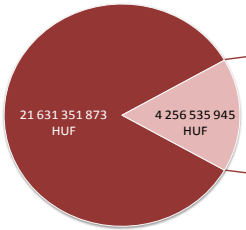
TOP10 BRAND by all reimbursement paid in July 2016



| TOP 10 - BRAND | Distributor | Reimbursement |
|----------------|---|-----------------|
| CLEXANE | SANOFI-AVENTIS Zrt. | 570 415 144 HUF |
| GLIVEC | Novartis Hungária Kft. | 529 022 130 HUF |
| XEPLION | Janssen-Cilag Gyógyszerkereskedelmi Market | 439 772 780 HUF |
| TECFIDERA | Biogen Idec Hungary Kft. | 310 143 046 HUF |
| SPIRIVA | Boehringer Ingelheim Pharma Gesellschaft m. | 307 847 726 HUF |
| LANTUS | SANOFI-AVENTIS Zrt. | 288 027 964 HUF |
| TASIGNA | Novartis Hungária Kft. | 280 595 886 HUF |
| HUMULIN | Lilly Hungaria Kft. | 279 627 543 HUF |
| SUTENT | Pfizer Kft. | 270 595 160 HUF |
| LEVEMIR | Novo Nordisk Hungária Kft. | 237 141 838 HUF |

Source: Healthware analysis based on the sales turnover that pharmacies produced from POM

TOP10 ATC by all reimbursement paid in July 2016



| TOP 10 - ATC | International non-proprietary name (INN) | Reimbursement |
|--------------|--|-----------------|
| V06D | other nutrients | 579 588 196 HUF |
| B01AB05 | enoxaparin | 570 415 144 HUF |
| L01XE01 | imatinib | 529 022 130 HUF |
| N05AX13 | paliperidone | 506 578 904 HUF |
| C10AA07 | rosuvastatin | 413 021 787 HUF |
| A10AE04 | insulin glargine | 397 709 495 HUF |
| A10AB01 | insulin (human) | 330 676 109 HUF |
| C09BA04 | perindopril and diuretics | 311 533 409 HUF |
| N07XX09 | dimethyl fumarate | 310 143 046 HUF |
| R03BB04 | tiotropium bromide | 307 847 726 HUF |

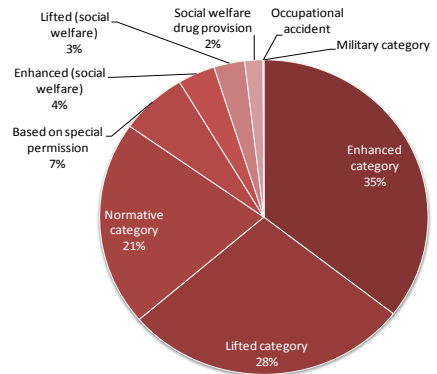
Source: Healthware analysis based on the sales turnover that pharmacies produced from POM

Average number of medical sales reps; 07/2016

| | |
|------------------|-------|
| All | 1 714 |
| Medical products | 1 453 |
| Medical aids | 245 |
| Both | 16 |

Source: Healthware analysis based on OGYI's

Drug reimbursement by legal title; 07/2016



Source: Healthware analysis based on the sales

TOP10 ATC by number of patients in July 2016

| TOP 10 - ATC | International non-proprietary name (INN) | Patients |
|--------------|--|----------|
| B01AC06 | acetylsalicylic acid | 343 563 |
| C09BA04 | perindopril and diuretics | 288 852 |
| C08CA01 | amlodipine | 248 250 |
| C07AB12 | nebivolol | 244 488 |
| C10AA07 | rosuvastatin | 217 243 |
| C10AA05 | atorvastatin | 212 758 |
| A02BC02 | pantoprazole | 211 366 |
| M04AA01 | allopurinol | 205 069 |
| C09AA04 | perindopril | 174 762 |
| C07AB07 | bisoprolol | 168 773 |

Source: Healthware analysis based on the sales turnover that pharmacies produced from POM

Advantages of implementing EESZT in data processing — Case study

Building up and gradually installing Electronic Health Cooperation Service Space (EESZT) has been the largest IT development in Hungarian healthcare recently. Its aim is to digitize all information of the whole sector, including General Practitioners, outpatient and inpatient care, health visitor service and the pharmacies. Test phase has already been started, and production phase will start in the first quarter of 2017¹.

In the current system, data storing, communication and data exchange, and collaborations among the institutions are insufficient² in general, the government wants to improve these with the implementation of a centralized model. The Service Space will be able to create the conditions of the highest level integration of the sector that have been reached so far. Clinical data will be available not just via the local IT service providers but centrally as well, and the opportunity of the quick data merging will be available with the permission of the patients.

The patients can control the collection and use of data: any citizens can set via the Client Gate, which healthcare data can be stored centrally and who has the access to the archived documents. In the future it might be possible for the patients to even require retrospective analysis based on the stored data.

This innovation will affect the medical records managed by the National Health Insurance Fund of Hungary (OEP). For the time being, healthcare data is recorded and stored in separated local systems, and main documentations are commonly poorly structured³. Ex-post verification and correction is often necessary to reach the quality demand of the data supply for OEP⁴. With the implementation of EESZT, data will be stored in a single central database. The process of data providing and report sending is going to happen in the EESZT system, so optimally organized reports as well as rapid, flexible connection among databases of the data centers might be achieved in the future, which will result more consistent databases.

Beyond all of these, setting up a new database is planned for the end of 2019, which would be based on medical records filled out by the General Practitioners and it would provide comprehensive and up-to-date information about the health status of all Hungarian citizens. More than a dozen of risk factors and diseases are going to be recorded, and all of the patients are going to be categorized by their health status, and it is going to be shared via the system of EESZT.

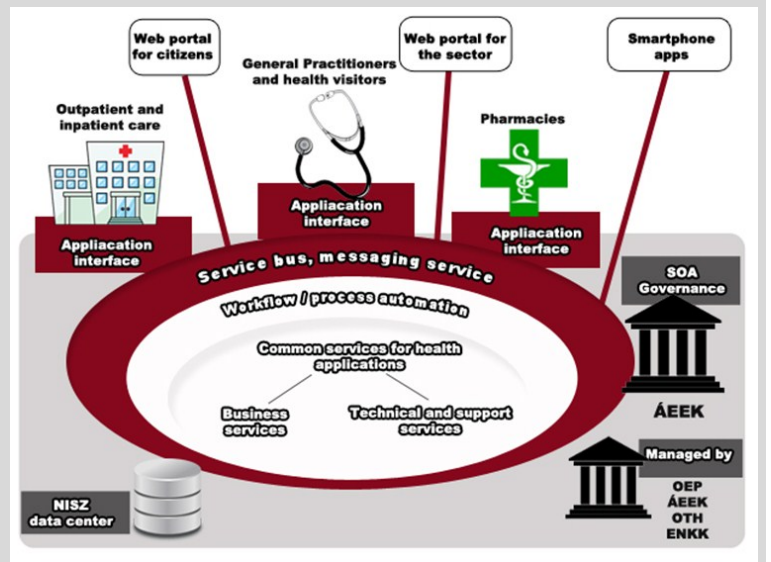
The Healthware Consulting Ltd. works in daily cooperation with the OEP in the data management of many researchers that have effect on a lot of different indications and topics. Of course, the OEP-data means valid and representative source, which serves perfectly the data needs of the researchers. According to our expectations there would be advantages of the widespread use of EESZT for our clients:

- data providing can be faster; due to the institution's data supply towards OEP will simplify
- the centralization may reduce the redundancy of the databases in the whole sector and make them more consistent

- the databases are going to contain more data, which will be more comprehensive and up-to-date, so some of the diseases and their correlation can be researched more accurately, and it can provide opportunity of prospective observational studies
- in case of data requests about diseases that affect only a few patients, even improvement in data can be perceptible

We hope that the operation of EESZT will actually meet the expectations and it will have positive effects on all members of the Hungarian healthcare.

Logical structure of the EESZT's operation:



¹ http://www.medicalonline.hu/informatica/cikk/as_e_health_feljesztosek_nyomaban
² http://nkfia.kormany.hu/download/f/d2/b0000/riop233_utmutato_final_11_28.pdf (5-6. pages)
³ http://nkfia.kormany.hu/download/f/d2/b0000/riop233_utmutato_final_11_28.pdf (5-6. pages)
⁴ http://www.honvedkorhaz.hu/container/files/attachments/478/szerzodes_hbcs_audit.pdf
⁵ <http://docplayer.hu/5369090-Nemzeti-egeszsegugyi-informatica-e-egeszsegugyi-elektronikus-kohziteles-nyilvartartask-es-agazati-portal-felletesi-projekt-belyzettelentese.html>