

Addressing the EU diabetes epidemic – Partnership opportunities between Authorities & Pharma

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Globally, 4.6 million deaths are attributable to diabetes annually and in some countries children and young people die for lack of insulin without ever being diagnosed. Diabetes ranks in the top 10 causes of disability worldwide and undermines productivity and human development. If no action is taken, the number of people with diabetes is predicted to rise from over 366 million in 2011 to 552 million by 2030 or to one adult in ten. No country and no sector of any society are immune. The challenge is to reduce the human and financial costs through early diagnosis and effective management and to prevent new cases of diabetes developing in so far as this is possible.

Early death is only one component of lost income and many people with diabetes suffer from potentially avoidable disabling complications preventing them from working. This represents a substantial loss to the economy and significant expenditures to the social security systems.

The diabetes care is a very complex issue with substantial medical, societal and economical aspects; therefore an effective solution of diabetes needs the strong involvement of all key stakeholders: the medical science, authorities, pharma companies and associations. These players' role is complementary to each other; therefore a full cooperation among them is a must to provide a complex solution to the complex issue of diabetes.

INTRODUCTION

Diabetes is recognized as a worldwide pandemic of the 21st century, world leading organizations, like the WHO and IDF, as well as the EU Parliament have been working out action plans to get prepared to counteract diabetes and its consequences.

This article summarizes the WHO driven initiatives as well as those adopted by the European Parliament. The article also gives a short insight into the current Hungarian situation highlighting opportunities in Pharma & Authority cooperation.

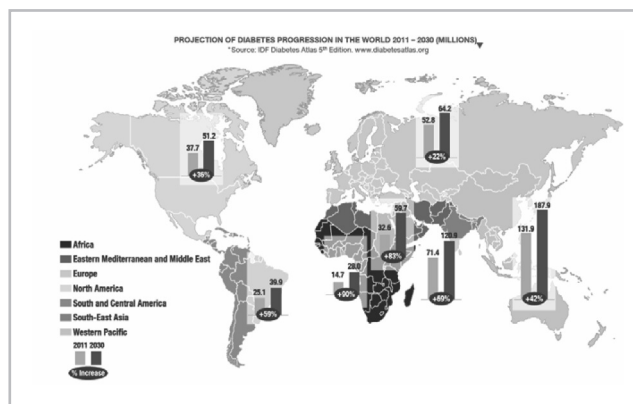
GLOBAL BURDEN OF DIABETES

Diabetes is a global burden both from medical, societal but also from economic point of view. The prevalence of diabetes growing significantly all over the world from 2011 to 2030, as seen in the graph 1. The prevalence of diabetes in

North America will grow by 36% up to 51,2 Mio, quite similarly to Europe, where 64,2 Mio inhabitants would suffer from diabetes by 2030 [1].

In all the regions that have previously been less affected by diabetes growth rates will accelerate even faster, so Asia, Eastern Mediterranean and Middle-East, as well as Australia, but also Africa and South America will be seriously affected by diabetes and its consequences.

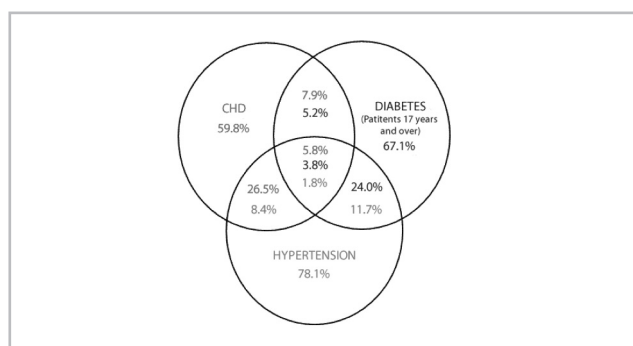
The consequences of diabetes can be evaluated from medical but also from economic aspects.



Graph 1. Worldwide prevalence of diabetes

The medical & societal aspects

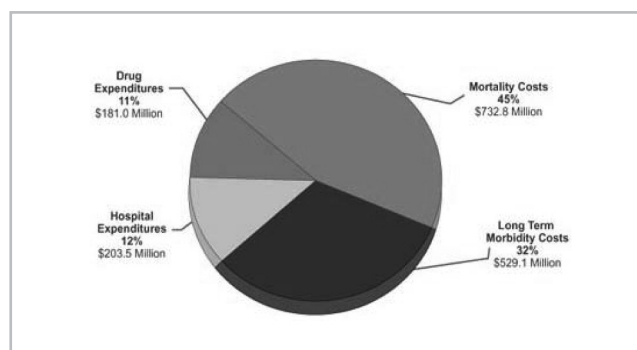
Diabetes is a metabolic disorder that affects other conditions and is affected by other conditions, too. The most common co-morbidities are hypertension and chronic heart disease (CHD). (Graph 2.) Their interrelations are clearly demonstrated through many clinical trials. These co-morbidities affect not only the individuals with diabetes, but they also have a great societal impact just considering family, or the closer company of the diabetes patient [2].



Graph 2. Occurrence of diabetes and co-morbidities

THE DIRECT COST OF DIABETES IS ALREADY UNSUSTAINABLE

Due to the fact that diabetes is a complex disease with co-morbidities that may need short and long-term care, the total cost of diabetes is exponentially exceeding its drug expenditures representing only 11% of total diabetes care. (Graph 3.) The long-term consequences of diabetes are the long-term morbidity and mortality costs, making together 77% of costs of total diabetes care. These direct costs of diabetes care impact national social security systems significantly. Based on results of the EU-wide Diabetes Audit run in 2010-11, approximately 8-9% of GDP is spent on diabetes care on average in 47 EU countries [3].



Graph 3.
Cost of diabetes estimated in the EU

Diabetes has significant indirect impact on national economies

Beyond the direct costs attributable to diabetes in national economies, there is a significant loss at society level; because diabetes has disabling complications preventing patients from working. This represents a substantial loss to the economy and significant expenditures to the social security systems.

HOW DIABETES EPIDEMIC IS ADDRESSED IN GLOBAL INITIATIVES?

Diabetes as a pandemic and the need to get prepared to counteract has been declared by international institutions and organizations. UN General Assembly devoted attention to non-communicable diseases (NCDs), with the attendance of 34 Heads of State and 120 member states expressing concerns about global burden of NCDs and committing to actions in the format of a Political Declaration on NCD Prevention and Control. [4] The four most prominent NCDs are cancers, cardiovascular diseases, chronic respiratory diseases and diabetes.

The re-enforcing point was the Summit of UN General Assembly on Non-Communicable Diseases held on September 19-20, 2011 in New York. Diabetes was in focus of the Summit on the four most prominent NCDs: can-

cers, cardiovascular diseases, chronic respiratory diseases and diabetes. IDF (International Diabetes Federation) declared a new era on this Summit for IDF itself and for the 220 member associations in fighting diabetes, with the main objective of the Summit to launch a Global Diabetes Plan.

The outcomes of the Summit were significant, political declaration was formed on NCD/Diabetes Prevention and Control adopted by the 193 member states of the United Nations. Commitment was expressed to turn Political Declaration into actions. In order to help this to happen an Advocacy guide was published.

SUMMARY OF RECOMMENDATIONS OF THE POLITICAL DECLARATION ON NCDs

National leadership and ownership

- by 2013 multisectoral national NCD policies and plans needs to be established

Early diagnosis and treatment

- prioritize early diabetes detection, screening, diagnosis and treatment
- Increase access to affordable, safe, effective and quality medicines and technologies, including through the use of generics and patent licensing flexibilities
- Improve affordability, accessibility and maintenance of diagnostic equipment and technologies

Prevention

- Promote health policies through patient education
- Advance implementation and strengthening of cost-effective population wide interventions to reduce NCD risk factors.
- Promote healthy diet through implementation of WHO recommendation on marketing of non-alcoholic beverages to children, the elimination of trans-fat, reduction of salt, sugars and saturated fats, encourage policies that support production of healthy foods.
- Increase physical activity by giving greater priority to physical education in schools; urban planning, active transport, work-site healthy lifestyle programs and increased availability of safe environment in public parks and recreational spaces.
- Promote inclusion of NCD prevention and control within sexual and reproductive health, and maternal and child health programs including breastfeeding for the first 6 months.

Health system strengthening

- Strengthen health systems to support universal coverage, primary healthcare and cost-effective integrated services for prevention, detection, treatment and care of NCDs.
- Strengthen information systems for health planning and management.
- Strengthen health-care infrastructure, including procurement, storage and distribution of medicines.

- training and retention of health workers.

Research and development

- Strengthen national capacities for quality research and development on NCDs and its translation into programs on the ground.

Resourcing

- Identify and mobilize adequate, predictable and sustainable financial resources via domestic bilateral, regional and multilateral channels, and innovative financing mechanisms.
- Provide technical assistance and capacity building to develop countries for NCDs, and enhance the quality of aid, and fulfill Official Development Assistance (ODA)-related commitments.
- According to national priorities prioritize budgetary allocations for NCDs and establish taxation measures where appropriate.

Collaborative partnership with non-governmental organizations (NGOs)

- Foster collaborative partnership between governments and civil society
- Ensure the full active participation of people with NCDs in national responses
- Promote capacity building of NCD-related NGOs at national and regional level

Monitoring and evaluation

- Strengthen country-level surveillance and monitoring systems
- By 2012, develop a comprehensive global monitoring framework for NCDs and set of voluntary global targets and indications
- Consider national targets and indications

Follow-up

- In 2012, UN Secretary General to present recommendations for a multisectoral NCD partnership
- In 2013, UN Secretary General to present a report on progress on NCDs and impact on internationally agreed development goals
- In 2014, UN to hold a comprehensive review and assessment on progress achieved

IDF launched its global Diabetes Plan at the UN Summit turning Political Declaration into actions with the following key messages:

- Increase awareness of diabetes
- Governments to give priority to diabetes
- Non-governmental organizations (NGOs) & companies to co-operate with governments
- Promote and disseminate NCD political declaration on NCDs
- Strengthen working relationship with governments
- Foster partnership
- Continue momentum at national, regional and global conferences

AT EU LEVEL

At EU level diabetes was in focus of an Europe-wide audit that analyzed the diabetes situation in 47 EU countries [5].

Main findings were diabetes is an escalating epidemic with a growing cost burden. Approximately 8-9% of GDP is spent on diabetes care on average in 47 EU countries.

The number of people living with diabetes in 2030 will grow to 16.6%, the general healthcare cost for an EU citizen with diabetes is on average €2,100 a year [7], whereas these costs will inevitably increase given the rising numbers of people with diabetes, the ageing of the population and the associated rise in multiple co-morbidities. There is no cures are currently available for diabetes and research is still needed to clearly identify risk factors for diabetes type 1. Diabetes type 2 is a preventable disease, but needs effective prevention strategies.

National diabetes plans show only slow progress, only in 25 (including Hungary) of 47 countries have National Diabetes Plan, but the variety of plans is huge. Even in countries implementing national policies, in many cases, robust and effective monitoring and evaluation systems are lacking. There is lack of funding and infrastructure to coordinate the diabetes research in the EU, which negatively impacts the competitiveness of EU diabetes research. And there was no European strategy for addressing diabetes.

Based on these findings the European Parliament worked out a strategy on diabetes. This action plan was formalized in the European Parliament resolution made as of March 14, 2012 on Addressing the EU diabetes epidemic, which is a non-binding policy guideline, addressing the following issues:

- an EU Diabetes Strategy managed by the European Commission
- member states' national strategies coordinated with the EU
- improved coordination of European diabetes research by fostering collaboration between research disciplines and creating general, common infrastructures to facilitate the European diabetes research efforts
- support for diabetes funding under the current and future EU Framework Programs for Research
- a continued patients' access in primary and secondary care to high quality interdisciplinary teams, diabetes treatments and technologies in the member states
- elaborating common criteria and methods for data collection on diabetes

The resolution gives well defined recommendations to national governments and regarding national policies as:

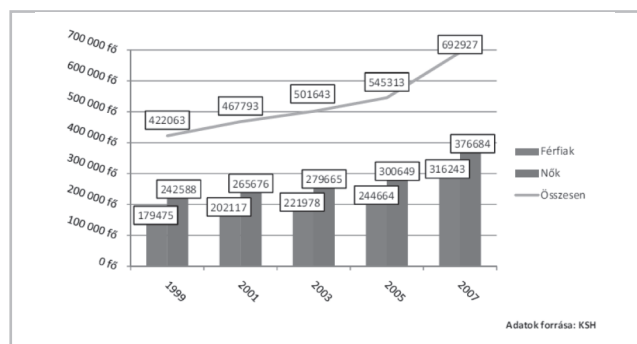
- Establish and implement national diabetes primary prevention programs
- Compile report and information on current epidemiology status based on common measurement criteria

- Establish an EU-wide strategy
- Encourage cooperation between countries in exchange of good practices in prevention & screening & control
- Collect, register, monitor and manage comprehensive diabetes epidemiological and health economic data
- Develop, implement and monitor national diabetes plan for evidence based disease prevention, screening and control
- Ensure access to high-quality diabetes treatment and technologies
- Women need targeted policies (pregnancy/post-natal period)

This is a clear guidance for the national governments. In the next session we will shortly analyze the current Hungarian situation.

Hungary:

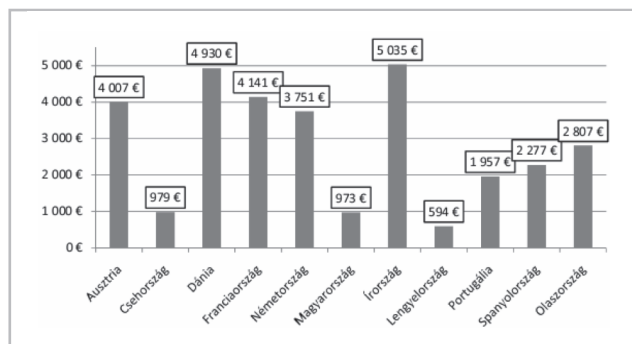
The prevalence of diabetes in Hungary is increasing; in 2007 it reached close to 693 000 people, and it will also be growing well over 700 000 by 2025 based on estimations [6.]



Graph 4.
Prevalence of diabetes is expected to grow in Hungary

The current situation of diabetes care in Hungary is not satisfactory, as diabetes is a major cause of morbidity and mortality in Hungary and the trend is increasing as seen in the graph above. The 692 927 patients with diabetes represents a 6% prevalence in the total population. In order to counteract these trends, in 2007 a National Diabetes program was worked out by the Hungarian Diabetes Association and a National Health Institute. Beyond these setting up of a monitoring system was also planned, but – as Europe Audit found – the progress of implementation is rather slow.

Having looked at the reasons of the poor epidemiological situation of diabetes in Hungary we can find the lowest per capita spending (graph 5) on diabetes in Europe [7]. Since 2011, new measures are in place, the most significant of which being the drastic reduction of the pharma budget, pushing diabetes care in an even worse situation. Financial protocols that should help in improving the quality of diabetes care are waiting for publication since 2 years, putting diabetes care in a worsening vicious circle.



Graph 5.
Per capita spending on diabetes in EU

COOPERATION BETWEEN PHARMA & AUTHORITIES FOR PATIENTS AND FOR HEALTH

Objectives of Pharma and Authorities in diabetes disease management are common, to improve health outcomes of people with diabetes (normoglycaemia, co-morbidity reduction), prevent the development of type 2 diabetes (primary, secondary) and to increase patient compliance, as a key success factor.

Cooperation between pharma and authorities based on common goals is a must from patients' health point of view, but it is also a highly rational approach because of the different nature and capabilities of pharma and authorities and physicians' & patients' associations activities complement each other very well, too.

Significant improvement of diabetes care can only be achieved through the cooperation of all key stakeholders: pharma & authorities & physicians' & patients' associations

Key points of cooperation strategies based on 2011-2012 program of the International Diabetes Federation (IDF)

- Strengthening institutional frameworks with better collaboration among different sectors in connection with healthcare e.g. education, treasury, employment focusing on diabetes.
- Integrate and optimize human resources and health services, by building good primary care system and enforce interdisciplinary approach of healthcare system
- Review and streamline supply systems, by ensuring transparency in reimbursement and access provided to medicines
- Generate and use research evidence strategically by building research capacity and supporting local evidence and healthcare effectiveness research to improve patient access to treatments.
- Monitor, evaluate and communicate outcomes by sharing information between specialist and primary care in order to reduce duplication of services and increasing and monitoring appropriate use of resources, services.
- Allocate appropriate and sustainable domestic and international resources means diabetes and related co-morbidities need to be integrated into national and international health and development policies and plans, assu-

ring predictable funding through mobilizing domestic resources, and using tobacco and alcohol taxes to fund hospital infrastructure and diabetes prevention programs.

- Adopt a whole of society approach by engaging business and industry (health centered approach in architecture, reducing marketing of unhealthy food and adopting socially responsible business policies and practices as well as strengthening civil society.

Key success factors of implementation are: effective healthcare system, serving for prevention and treatment, access to medicines, transparency in reimbursement and simplified services and patient care.

High level medical care is key, but it is not able to solve the burden of diabetes alone.

Objective is to have measurable improvement in patient outcomes through complex disease and patient management programs. Partnership between key stakeholders both pharma and authorities needed for success.

Potential pharma activities

- R&D, high-quality therapeutic solutions
- Clinical trial and registry management

- Health technology assessment (HTA), cost-efficient evaluation of programs
- Know-how on disease and patient management.
- Education knowledge & experience both for patients and physicians
- Communication

Potential authority activities

- Favorable regulatory framework
- Effective institutional framework
- Prioritize diabetes care in financing and in reimbursement
- Local and EU funding
- Regulate multi-sectoral partnership

CONCLUSION

Diabetes care is a worldwide issue with several medical & societal & economic aspects; therefore its solution needs the full involvement of all stakeholders. On the other hand there is a long series of potential cooperation opportunities that can be used all over the world. These opportunities also apply for Hungary. Pharma industry in Hungary is open for the cooperation, because "Health is Wealth".

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A SZERZŐ BEMUTATÁSA



Christophe Gourlet 1988–1993 között a Price Waterhouse franciaországi képviseletének munkatársa, 1993-ban csatlakozott a sanofi-aventis vállaltcsoport pénzügyi igazgatóságához, mint a gyógyszer üzletág konszolidációs vezetője. Ezt a pozíciót 1997-ig, a cégcsoport portugáliai adminisztratív és pénzügyi igazgatóságára történő kinevezéséig töltötte be. 2000-től cégcsoport londoni adminisztratív és pénzügyi igazgatóságának munkatársa, 2003-tól Ázsia, Közép-Kelet, Keleti országok adminisztratív és pénzügyi igazgatóságán. 2004-től a sanofi-aventis üzleti támogatásokért felelős alelnöke (Business support vice

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