Foreword by Ulrich Laaser

Dr. Hans Stein has been on the European Union (EU)-Health stage for more than 25 years, starting with the very first Health Council in 1977. As an official of the German Health Ministry (Head of the EU Health Policy Unit) he represented Germany in countless EU (Council and Commission) committees and working groups concerning health policy and public health research. He not only organised the Health Council of four German EU presidencies, but also published a large number of articles mainly in international journals and books. After his retirement in 2002, Dr. Stein continued as a free lance consultant to a number of EU institutions and a lecturer in German, Dutch, Austrian, and English Schools of Public Health.

Personally, I probably met Hans Stein the first time in 1977 when in West Germany a discussion started about a "big" population study on cardiovascular health. He worked already for several years in the Ministry of Health (the name of the ministry at that time may have been more complex and I forgot it) but, different from many political administrators, he was fascinated by contents and not by formalities. He paved the way for the German Cardiovascular Prevention Study (GCP) targeting five regions with together around one million population for more than a decade (1979-1994). Hans Stein started his long chain of contributions to population health and health policy with a presentation in my then High Blood Pressure Department in Heidelberg and I remember how difficult it was to convince him to speak in public about prevention. That changed later completely when he became a European figure representing the German Government in the endless and tiring deliberations foregoing the milestone treaty of Maastricht. I shall never forget how Dr. Stein presented a historical dialogue with his former Dutch colleague Jos Draijer at the 25th anniversary of the Treaty at a celebration in the very city of Maastricht. Hans Stein remained an engaged sceptic with an insurmountable enthusiasm, truly a rare mélange, obvious also from his review below of the European health policy development since Maastricht.

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The Maastricht Treaty 1992: Taking stock of the past and looking at future perspectives

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Abstract

Aim: The article contains a personal view of the history as well as the future of the European Union's (EU) health policy. Describing and evaluating the developments on the road from the Treaty of Maastricht to a new Europe it asks and tries to answer the question if we – especially the EU Member States – really know where we want to go to and how to get there.

Method: Based on personal experiences, countless EU documents, as well as scientific publications the paper shows the impact EU Health policy has had in the Member States in the past.

Historical development: Considering that the legal basis for health has been and remains to be very weak limiting EU action to support, coordinate, and supplement actions of Member States – which, as a rule, still consider health to be first and foremost a national responsibility and therefore do not want interference from international institutions – the amount and content of EU health activities in the past years has been quite remarkable. Health policy may not be an EU priority and as a crosscutting policy sector it is dominated by many other EU policies. However, especially the "hard law" regulations and directives of the Internal Market give EU the power and competence to achieve health objectives. The size of this growing influence is shown by direct interventions, made possible by the legal acts to improve economic policy coordination. Health and health care in this context are considered as a key policy area for economic growth and EU macroeconomic policy. On the other hand, there is a risk that such regulations affecting health policy and population health may be dominated too much by economic institutions and their interests, whereas health authorities play only a minor role to date.

Conclusion: For the future of EU health policy it is essential that its position is considerably strengthened, in order to assure that health interests of the EU population are sufficiently safeguarded.

Keywords: European Union, future perspectives, health policy, Maastricht Treaty.

Conflict of interest: None.

Introduction

As a rule, a 20th anniversary, especially when it concerns an event considered to be a historical landmark, is a cause for celebration. The Treaty of Maastricht was finally negotiated in an intergovernmental conference by the Member States of the European Union (EU) and signed on the 7th of February 1992 in Maastricht, The Netherlands (1). It came into force on the 1st of November 1993 after it had been ratified in all Member States by national parliaments, in some cases adopted even by a population referendum.

It is not only a cornerstone in the general development of the European Union, comparable to the establishment of an economic and monetary union with a common currency, but it also contains for the first time a specific legal basis for health as a European issue. It is worthwhile noting that, this process was dominated by the governments of the Member States. Commission and European Parliament participated on the side lines with very limited power to influence content and process. Nevertheless, this event certainly would have deserves to be celebrated. But, surprisingly, except for some small meetings in Maastricht, initiated by local institutions, there were no celebrations by the European Union in Brussels, or in national capitals.

This situation should be a cause for concern. Is it considered to be so critical that nobody wants to be reminded of how, when and where European integration started? Were the experiences during the last 20 years in general, as well as with the implementation of the health mandate specifically that bad and negative? Has the European vision got lost or was it just forgotten? Has The European dream ended? Or, is it that the EU has too big difficulties occupying the minds in adapting itself to the present situation characterized by the economic crisis and globalisation?

Looking back as a base for future developments

It is the purpose of this article not only to describe how the EU health policy has developed in the 20 years since the Maastricht treaty was signed, but also to develop concepts for the future.

Whether and how much it was a success story and what future perspectives are needed and realistic, cannot be judged only by looking at health issues. No EU policy field develops in isolation. Especially in health with its horizontal character progress depends to a great deal on the overall EU development, its problems, and how these are solved. The present EU crisis, in many ways related to the economic situation, was not caused by health issues but health problems and even national health policies are affected by the crisis and the measures taken to improve the situation. “Health in all policies” (2) is not only a mandate, but also a description of the situation.

It will be shown how the newly created instruments to establish a “European Economic Governance” such as the European Semester (3), the Stability Pact (4) and others not only go far beyond the existing legal base, but will influence national health systems and policies by increasing the Commission’s power to intervene at a national level.

Lack of interest in the past

The existing lack of interest in the historic development of the European integration in general, and especially in the EU health policies may be regretted, but it can be explained by two interrelated developments:

- Lack of positive commitment of EU citizens to European unification, and;
- EU enlargement implies growing economic gap between Member States.

Lack of commitment by the citizens

The project of European unification faces presently the biggest existential crisis of its history. Nobody really knows when and how the crisis can be overcome or, at least, be mitigated. Timothy Garton Ash (5) in an essay "The Crisis of Europe" describes in great detail how the Union came together and why right now it seems to be falling apart. In his view "The project of European unification for about 40 years could rely on at least a passive consensus among most of Europe's national publics", today there is a lack of commitment to European integration nearly everywhere. It is obvious that a growing number of citizens in many countries do not believe anymore that the EU can at least contribute to solving their problems. Even worse, they consider the EU itself to be the problem. These sceptical and critical views about the EU have existed in many countries for quite a number of years. But, Eurobarometer (6) as well as national polls, especially the results of the elections 2014 for the European Parliament, show that a growing number of citizens in many countries have lost confidence in the EU. Surprisingly, this feeling exists even in Germany or the Netherlands, two signatory nations of the Maastricht Treaty, for a long time firm believers in European integration, including even a Political Union, countries that are not suffering from the present economic crisis.

European integration has been rightly described as a project of elites with little even indirect participation of the citizens. They were seldom asked if they agreed to European solutions. And they were certainly never asked, if they wanted European solutions in health matters. Had this been the case, a clear "No" would have been the answer, even if they could not have imagined how these solutions would look like.

EU enlargement and the economic gap

In 1993, only 12 Member States negotiated and signed the Maastricht Treaty. Since then, we have had three new treaties – of Amsterdam, Nice and the still valid one of Lisbon (7) – as well as a failed attempt to establish a European Constitution. More importantly, the EU has increased tremendously in size. From 1993 to 2014, altogether 16 new states have joined the EU and even more association negotiations are going on and will soon lead to even more Member States (MS). At the same time some MS – especially the United Kingdom – consider to leave the EU unless their special interests are taken care of. For the new MS, the date of their own accession as well as a solution of their present day problems are more important than a Treaty which was signed 20 years ago.

The astonishing and unexpected enlargement and expansion of the EU from original six to now 29 and possibly soon 35 Member States in a few years is not a question of numbers alone. Whereas EU structures and mechanisms, originally designed for only six MS have largely remained unchanged, this enormous growth combined with a financial and economic crisis has created big, yet unsolved problems. On the one hand, there is a growing small vs. big MS situation. Whereas eight MS have a population of five million or less (Luxemburg, Malta, and Cyprus being the smallest with only 0.5 million inhabitants), seven MS have a population between 6-10 million, and only 12 have more than 10 million. Small size populations lead to small size economies. There are enormous differences in the present economic situation of some, often new MS. In health, this means that not all MS have sufficient financial and personal resources to offer their population all health services that are needed. This has already led to a growing 'health gap' (8). Reducing these health inequalities is essential in that it will contribute to social cohesion, i.e. reducing poverty and social exclusion. It requires a new dimension of EU solidarity including support and assistance. The classical EU instruments of cooperation and coordination are not sufficient any more to cope with the present situation.

Weaknesses and shortcomings of EU health policy

Health – an EU priority?

Health has never been a priority of European integration and it is highly improbable that it will ever become so in the future. Despite a number of positive achievements in the past, health has not become a central objective of EU policy making. Contrary to environmental policy or research – to name just two health-related similar policy areas – health has not been named in any of the various EU treaties as an EU objective. In Article 3 of the Treaty of Maastricht, where the purpose of the various EU policy areas has been described, it states about health as follows: *"A contribution to the attainment of a high level of health protection"*, which is not exactly a very ambitious objective.

On the contrary, whenever in the past years a reduction of EU activities and competence has been demanded by MS, health always has been a strong candidate, offered even by the Commission. With this background, it is not surprising that the power and influence of the Health Commissioner and his General Directorate has never been high. His responsibilities were always limited, and the financial and personal resources are small, especially when compared with areas like agriculture or research. It is not surprising that big Member States in the usual battle to get an influential Commissioner have never shown any interest to get this office. In the past twenty, years Health Commissioners have therefore come from smaller countries like Greece, Ireland, Cyprus, and Malta.

The same applies to the new Commission coming into power in September 2014. The new Commissioner for Health and Food Safety, Vytenis Andriukaitis, comes from Lithuania, also a small country. But, differing from all his predecessors, he has experience in EU matters as well as a very convincing health background: he is a surgeon and was Lithuanian Minister of Health and, as such, responsible for an impressive health agenda during the Lithuanian EU Presidency in 2013. As health remains an independent EU policy area – combined with food safety, for a long time a major EU priority – the expectation can be justified that health might become more powerful in the future.

The Commission has always been called the 'Guardian of the Treaty' (9), from whom it was expected to work for more integration. However, as far as health is concerned, it has shown only little interest in the past to improve the status of health as a European topic. It appears that most if not all successful proposals have come from others; in 1977, for example, a Belgian initiative to establish a Health Council and in 1985 a French proposal in the Rome Summit to establish 'Europe against Cancer' as a European responsibility (both, by the way, many years before health was established formally as a European task in the Maastricht Treaty). Furthermore, in 1995, the initiative of the European Parliament to strengthen the EU health Mandate and legal competence resulted in the Amsterdam Treaty 1997; and, finally, the many decisions of the European Court of Justice, beginning 1998 with the famous "Kohll and Decker" cases about patient mobility. The last phase started in 2012 with various summit decisions to establish a 'European Economic Governance' with new instruments including *"Health care as an answer to the economic and financial crisis, going far beyond the existing EU legal base"* (10).

It seems that others discovered much earlier than the Commission the health potential of the main EU objective, namely the Internal Market.

Health and the internal market

It is often overlooked that national health systems, however differently they are organised and financed, are strongly related to and have been integrated into the Internal Market with its

four freedoms (11) embracing the free movement of goods (pharmaceuticals and health technology), free services (physicians, nurses), cross-border capital (e.g. investing in rehabilitation clinics), and people, i.e. patients looking for treatment outside their home country.

Right from the beginning, health systems have been influenced and even regulated to some extent by regulations and directives of the EU market and the competition therein. Health care is, and it has always been, a central element of European and national economies. It is a big, possibly the biggest part of the Internal Market and it is permanently growing. About 8.5% of the national gross domestic product is, on average, spent for health. In Germany, this means every year more than 250 billion Euro. Millions of people – especially doctors and nurses – work in the health care systems. In Germany, about 12% of the working population is employed in the health sector (12). Many of them, especially in the new MS, make increasingly use of their right of free movement and work in other EU countries. In the receiving countries this contributes to solving the existing shortage problems, whereas at the same time it leads to growing difficulties in their home countries.

The main objective of the regulations and directives, the most effective EU tools, is to establish a functional internal market (13).They apply fully to the health systems and influence the development and content of national health policy. In addition, they are a powerful treaty base for influencing and even removing those MS policies such as health that might interfere with the aims of the Internal Market.

Scott Greer (14) describes the results and consequences of the Maastricht Treaty in his essay 'Glass half empty': *"The Euro zone and the Internal Market overshadow the health effects of Maastricht: It is comparatively easy to find the treaty authority for legislation promoting the internal market and EU law and courts are sceptical of public health or other rationales for legislation impeding the markets development"*. He names as prominent examples the patient mobility decisions of the European Court of Justice, which culminated in the Directive on Patients' Rights in Cross Border Mobility (15). Furthermore, the application of competition and the state law for health care providers, and the integration of pharmaceuticals' regulation around the European Medicines Agency. Finally, he summarises his considerations about the effects of the Maastricht Treaty on health as follows: *"The first mention of health was the harbinger of more effective promotion of health issues within EU policy making. In time, however, the Internal Market and the single currency have had the biggest health consequences"*. This was not really what the MS had in mind when in 1992 they established a specific EU Public Health Mandate.

Position and interests of Member States

Health has always been considered to be first and foremost a national responsibility. States all over the world with hardly any exception want to keep their complete and undiminished integrity and full autonomy to organize and run their health systems the way they want it. Health systems, different as they are, often are considered as a part of the national heritage and culture. Countries do not want any interference from outside, be it by the EU, or be it by the WHO, which by the way is more accepted than EU institutions, but not more effective. For many years national governments – in full agreement with their citizens and the medical professions – have jealously and on the whole successfully prevented the transfer of any substantial health policy issues to a supra-national level, except for the indirect effects of the Internal Market as discussed above. They, therefore, still have a great difficulty in accepting health policy as a matter of the EU concern. It seems that health policy is one of the last realms and retreats of national policy competence which had to be defended.

It seems also that health policy is a political sector which more than others absorbs and reflects national developments, traditions, and cultures. Health systems are seen as the result of decades of development and the individual response to a country's social situation and profile. The answers given a long time ago by Bismarck and later by Beveridge regarding health seem to be sacrosanct even if a lot has changed since their time. Safeguarding the pluralism of national health systems is considered to be a value by itself which has to be kept safeguarded at all costs against influence from outside even if the problems faced everywhere are quite identical and the solutions are at least similar. It seems to be overlooked that the EU might be a supporting strategic partner to overcome vested stakeholder interests that at the national level would not be possible.

These popular but nevertheless antiquated views neglect a number of essential facts important for health. Individual MS alone cannot cope sufficiently with outbreaks of infectious diseases like H1N1, food safety issues, biological or chemical terrorism and health threats from climate change. Growing new health dangers and threats which 'don't respect borders' is a common saying, presently Ebola being an example (16). The development and evaluation of new technologies and pharmaceuticals especially combating rare diseases and the establishment of whole new areas such as e-health and telemedicine expand beyond the national level. Therefore, possibly the best argument for the need of an EU health policy is the undisputed fact that health is influenced and determined to a great extent by factors and policies far outside national health care systems namely environment, work, transport, education, research and, most importantly, the economic situation of society and the individual. As all these policy areas are shaped more and more at the EU or even global level in different ways by binding regulations or international treaties. Health interests have a chance of success against powerful industrial lobbies only at this international level.

The essential instrument for achieving this is "Health in all policies". It is not only named in the Article 35 of the EU Charter of Fundamental Rights (17), but it is also the most important part of the EU legal base for health. Even if today it is still more a vision and not a reality, there is hope that at the EU level it can become true. Commissioner David Byrne (18) expressed this as follows: *"The future of health is not characterized by national isolation but by international cooperation, governance, and partnership. A more cooperative, integrative and proactive health policy will lead to a more healthy society characterized by enhanced economic output and reduced strain on national health care systems".*

To make this hope come true, it not only needs political will, but also sufficient instruments. Does the EU have them? Can they be developed? The biggest obstacle is the MS' attitude as described below.

Development of health competence from Maastricht 1992 to Lisbon 2010

Article 129, Treaty of Maastricht, 1992

The EU "Public health" competence as laid down for the first time in Article 129 of the Treaty of Maastricht, often but never substantially changed in the subsequent treaties, fully reflects the defensive and negative position of MS. As only a 'supportive competence' it always was and still is the weakest legal base possible – in great contrast to the other strong categories such as exclusive or shared competences. It gives the EU no power to establish binding legal regulations or directives. Its competence is limited to "carry out actions to support, coordinate or supplement the actions of the Member States" according to Article 6 of the Treaty on the functioning of the EU (Treaty of Lisbon). The "protection and improvement of human health" is on the same unsatisfactory level such as culture or tourism.

The establishment of a legal base for EU health policy has never been the object of an overall plan or strategy of any EU institution. Right from the beginning, there have been permanent

conflicts between European activities and differing national positions on the one hand, and economic interests versus health needs on the other. In these conflicts, health interests find only little support.

The Europeanization of health policy and the implementation of EU Health competence were *"A dynamic but still rather unplanned process of policy harmonization and policy adaption. It offers an example of effective and inspired muddling through, rather than of a consistent and clear cut European concerted strategy"* (19). It is worthwhile to take a look at the evolution of the legal base of the EU Public Health mandate, especially as today treaty changes are being discussed to reduce EU power in favour of increased national responsibility.

Before the Treaty of Maastricht in 1992, there was no specific legal base for public health activities. The first EU action program 'Europe against cancer' 1985 initiated by a Summit in Rome and, therefore, had to be based on a catch of legal base, in that a Commission proposal could be agreed unanimously if the Treaties did not provide the necessary power. This legal base still exists today in the Article 352 of the Lisbon Treaty, but it cannot be applied to health any more, as there is a specific legal base for public health, established in the Article 129 of the Treaty of Maastricht in 1992.

The main components of Article 129 were slightly reworded in the following treaties, but essentially are still valid:

- Community action should encourage and support MS' cooperation in order to achieve a high level of health protection, and;
- Community action should be directed towards preventing human illnesses, especially by promoting research into their causes, their transmission, as well as health information and education.

The only instrument to achieve this, were supportive activities. Consequently the only activities that took place were 'Action programmes' and 'Recommendations'. Any binding legal measures such as regulations or directives are impossible. Health Care was not even mentioned and MS, especially the new ones, watched very carefully that EU action did not go an inch beyond these agreements.

Quite soon, it became obvious that this very limited and weak mandate and its legal base were not sufficient to enable the EU to react appropriately to new challenges or at least to contribute sufficiently to their solution. Examples for these new problems, which most MS were unable to cope with alone, included new health threats such as AIDS, SARS or Ebola, the economic crisis and its effects on health systems, as well as bio-terrorism, to name just a few. Regarding one threat, the BSE crisis and the Jacob-Creutzfeld Disease, the Commission handling it was paying more attention to the commercial interests of farmers than to health risks for humans, which led the European Parliament to demand a strengthening of the public health legal base, which took place in a new strengthened formulation in the Article 152 of the Treaty of Amsterdam (20), which was not only upheld, but even strengthened in all further Treaty changes (Nice 2003, Lisbon 2010).

The Lisbon Treaty 2010

Many years later, in 2010, the Lisbon Treaty was agreed to and ratified. Its ratification was relatively easy because it was not a completely new text but just modified the pre-existing Treaty of Nice. It consists of two parts (Treaty of the EU containing common provisions and principals and Treaty on the EU functioning) containing the strengthened competences of the Commission as proposed in the failed attempt to agree on a European constitution in 2004.

Despite the permanently ongoing discussion about increasing or decreasing EU competences, the necessary changes of the Lisbon Treaty seem highly improbable because the needed unanimous agreement and ratification by 28 MS and even more in the future. As the Lisbon

Treaty will be the legal base of all EU action for a long time, it is appropriate to look at the changes in the health provisions to see how far future challenges could be met by EU activities.

The provisions in the Treaty on the functioning of the EU are peculiar, difficult to understand, and even contradictory. Whereas Article 4 mentions health aspects as an area of shared competence: *"Common safety concerns in public health matters for the aspects defined in this Treaty"* [2k], the Article 6 also names it as the first area for supportive, coordinative and supplementary competence : (a) "protection and improvement of human health".

Health is the only policy area mentioned in two different competence categories. Is there a difference between public health and human health? Is there a difference between common safety and protection? Most likely this is a badly formulated remnant of the foregoing discussion around a constitution, where health as a whole was originally planned to be a 'shared competence', which many MS did not want. The background for a potential shared competence was the threat of 'Bio-terrorism', which was considered to be a common safety concern to society and not just a health threat.

Whatever the explanation may be, as the EU-related contents of Public Health are described in great detail in the Title XIV of Article 168, it is obvious that with few exceptions Public Health continues to be only a supportive competence, which aims at encouraging and supporting MS cooperation. In spite of the detailed description in the Article 168, this leads to less and not more clarity. In comparison to the lengthy elaboration of one page in Article 168, the really important area Internal Market consists of involves only some lines in Article 26.

The well-known MS position to keep the EU as far away as possible from influencing their health policy is fully upheld. There is no harmonization of systems in any way. There still is hardly any possibility for binding hard law legislation (exceptions: Article 168 No. 4 dealing with quality and safety of organs and blood, veterinary and phytosanitary fields with direct relation to public health, and quality and safety of medicinal products as well as devices).

However, there are at least some small improvements. The scope and content of the Commission support of cooperation, i.e. financing, is increased by naming concrete possibilities such as establishment of guidelines and indicators – both basic for the establishment of a permanent EU health information system – as well as the organisation of the exchange of best practices, periodic monitoring and evaluation. Furthermore, the door for the first time is slightly opened for health care as there are positive words about improving the complementarities of health services in cross-border areas, something that has been happening for a long time in many 'EUREGIOS' without Commission participation or support.

Health in all Policies (HiaP)

The most important change, however, is the new first sentence introducing Article 168, also contained in Article 35 of the EU Charter of Fundamental Rights:

"A high level of human health protection shall be insured in the definition and implementation of all the Unions policies and activities".

This very clear statement, which gives the EU an undisputable legal right und political mandate, is quite unique as it is not contained in any national constitution or bill of human rights. It not only means that all other policies have to avoid or at least limit negative health effects, but it also provides a legal base to use all policies directly or at least indirectly for binding and obligatory "health legislation". It gives the EU the power and the competence to establish 'hard law', to achieve health aims and targets.

The EU fight against tobacco was the biggest EU health policy success story; it was made possible because 'hard law', based on Internal Market competences, was used to establish the

needed binding directives. They were disputed and fought bitterly by the active and powerful tobacco lobby, but despite of all their attempts expressively legally confirmed and even promoted by a number of European Court decisions.
Despite of this encouraging example, Health in all Policies today is mainly a vision and far away from being an overall reality. It is tremendously difficult to apply and implement it, as other policies which want to achieve their own aims and health impacts, as a rule, are of little concern to them. Last but not least, powerful stakeholders – not only industry but also social partners – have foremost economic and not health interests and, at a political level, it is the economy that counts.
As an example, the EU strategy to 'Reduce alcohol-related harm' failed to a great extent because of the negative consequences for various other EU policies and regulations (agricultural subsidies, harmonisation of taxation and the removal of trade barriers in the Internal Market). It is the most prominent example of failure of the HiaP principle. Despite the undisputable fact that alcohol is a main cause for diseases and health, the economic interests were stronger and prevailed. The EU is worldwide the biggest alcohol producer in a growing and very profitable market which had to be safeguarded. Thus, the EU market laws weakened the restrictive alcohol policy in the Nordic countries with the result that drinking alcohol already in adolescence became their biggest health problem.
To transform the Health in all Policies principle from vision to reality it is essential to be able to compete with and to influence countervailing economic and industrial powers. This requires adequate organisational structures as well as institutional mechanisms for resolving conflicts and the development and permanent use of support tools such as health impact assessment. Above all, it is essential that those who are responsible for health in the Commission (Health Commissioner and Health Directorate) and in the MS (Health Ministries and stakeholders) have the political will, as well as the power to do it. All of that is missing nowadays in the EU.

Achievements and impact of EU Health Policy
After more than 20 years, it is justified to ask two simple questions:

i. Have EU activities led to better health in the EU?
ii. Have EU health actions and health-related legal regulations had a noticeable impact in the MS and on the national health policies?

Both questions may be simple, but are difficult to answer. A short, but honest, answer would be: We just do not know! As, up to now, no overall evaluation (Health Impact Assessment) of EU activities has been made in the EU or in any MS, we can only give some general indications based on EU/WHO/OECD health information systems and health monitoring, mostly created by EU funding and networks. This enormous increase of knowledge about the health situation and health systems and their development, easily available to everyone, is possible the biggest achievement of EU health policy, to date. We know today more than ever before, but the central question remains: are EU and national policies based on this knowledge?

Health Status
European countries have achieved major gains in population health in recent decades. The situation in the EU is better than in most of the other parts of the world. *"Life expectancy at birth in the EU has increased by more than six years than 1980 to reach 79 years in 2010, while premature mortality has reduced dramatically. Over three quarters of these years can be expected to be lived free of activity limitation"* (21). On average, across the EU, life expectancy at birth for the three-year period 2008-10 was 75. 3 years for men and 81.7 years

for women. The report explains this situation by *"Improved living and working conditions and some health-related behaviours, but better access to care and quality of care also deserves much credit"*.

The question is, if and how much these factors have been influenced by EU policies. A scientific evaluation in 2003 of the EU "Europe against Cancer Program" (22) comes to the conclusion, that this programme appears to have been associated with the avoidance of 92,573 cancer deaths in the year 2000, or a reduction of about 10% of the EU overall. These exact figures might be questioned, but the phrase 'appears to have been associated' is applicable also to the positive EU influence on the overall improvement of the health status of EU citizens. There can be little doubt that many EU activities that have been directed at reducing risk factors to health, be it tobacco smoking, alcohol consumption or overweight, have contributed at least to some extent to their reduction. The reduction of tobacco consumption by adults in most EU Member States (examples: 15% in Sweden and Iceland from 30% in 1980, but still over 30% in Greece, Bulgaria, Ireland and others) would not have happened without the EU activities such as public awareness campaigns, advertising bans, and increased taxation. Indeed, the reduction of smoking is the biggest EU Health success story until now.

By influencing mainly non-medical factors, the EU has contributed quite substantially to the present positive health status, whereas 'governance of health care' factors such as proper access to health care, number of doctors and nurses, health care spending and the like have hardly been effected by the EU.

Even if the health status within the EU can be considered to have improved overall, there still is the unsolved problem of large and still growing inequalities between different countries. The gap between EU-MS with the highest and lowest life expectancy at birth is around eight years for women and 12 years for men. But, there is also a large gap within countries mainly between socio-economic groups. However, the EU has tried to reduce these gaps, where it was not successful.

Impact in Member States

The process of transforming visions into reality, of developing EU health policy and implementing it in the MS had to overcome countless barriers, was not very transparent and still is very slow. It has been described by Lamping (19), a German political scientist as *"Discontinuing, incoherent sometimes fairly accidental and even undemocratic with little logic and rationality , self dynamic, not political but technocratic, determined by interest groups, based mainly on voluntary cooperation with little room for binding legal acts"*.

On the same lines, Hervey and Vanhercke (22) describe EU health policy as *"A patch work of actors and institutions which decide and implement law, policy, and governance"*. They name five different domains as components of EU health policy that MS have to improve: Public Health, Research (both are soft law areas with no binding obligations to MS), Internal Market, Competition, and Social laws. There is no overall leadership and more competition than cooperation. Whereas national health policy as a rule is the domain of one political administration (the Health Ministry), supported by health experts, the EU health patch work consists of institutional structures and procedures that often were developed for domains that have no health interest at all. As a consequence, EU health is not only not an EU priority but also a highly contested area with a permanent conflict between health and economic interests. Also, there is only little transparency. EU Health policy is mainly a field for experts with little citizens' participation. Scott Greer (15) called it a 'secret garden' which should be turned into a 'public park'.

Considering the weak legal base, the lack of political commitment and interest of the MS but also within the Commission, and the limited financial and personal resources available, the amount of health and health-related activities that have been developed and undertaken by this 'patch work' is quite astonishing. Starting with its first programme "Europe against Cancer" in 1985, a countless number of soft law activities (strategies, recommendations, programmes, projects, studies, networks, frameworks, concerted actions, establishment of agencies, platforms, and committees etc.) have taken place. The amount of binding legislations (hard law) is of course much smaller, the most important being those on tobacco issues including advertising, blood safety, pharmaceuticals, medical devices, professional qualifications, food safety and – the first small step into health care – the "Patient's Rights" directive on cross-border health care. The latter was enforced by a number of decisions of the European Court of Justice. There is hardly any health problem or major disease that has not been the object of EU activities.

The most comprehensive overview is contained in a "Welcome Package Public Health", prepared in 2009 by the Policy Department "Economic and Scientific Policy" (23) of the European Parliament, to serve as a reference tool for incoming Members of the European Parliament. A similar document seemingly was not produced for the new European Parliament 2014. In more than 120 pages, this document, available on the Internet, names and describes all past, ongoing and planned EU activities. The integration of health into other policies, however, is described on just one page and these other policies are not even named.

Furthermore, the document says nothing about the impact on the MS. This is to some degree understandable because there is hardly any knowledge about the actual impact of EU health-related activities on the MS. There is no overall evaluation, no general Health Impact Assessment. Of course the many different activities, strategies, programs, and projects, as a rule are evaluated, but these evaluations say nothing about their impact. Health impact assessments of Health in All Policies are conducted in a small number when new policies and regulations are being prepared, not when they have been implemented.

There is hope for at least a partial improvement in the future. The "Patient Mobility Directive 2011" not only had to be implemented by the MS until the end of 2013; they also have to report to the Commission about what they have done. These reports have to include detailed information about patient movements and the cooperation between MS in border regions, European reference networks, rare diseases, e-health, and health-technology assessment. As of 2015 the Commission has to give an overall report to the Council and the European Parliament, we will then know a little more about national impact, at least in some areas. Today, we still know only little, actually too little, about the impact of EU Health policy. Only a few documents contain information about success or failure:

i. The most negative report is an evaluation conducted by the European Court of Auditors in 2009 of the 3rd EU Public Health Programme 2007-2013 (24). This report considered it a waste of money, because it contained no strategy, was badly implemented, the projects funded had little policy connection, and there was no follow up. The Commission accepted this harsh criticism and promised positive changes in its future programmes, especially in the following next 4th programme. Also, from author's experience as a project evaluator it seems justified to say that since 1978 the many hundreds, even thousands of projects funded in the various Public Health as well as Research Programmes very rarely had relations to political activities, be it in the EU, be it in the individual MS. Although it was the expressive aim of all these programmes that the funded projects should contribute to the improvement of health of the European citizens, it was never really evaluated if and how they achieved this. Many of the projects improved knowledge, but only a few led to political action.

ii. Surprisingly the most positive document is the "Review of the balance of competences between the United Kingdom and the European Union in Health", published 2013 by the UK Government (25). It is part of a comprehensive examination of the balance of competences between the UK and the EU to analyse what UK membership means to national interest. These documents were prepared for all EU policies to serve as a base for negotiations with the EU about a reduction of EU competences, which – if not successful – might even lead to the UK to leave the EU. This health review is quite remarkable for a number of reasons. It is the only document prepared by any MS government describing and evaluating the national impact of EU health activities. It not only contains the view of the UK government, but also – this is really unique – the views of UK citizens, industry and stakeholders, who were asked to give their opinion. Altogether, it was recognized that with very few exceptions the EU in health matters had a positive impact especially in Public Health (tobacco use, tackling obesity, alcohol abuse), as well as health security (where even more efforts were welcomed), sharing of information and data, as well as research funding. Benefits were also seen in Internal Market health care measures including the free movement of patients and of health professionals, to reduce shortages. Only in a few areas adverse consequences of cross sector EU legislation were noted: The directives on clinical trials, data protection, and working time. The current balance of competences between EU and UK were considered appropriate, but should not be extended further. Considering these positive views in a country where generally the EU is looked at in a negative and critical way, it may be good to have similar surveys in other countries.

iii. A midterm evaluation about the implementation and impact of the EU Health Strategy 2008-2013 (26) contains some key conclusions that could be applied to the EU Health policy as a whole. It acknowledges that there is a high level of activities at EU and Member State level, but it is uncertain if the outputs at MS level can be attributed directly or exclusively to the EU Health Strategy. Thematic or structural similarities between EU and MS activities were identified but considered to be a reflection of similar priorities, a discernable direct of EU measures was not found, its influence an national strategies was considered limited. The main value of the EU Health Strategy was described as follows: *"It acts as a guiding framework and to some extent as a catalyst for action"*.

These findings coincide with the results of a conference on "European Public Health, 20 years of Maastricht Treaty", 2013 in Maastricht (27). It names a number of positive developments as the result of EU health policies:

- Building of a public health infrastructure (agencies & permanent networks);
- Establishment of the EU as a reference point for policy makers/professionals, i.e. the establishment of a change agent for innovation;
- Demand for capacity building initiating a boom of new education;
- Development of European-oriented knowledge and skills.

It seems that the highly fragmented EU health policy as it is gradually taking shape has up to now only limited, indirect, and even unintended affects often on national health systems and policies. It has, however, contributed considerably to the development of Public Health, an area which in many MS is underdeveloped and needs this support.

Health and the EU Crisis

The present EU crisis was not caused by health, but it influences EU health policy and the national health systems. The crisis started as a financial and economic one, but it has led to a general EU crisis. It still is uncertain, when and how it will be solved, but very likely the measures taken to control it will change EU objectives, structures, competences and instruments. The future EU will be quite different to the one existing in 2014.
As early as in April 2012, the former EU Health Commissioner John Dalli, who later was forced to retire under still not clarified circumstances, said at a COCIR conference in Brussels (28): *"A key challenge we are facing today is to prevent the economic crisis from triggering a health crisis. This may sound dramatic but the risk of this should not be underestimated"*.
Largely unnoticed by the media, the public opinion, and by the Public Health Community as well, a health crisis soon became a reality in many EU-MS, especially in those which because of their critical economic situation received financial aid through the "Economic Adjustment Programmes". Examples of impact and extent of the health crisis are shown by the following figures in the "Briefing notes" of the European Public Health Alliance (29):

- Rise in unemployment in the EU-28 from 7.2% in 2007 to 9.7% in 2010 and 11.0% in 2013 (Greece 27.5%, Spain 26.2%, and Croatia 17.6%), especially the deterioration of youth employment which in 19 of the 28 MS stood at over 20% in 2013.
- Mental health and suicides rates, which until 2007 had been consistently decreasing rose in the EU from 11.4 % in 2007 to 11.8% in 2012, alarming in some MS such as Greece, Spain, Ireland and Italy.
- Cutting health budgets as well as other resources and frequent measures to reduce costs in nearly all MS have reduced the availability of frontline services and institutions.
- Austerity measures concerning health professionals such as reducing salaries (pay cuts between 10-40%) have led to a growing migration which endangered health services in some countries.

All these measures concerning the organisation and delivery of health services belong fully to the responsibility of MS, which the European Commission has to respect. Although the Treaty and therefore the limited EU health competence – excluding most aspects of health care – remain unchanged, the balance of power between the EU and MS in health care is changing in favour of the EU as a number of new instruments were created since 2011. They are intended to strengthen the EU governance of economic policy but have of course an impact also in the health sector. The new instruments should enable the Commission to intervene directly in national health care policies from a financial perspective and force national health systems to contribute to the achievement of the economic EU goals. These interventions concern not only "crisis states" receiving financial aid from EU, the International Monetary Fund, and the European Central Bank, but all MS in the context of a common macroeconomic policy.
Direct interventions by international into national health systems are not within the EU competences. In the past, this kind of interventions has been restricted to developing countries receiving financial aid. However, those countries receiving financial aid from the EU "Economic Adjustment Programmes" are in a quite similar situation. They have been obliged to undertake a wide range of austerity health actions demanded by the so-called TROIKA. These austerity measures are not always fully in line with widely accepted health values such as full access for everyone and good quality of medical services.
There are, on the other hand, also EU initiatives that address health care reforms in all MS in the context of a common economic policy. These direct interventions are slowly turning into a systematic EU surveillance, backed by the power to issue early warnings and to apply even sanctions. The most important new legal act that makes this possible is the so-called Fiscal

Pact *("Treaty on Stability, Coordination and Governance in the Economic and Monetary Union")*, agreed by only 25 EU-MS as an intergovernmental agreement which does not replace the EU Treaty, but is nevertheless enforced by the Commission.
The most important tool to improve policy coordination of macro-economic structural issues in key policy areas is the "European Semester for economic policy coordination" that was launched in 2011. At that time, health was not considered to be a key policy area that had to be included. But, this changed in the same year when the Ecofin Council demanded the Commission to include health. Since 2012, Health Care is included and considered to be a key policy area for economic growth and a permanent part of its five components. Since then, it is described in the Annual Growth Survey (AGS), presented every year by the Commission, a part of Strategic Advice & Orientations, contained in the "National Reform & Stability Convergence Programmes of the Member States", and the object of Country Specific Recommendations given by the Commission and the Ecofin Council (30-33).
Although the EU Health Competence as laid down in the Treaty is and will remain weak and limited mainly to Public Health, denying any EU actions in health care and health systems, it is firmly established as a key policy area of EU macroeconomic policy. All decisions are dominated and made by economic actors and structures in all of the European institutions with mainly economic interests in mind. Those responsible for health play a minor role in the decision making process.

Future perspectives
An article about the past developments in the EU would not be complete without taking a look at future options and perspectives. There is a large number of publications describing and criticising EU health policy, but there are hardly any books or scenarios about its possible future. Scenarios of the future are manifold. As far as health is concerned, three factors have to be taken into account:

i. The future EU
ii. New challenges and new solutions
iii. The role of health in a future EU

The future EU
The EU is here to stay. There will be changes. The number of its members will continue to grow – there seems to be almost no limit. Industrial ties and economic interests will guarantee its pertaining future existence. Some countries may leave the EU, the main candidate at the moment being the United Kingdom. This for many reasons would have negative effects on both sides, especially in Public Health, as the English Public Health Community appears to be the strongest one. Growth, however, will also continue to increase problems in two ways. On the on hand, the differences between MS such as size, population, economic situation, resources and the like, will lead to more inequality, for many aspects including health. On the other hand, the EU will have to cope with its growth with structures and instruments that were designed for a small community of six countries, all of which similar regarding their economic situation.
In order to adapt the EU to be able to better master new challenges and tasks, it is essential to change not only its objectives and priorities but also its competences, structures and instruments, including a new balance of power between the three institutions - the Council, the Commission, and the European Parliament. This normally could only be done by a fundamental change of the Lisbon Treaty, however, that is almost impossible, not only right now, but also in a foreseeable future. It needs unanimity by all MS and ratification – partly by a national referendum – again by all MS. Because of this, the debate about a new treaty,

including the establishment of a Political Union, has stopped. We will have to live with the Treaty of Lisbon for a long time.
The answer possible at the moment – and for some time – can only be a Europe of two speeds, in no way a new development. We already have an EU of at least two speeds in areas in which not all MS could agree on a common way forward. The Schengen agreement on border regulations and the creation of a Monetary Union, establishing the new currency EURO in most but not all countries, are the most prominent examples. Lately, and more relevant for the health, is the creation of the Fiscal Union (Treaty on Stability, Coordination and Governance) agreed up to 2012 by only 25 MS as an intergovernmental agreement, part of a new economic governance framework. In the future, supranational and intergovernmental agreements of this kind outside the EU "Acquis communautaire" and its legal base will partly replace the existing EU instruments and influence national policies more than ever before in many areas including health.
The impact of this new situation on national welfare, social as well as health systems, has not been considered sufficiently yet. To date, EU and national health authorities play only a minor role in this process dominated by economic interests. There is a danger that health values and interests could be neglected, especially when they clash directly with economic interests. For the future of health it is essential, even vital, to ensure that those responsible and accountable for health policy at the EU as well as national level take part in this process with sufficient power to safeguard health interests.

New challenges and new solutions

Presently, EU Health policy is faced with two main, totally different challenges:

- The overall EU crisis mainly caused by economic and financial problems;
- The outbreak of Ebola, one of the biggest health threats ever.

In both cases, the EU has done too little and too late. Especially in the case of Ebola, the EU was badly prepared and, so far, is largely invisible (16). Even the new European Centre for Disease Control, founded in 2005, was much too weak to create a common anti-Ebola policy of the European Institutions and the MS. As difficult as it may be to master these problems, they are at the same time an opportunity to move forward. The development of the EU health policy has often been crisis driven. There is justified hope that the new situation will lead to new solutions, only possible in a time of crisis.
In the past, the progress of EU health policy was triggered by new challenges and dangers which could not be tackled sufficiently on the grounds of the existing legal base, structures and instruments. Communicable disease outbreaks (AIDS and HIV-blood contamination, CJD, SARS, and especially BSE posed severe threats to health, similar to bio-terrorism) are prominent examples enabling progress that otherwise would not had taken place:

- Treaty changes strengthening the EU legal base for Public Health;
- The EU Health strategy with strategic objectives and principles;
- New organisational structures within the EU;
- Shift of competences (food, pharmaceuticals) to health institutions;
- Intensification & institutionalisation of new cooperation capacities;
- Creation of comprehensive databases & information systems;
- Establishment of agencies in health-related areas (altogether nine);
- The new instrument of "Open method of Coordination (OMC)", applied to health;
- Closer cooperation of the EU with WHO and OECD.

Most importantly, they brought about changes in the attitude of MS. These were influenced to some extent by the needs and expectations of new MS which considered it essential to add

health care and finance issues to the EU health agenda. MS still consider health to be, first and foremost, national responsibility but there is a slowly growing feeling *"…that health policy should no longer be discussed exclusively in terms of national autonomy and sovereignty"* (19). EU power and influence related to "All Other Policies" has already changed the environment in which national health policy takes place. As there is also a feeling that many problems, be it in health care or fighting new health threats cannot be solved effectively at the national level, it is increasingly recognized that the EU health policy is not simply a continuation of national health policies, but it is in many ways different.

The legal basis

A new and more precise formulation of the EU health competence (Article 168) is needed, but obviously not possible as it would require a change of the Treaty. However, a new consensus could and should be achieved as to how the Article 168 should be interpreted and implemented. The EU should not continue to be active in every possible health arena, many of which are already sufficiently covered by national health policies. It should concentrate and limit itself to those issues, where MS need EU support, because the objectives of the action cannot be sufficiently achieved by the MS. This is not new, but simply the subsidiarity principle as laid down in the Article 5 of the Treaty, which in the past has been neglected too often. If this is done, there is no need to continue the permanent debate about giving EU health competences back to the MS. A renationalisation desired by many would take place automatically.

Internal structural reforms

To be better prepared for facing future challenges, structural reforms are essential, which include but go far beyond 'Complementing national policies' and 'Encouraging cooperation between MS', without intending a harmonisation of national health systems.

These should include:

i. The internal reorganisation of the Commission which should increase and not decrease the areas for which the Health Commissioner is responsible, including all those with a priority health interest.
ii. Increasing, stabilizing, and institutionalising the EU problem-solving capacities by establishing new health agencies (examples: health technology assessment, rare diseases, E-health, or health information systems), strengthening the administrative power of the existing ones, and creating new observatories and permanent networks in order to improve the diffusion of best practices.
iii. Advance, even institutionalise, a closer cooperation with WHO and OECD making use of their reputation, knowledge, experiences, manpower, worldwide resources and avoid double work. In the long run, this should result in a common institutionalised Global Health Policy with many partners.

The role of health in a future European Union

Again, EU health policy is here to stay. It is no longer questioned any more that Public Health should remain to be an EU policy of its own. Nobody is demanding any more a total renationalisation. Nevertheless, the EU Public Health Policy as such is far away from being or becoming a European priority. It is, at best, only a side issue on the European stage with little power and low resources.

But, this is not even half of the story. Health as an issue, not as a policy, has been transformed during the past years from a non-topic to one of the most important EU fields. In the main stream of EU politics, i.e. policy coordination on macro-economic issues, health has become

and will remain a key policy area. This elevation is fully justified considering its economic implications and its position in the four freedoms of the Internal Market.
Nevertheless, the EU Health Policy is and will remain a patch work consisting of many different parts and partners. It is a complex cross-cutting policy sector and is part of and regulated in a multitude of other policy sectors like environment, consumer protection, industry, research, transport, agriculture, competition, information and – most importantly – the EU Internal Market policy. Health policy and especially health care are an intrinsic and relevant part of the European Market of goods and services, which are affected and partly even harmonized via simple market compatibility. The decisions are taken issue-specific, fragmented, not very transparent, and mostly guided by economic interests. The EU is foremost an economic union and partly even a political one, but not a social union. Health, contrary to social progress or environment, is not mentioned as an EU objective in the Lisbon Treaty. Health, as a key policy area, is only of interest as long as it is part of another policy and has positive or negative economic implications.
Health authorities within the EU-Commission, the European Parliament, and the Council of MS, at best, play only a minor role in the economy dominated decision making process. It is obvious that health values and interests could easily be neglected, especially when there is a clash with economic interests. It is essential and vital for the role of health in a future EU to ensure that those accountable and responsible for health at the EU and national levels take an active part in this decision making process with sufficient power to safeguard health interests. In the past, this was partly achieved by shifting more competences within the Commission from agriculture (food), or the Internal Market (free movement of patients and professionals, pharmaceuticals) to the Health Directorate. This was much more than just an internal organisational act by the Commission because it had consequences for the decision-making process in other EU institutions. Whatever belonged to the tasks of the Health Directorate was automatically decided by the Health Council and the Health Committee of the European Parliament.

Conclusion

EU health policy as a whole has not been an unequivocal success story: there are weaknesses but also strengths. Its main strength is that it has become a permanent part of the European integration process. Hardly anyone is demanding its renationalisation anymore. Considering its weak legal base, the restrictive position of the MS, and the activities of recognised international organisations such as WHO or OECD, it is astonishing to observe what has been achieved. A ‘non-topic’ has developed into a key policy area of the EU economic policy. This is not due to a sudden discovery of the value of Public Health – the esteem for EU action in this area is still low – but relies entirely on its economic consequences. However, there is also the danger and even to some degree a tendency that the EU health policy might be reduced to narrow Public Health issues alone. Therefore, public health activities should not only be continued but, in due time, considerably broadened and strengthened. In the future, the main task will be to safeguard health interests in ‘All Areas’ including economy, to ensure that economic interests do not precede health. This task should not be left to Non-Governmental Groups, as valuable as their contributions will continue to be, but should be the task of health authorities within the Commission and in the MS. To be successful, this requires political power as well as adequate organisational structures, giving health authorities more power instead of taking it away from them. In addition, it needs scientific evidence that could be provided by the EU-funded public health actions and research. If this happens, there is no reason to have doubts about a positive future of the EU health policy.

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