



BUILDING THE EUROPEAN HEALTH SYSTEM

SYNTHESES AND RECOMMENDATIONS

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PREAMBLE

Guy Vallancien, Président, CHAM

This is a major project that will require more cohesion between member countries or at least those willing to develop a real "European health area". This means a Schengen type of agreement on medical research, artificial intelligence, health prevention and health care while our old continent is suffering from political fractures and populism. Are we going through another crisis just like the many crises experienced before or is it a serious society issue? Is it the end of a European civilization - white and Christian - which was able to win the battle against hunger, develop trade and industry, and promote human rights. Europe numbers 515 million people who are well fed, protected by a welfare system, living in a mild climate, happy with their well being and a brighter future. We went from individual rights to "I can do it too" and "I can say anything I want", forgetting our collective duties to society. Let's not mimic the Marquise de Pompadour, who, while Quentin Latour was painting her portrait at Versailles, replied to the king Louis the XVth, who announced the defeat of the French armies at Rossbach, "let's enjoy life now, when we will be dead the world will take care of itself". Are we aware that in 2050 the planet earth will number 4.5 billion Asians and Indians, 1.3 billion Americans and 2.5 billion Africans, 50% of whom under 25 years of age, while Europeans will number barely 500 million and a third of them will be over 60 years of age. Xi Jinping, Modi and Putin did not attend the opening of the 73rd plenary session of the United Nations in New York. The oldest civilizations are re-inventing a new world that will rise in the East.



We witnessed passively the startling emergence of digital economy. We are now dominated - if not crushed - by the US GAFA and the Chinese BATX that are taking over. Facebook is 14 years old and Google is celebrating its 20th anniversary while no European start-up was able to become a global giant in the same short period. With its funding of 1 billion Euros over 10 years, the European Human Brain Project is definitely not up to speed and it is undermined by infighting. In the meantime China is planning to inject \$152 billion in the development of Artificial Intelligence between now and 2030. We are not playing in the same court. A Chinese humanoid robot called "Xiaoyi," - (the small doctor) managed to graduate in medical studies with above average grades and answered the exam questions 10 times faster than its human colleagues. It will be deployed in remote Chinese regions where there are no medical doctors.



Considering the high level of our medical services and our highly qualified medical professionals, health could become the theme of choice to promote European harmonization. There are two pending health issues: improving citizens' protection and fostering inventions and new medical technologies that will be made available to patients. But do we really want to rise to the occasion? If the answer is yes we have to make a quantum leap to bring researchers together and inject - not millions - but tens of billions of euros to catch up for lost time, with the hope of getting back in the race. Using ethics as a shield against the unknown is naïve and foolhardy.

Our challengers will laugh at us and at our morals. They have the will and the power to surge ahead. We are moving slowly while the rest of the world is moving away at digital speed. Let's wake up! Stand up Europe! We have not lost anything yet but the task must be embraced now. Let me conclude with that quote:

"We live in a fast changing world, we live through challenging times and the most daring ideas will lead people to do in one year what we used to do in one century. Thanks to railways, Europe will soon shrink to the size of France in the middle Ages! Thanks to steam ships, we can cross the ocean faster than we could sail across the Mediterranean Sea a few decades ago! Before long, man will travel the earth like the gods of Homeric times who could roam the skies in a few steps. In a few years, the electrical wire of the Concorde Square in Paris will be part of a grid wrapping the Globe. One day we will see two huge countries, the United States of America and the United States of Europe, reaching out over the seas to exchange products, know how, manufacturing facilities, art, creativity, in order to organize the world, promote innovation and combine their efforts in a pursuit of well-being for all. I am calling on the English, French, Belgians, Germans, Russians, Slavs, Europeans and Americans. What can we do to reach this golden age as soon as possible? We should love each other."

Signed by Victor Hugo. This is a quote from his speech at a Peace Congress in Paris 169 years ago, in 1849.

STRUCTURING A HEALTH SYSTEM

Should a European Health system lead to harmonization of national policies?

A coercive European health system should be based on a European moral contract, under which healthcare access rights would be enforced throughout the territory. EU also requires an extended cooperation to exchange data and develop shared digital tools, including European medical records, currently under construction.

A single digital market is a prerequisite for the deployment of a European health policy

A European Health system should also take on board Artificial Intelligence. Its development is based on two conditions: access to mass data and access to a market large enough to produce a satisfactory return on investment. Both conditions entail creating a digital common market.

Harmonization of national policies v/s resource pooling

Even if national education programs are not intended to be aligned or harmonized, EU should evolve towards common standards of excellence. As a lack of European consensus would lead to weak European policies, EU is expected to promote cooperation and pooling of resources while respecting national prerogatives. The same goes for evaluation, an area unlikely to be centralized but that should open up to transnational cooperation.

A Protective Europe

By pooling resources while respecting national prerogatives, Europe must become protective. Pooling will improve EU's capacity to achieve results. It will make it possible to develop tools to complement national policies and deploy tools that isolated Member States could not afford on their own.

Resource pooling as an alternative to the creation of a High Authority of European health

Altogether, transnational cooperation based on Common European foundations should let Member States benefit from a European system. That path could eventually lead to the creation of a European Health Authority. However, it might take a long time before it happens.

DEPLOYMENT OF A CONTROLLED DIGITIZATION

Access to data will promote access to innovations

GDPR is one step ahead for the protection of personal data, but it may also become a burden for research programs. Still, more than ever the health industry needs data to develop prevention tools. In that scenario, personal health data becomes an important component of the collective assets, considering its potential contribution to the development of artificial intelligence tools and the definition of medical procedures.

A European model for Artificial Intelligence

In the field of artificial intelligence, Europe cannot backtrack. On the contrary, EU must go forward and keep in pace with China and the United States. If American, Chinese and European policies for data management are irreconcilable, Europe, can and must, build its own artificial intelligence model in compliance with GDPR to remain competitive and guarantee the confidentiality of users' information.

European Initiative for the development of health data

The European Commission is getting ready to promote access to health data at EU level. Research must rely on shared data, within a safe and secure technical framework. It is still work in progress, as Europe is not yet ready to offer the level of cybersecurity that one could legitimately expect.

European coordination, rather than centralization

Member States have their own digital policies. France for instance, added a digital component to its national health strategy. Denmark has mobilized energies to develop a national tool to access health data. These initiatives are supported by EU, in order to create a convergence among Member States for developing a common global framework. Once again, EU must coordinate, foster convergence and refrain from advocating a coercive centralization.

EDUCATION AND INFORMATION - CLEAR OPTIONS ARE NEEDED

From diverse education paths to a common foundation: when Member States and health professionals start pulling in the same direction.

Education curriculums for health professionals vary widely between Member States. Major regional disparities can be observed in the most decentralized countries. At first, even before attempting to define a European curriculum, Member States could agree on the definition of quality standards and excellence levels.

The common foundations would be shared by Member States and various health professionals. Like the LMD 3-5-8 model, a college degree would be required to become nurse and a graduate degree to become a medical doctor. Thus, future health professionals would learn about each other and from each other during their studies, which would contribute to a smoother operation of the health structures.

European prevention via the provision of scientific services

Confronted to the rise of populism and fake news, EU which is sometimes accused of being controlled by the lobbies, has to oppose arguments based on unquestionable scientific evidence. In its action for prevention and education, EU must promote convergence. If Europe has to integrate national cultural specificities, it must have - more than ever - scientific arguments at its disposal. In so doing, it could play the role of a service provider to Member States and supply scientific services. Prevention would remain part of the national policies, but it could be based on common scientific foundations.

European health or medical tourism?

Medical nomadism is mainly used for light care procedures and by well-off European citizens. Many member States do not see the business potential of that market and how it could contribute to their own health system.

That system is not a European Health System. In the European Health System, Member States must be mobilized to exchange data, best practices and spread information on medical treatments. Ideas are easier to exchange than patients. A sustainable European Health System must reach out to the territories, develop medical care everywhere in the territories and promote the development of telemedicine at national and transnational levels.

A PRESENCE BEYOND EUROPE

More than ever, Europe is competing with China and the United States. EU is lagging behind and struggles to give birth to European players become powerful enough to compete with GAFAM and BATX. The situation is even worse in the field of health.

From innovation to sales - market economy supports innovation

The quality of basic research in Europe is not at issue. Europe innovates, but its innovations have a hard time reaching the market. And its markets, taken individually, are modest compared to China or the United States. Europe has a track record as an innovator, but it can no longer increase its global market share and produce world leaders.

To develop global health leaders, Europe needs to mobilize all its resources to ensure that innovations reach European markets quickly. Ultimately, Europe will become a credible competitor to China and the United States if it can “make money” from its research.

Creating European markets for medical treatments

In the health care industry, opening borders to create a European market does not suffice to foster the emergence of European giants. EU will have to achieve some degree of harmonization in the management of patient care. Harmonizing national processes will make it possible to develop a range of services covering EU’s various health systems.

Economic and regulatory leverage

EU and Member States have legal and financial set ups that favor innovation. However, access to capital funding remains difficult. Public authorities must imperatively induce private players to invest in order to create a leverage effect. In order to let innovators gain access to funding, EU would need to create a European NASDAQ. In that scenario, leverage is not financial only. Investors and innovators, need a stable regulatory framework. Member States must respond to that need.

The necessary alliance between health and digital tech

Europe has nurtured remarkable skills and resources in health and digital sectors. Both sectors can no longer operate in isolation with a sense of mutual distrust. Digital technologies must be an integral part of health innovation. Innovation must focus on application development, especially mobile applications.

A real sense of urgency

Some people want to drop the precautionary principle, seen as an obstacle to innovation. France and Europe, must be aware that we have an emergency situation at hand. The war against China and the United States is not lost, but the time to react is NOW. Innovations’ time to market is too long. French and European stakeholders do not grasp the value of the first mover advantage. To snap market opportunities and expand beyond their borders, Europe and the Member States will have to use their evaluation devices as facilitators.

GUIDELINES FOR BUILDING A EUROPEAN HEALTH SYSTEM

Agnès Buzyn, Minister of Solidarities and Health, and **Jens Spahn**, Federal Minister of Health (Germany), reviewed the main guidelines to build a sustainable European health system.

European medical records

The planned EU medical records will include a patient summary sheet and the prescriptions of all European patients. This project for the medium term will require first the construction of digital spaces by every Member State.

Common standards of excellence for training

European cooperation must focus on education programs, not to standardize them, but with a view to come up with common standards of excellence.

A European prevention policy?

If prevention remains a prerogative of the Member States, the cooperation principle should make it possible to lay down common scientific foundations, starting with the risks that are easily preventable.

A European evaluation?

Even if it is unrealistic to aim for a centralized evaluation, Member States are expected to increase their collaboration in the area.

A Protective Europe

Resource pooling will be very useful for evaluation, crisis management or prevention. Europe can thus deploy resources in addition to those of Member States without replacing them. A Europe, focused on the services provided to its citizens, is a protective Europe.



CHAM
2018

Summaries



DIGITAL ECONOMY AT HELP HEALTHCARE

Mariya Gabriel, European Commissioner for Digital Economy and Society (UE)

With **Alexandre Regniault**, Partner, Simmons & Simmons, Vice-President, France Biotech (FR)



1. European Initiative for the development of health data

On April 25, 2018, the EU commission issued a press release on an initiative dedicated to the development of and access to: health data. There is an urgent need to strengthen the cooperation between EU members and to focus on health care. In the health sector, the competencies of Member States are clearly defined and jealously guarded.

The initiative of the European Commission is focusing on 3 priorities:

- Access to and protection of, the data;
- Database consolidation and boosting R & D;
- Development of applications - preferably mobile.

The E.U. Commission emphasizes the need for a project on human genome sequencing. Only 17 Member States are supporting that particular initiative. Unfortunately, France has not joined the project yet.

2. Use of personal data and cybersecurity

There are some blocking factors. You just have to check any web page on that issue to become a target of choice for numerous related ads. For reasons that are easy to understand, users are concerned. Sick people fear that their bank or insurance company may adjust their rates depending on their health condition. It is important to understand their fears. Europe is obviously not ready yet, to guarantee an expected level of cyber security.

3. National strategies and European coordination

The national health strategy presented in September 2018 includes a digital component. The EU Commission supports these initiatives, but wishes to promote coordination within EU. The Commission acknowledges that national strategies must - first - meet the needs of the various populations. In fact projects derived from national strategies qualify for European funding.

4. Algorithms and individual considerations

Digital technologies and Artificial Intelligence are disturbing at first. The development of algorithm based data processing could lead to disregard individual specificities. In fact, the patient would not be a stakeholder in the management of his medical treatment.

5. Value added by ethics to Artificial Intelligence

The European approach to Artificial Intelligence gives a controlling role to Man. He must be in charge of the process from beginning to end. Artificial intelligence must be at his service. This is how ethics will provide an added value to artificial intelligence. It is the path chosen by EU authorities. The European regulation must not be a stumbling block, to the contrary it is aimed at boosting artificial intelligence development projects that are both ethical and human.

6. Artificial Intelligence, labor market and digital skills - European rebound

Europe wishes to increase the resources available for digital skills development. In 2020, 90% of the jobs will require basic digital skills. We must take corrective action and bring into the digital world the people left behind. EU Countries must follow the same digital road map. In the next budget, the EC will propose a European digital plan that will prevent Member States from acting in isolation. The plan will focus on artificial intelligence, digital skills development and cybersecurity. EU Countries must follow the same digital road map. China and the United States will not wait for us and have no plan to comply with European standard.

HEALTH: A DECISIVE STRUCTURING FACTOR FOR MORE EUROPE

Speakers:

Francois-Xavier Albouy, Head of research, Chair in “Demographic Transitions, Economic Transitions” (FR) - **Nicolas Bouzou**, President, Asterès (FR) - **Francesca Colombo**, Healthcare director, OECD (EU) - **Mariya Gabriel**, European Commissioner for Digital economy and society (EU) - **Françoise Grossetête**, Member, European Parliament (EU)

Led by **Vincent Olivier**, President, RectoVerso (FR)



1. Benefits and drawbacks of a health-focused EU.

EU's contribution goes broadly unnoticed. The 24 European benchmark networks have notably improved research coordination for the benefit of patients. European hospitals have joined networks and contribute to knowledge development. Health care needs big data, but it makes sense only if it is on a European scale.

However, we are running out of enterprising spirit. It is not unusual to see regional University Hospitals quarrelling with each other. Government authorities are not always playing moderators. Even with a huge contribution from EU a number of steps must be taken first.

2. Scenario of a coercive European health policy

A coercive European health policy, focused on practical aspects of public health, would require extensive data transfers. It would be based on a European moral contract, under which access rights to healthcare would be enforced throughout EU.

3. Investing in artificial intelligence - the benefits of a single digital market

Artificial intelligence is fed with data. Its added value comes first from a data-driven learning process and comes to a lesser extent from complex algorithms. To develop artificial intelligence, we must develop the data content. Artificial intelligence is becoming more capital intensive and to amortize the investment we have to budget the capital expense beyond national borders. To develop a European artificial intelligence, we must create a single digital market. It is a simple and straightforward proposal. The U.S. and China can invest more resources as they have access to much larger markets than our small countries.

4. Data processing

While it is important to develop data content and access to the data, Europe must also develop the required processing resources. Data as such is of no use if it cannot be processed. EU wishes to create its own robots for 2022, to process its own data without having to entrust it to China for processing.

5. From basic research to applied research - facilitating market access

A broader access to supercomputers is needed to let small and medium businesses access the data. While the quality of European basic research is acknowledged worldwide, EU's applied research lags far behind that of the United States and China, in terms of patent filings: only 6%. To narrow the gap EU must give businesses an access to the market. Unfortunately if the economic rationale is easy to understand, the deployment is slowed down by political inefficiencies.

6. From giving money to research, to making money from research

EU's intelligence and ethics will not suffice to catch up with the United States and China. Europe is rich and smart, but it is small. Access to the markets must be its key objective. Europe is funding research, but the return on investment is not high enough. Supporting applied research in Europe makes sense only if the applications are in line with common market objectives.

MEDICAL TRAINING: THE BIG MESS

Speakers:

Sophie Kläschen, Dermatology resident, UKB (DE) - **Antoine Reydellet**, Occupational Medicine intern, HCL (FR) - **Marco Schetgen**, Dean, Faculty of Medicine at ULB (BE) - **Jean Sibilis**, President, Dean's Conference of Universities of Medicine (FR)

Led by **Mickael Benzaqui**, Medical Advisor, FNEHAD (FR)



Numerus clausus changes will impact us in 10 years. Depending on their field of expertise, students deemed redundant yesterday may become the practitioners that we will need tomorrow. Streamlined and more agile education/ training systems should be able to respond faster to the changing needs of the health system and the territories. Theoretically, an 8 to 10 year educational curriculum could be introduced. A graduate degree would be needed for a nurse, while a medical doctor would need a post graduate degree. Is it possible to contemplate such a simple system?

1. Numerus clausus - symbol of a policy doomed to failure

The Numerus Clausus is not delivering the expected results any more. It is bypassed by students who enroll in medical schools abroad. From a pedagogical point of view, it is an unfair and centralized system. Furthermore, the setting of a numerus clausus is misunderstood, as it does not always meet the actual needs of the health system. Therefore, abolishing the numerus clausus appears like a positive step. Regulation is still necessary, but numerus clausus is over.

2. French students going to medical schools abroad to bypass the numerus clausus are sometimes considered as cheats

Even with average grades around 15/20 it is possible to fail at the end of the 1st year at medical school in France. As a consequence, some students go and study in foreign countries, including Romania. For some students who had shining results throughout their school years, that first failure is hard to take. When coming back home in France, they should be treated as colleagues by practicing doctors and not as cheats.

3. The German case

In Germany, students are selected according to their baccalaureate results based on a 2-year work assessment. In fact the screening takes place before starting the medical studies. The issue is currently debated in France where the high school system is highly decentralized and deemed unfair

4. The Belgian case

Belgium has restored the numerus clausus. It is a small country with a very complex political system. The quota policy applies after 6 basic years, but the initial selection is controlled by the Flemish Community on one side and the Walloon community on the other side. Selection criteria differ widely between Flanders and Wallonia. The complexity of the system is even increased by the screening resulting from the federal quota. From an operational point of view, it is impossible to provide an agile response to the needs of a health system strictly based on a quota. Skills must be part of the selection criteria. A good doctor is not always the student who gets top grades at exams.

5. A new body of health professionals?

The creation of a single curriculum would be a major step forward. It is impossible to decide if a 17 or 18 years old student will be a good doctor during 40 years. With a single curriculum it is possible to train young people in various health sectors, in a progressive way, escaping the unfair selection via a single examination at the end of the 1st year. During their first three years in the single curriculum, the various specialists could speak to each other, thanks to the cohabitation, between future nurses, future physicians, future surgeons, etc. During these first graduate studies, students can take the time to discover the various health activities. Over a period of time students with different health options would learn about the work of the other students and share their knowledge and experience.

6. A European curriculum?

A global curriculum, could be used to create a common base, without going as far as an alignment at the EU level. It could also take into account specific characteristics based national structures which could hardly be aligned.

A EUROPEAN HEALTH AUTHORITY?

Speakers:

Dominique Le Guludec, President, French Health Authority (FR) - **Alric Rüther**, Head of International Affairs, IQWiG (DE)

Led by **Jacques Belghiti**, Member of the French Academy of Medicine (FR)



1. Should we dream of a high authority for European Health?

Is a high authority for European Health desirable? To answer the question, we must first identify the areas where Member States would be likely to share with other countries. How about assessments and guidelines? Do we really need to set up a high authority for European Health or is it easier to move forward in a progressive way by capitalizing on shared knowledge and resources?

2. Diversity, quality and differences

The European network is both rich and lively. There is a variety of national systems, but they are overall, high quality health systems. Step by step Europe can overcome the differences. It will gain the support of national populations if it focuses on health care quality.

3. Positioning of the High Authority on Health in France and in Germany

In France and Germany, the scope and fields of evaluation of the High Authorities on Health have their own specifics. In Germany, the High Authority for Health assesses the guidelines, but does not create them. In that regard, it is not subject to executive approval.

4. European Medicines Agency (EMA)

Membership in the European Medicines Agency is currently optional. France took a resolutely proactive stand and advocates the emergence of a European evaluation system with - in specific fields - joint testing funded by the European Commission.

5. Pooling the resources

The pooling effort must be clearly defined. Citizens must understand that resource pooling does not expose them to a risk of lower quality. Resource pooling could be used to invest in areas where each country would have problems investing alone. A phased deployment of a joint approach will insure a soft transition towards a common action plan. Each Member State must be able to gauge how it will benefit from resource pooling and scientific collaboration. Resource pooling must be seen as a mean to develop capacity.

6. Towards transnational care?

Europe can promote pooling, but it must leave enough room for cultural and national appropriation. Social diversity must be preserved. Via various pooling scenarios, Europe can lead the way to transnational care, but that cannot be binding on Member States. Consequently, Europe would have to set guidelines without enforcing directives.

7. Resource pooling will come before the creation of a High European Health Authority

All in all, the European Higher Health Authority is not born yet. But we must take a first step with resource pooling and optional transnational policies.

PATIENTS, TOWARDS TRANSNATIONAL HEALTHCARE

Speakers:

Terkel Andersen, President, Eurordis (DK) - **Thomas Berglund**, President, Capiro (SE) - **Sophie Boissard**, Group CEO, Korian (FR) - **Nathalie Salles**, Professor of Geriatrics, CHU Bordeaux (FR)

Led by **Philippe Denormandie**, Surgeon, AP-HP (FR)



1. Emergence of medical tourism

Tourism and medicine are becoming two interrelated concepts. Current medical nomadism, relates only to the management of relatively light treatments. But it could gradually expand to the management of heavier treatments. Europe does not seem to realize that it is an important and complex issue.

2. Medical tourism, just another type of tourism?

Some countries - France included - do not seem to be aware of the economic potential of their medical resources. Germany, on the other hand, has substantially developed a medical activity aimed at attracting paying patients from other countries.

3. From the expatriation of sun loving retirees to the expatriation of patients and pensioners in foreign hospitals or retirement homes

Just like retirees choosing to live in southern Europe, more and more geriatric and post-operative rehabilitation patients choose to leave their country, to settle in sunnier countries with a more affordable cost of living. New tourism organizations are being set up to attract these patients.

4. Is Europe shifting its focus from health to patients?

Ideally, resource pooling should lead to an access to treatment throughout all EU territories. If medical tourism is attractive for light treatments, medical tourism for heavy treatments is only available to the richest people.

5. Moving the skills and not the patients

In a patient focused Europe, health care must move to the territories. To prevent the European health policy from sliding into medical tourism, EU and Member States must band together to promote the exchange of data, best practices and the dissemination of health care. It is easier to spread knowledge than moving patients around. With telemedicine - on a national or transnational scale - it is easy to gain access to skills wherever they are, rather than sending patients on long medical journeys.

DENMARK: REGIONAL FUNDING AND DAILY DIGITAL CONNECTION

Erik Jylling, Executive Vice-President Health Politics, Danske Regioner (DK)

With **Guy Vallancien**, President, CHAM



1. Denmark - a simple system based on an in-depth reform of the political map..

Denmark is about the same size as the French Region called PACA (Provence, Alps & Côte d'Azur). However, the gap widens when comparing GDP, unemployment rate or the number of municipalities. In 2007, Denmark went through a major revamping of its institutions with new power sharing. Counties and municipalities were deeply reorganized, simplified and streamlined. The existing 14 regions, were merged into 5 new regions.

2. ... and a transformation of the funding system

Just like the political map, the Danish health system was completely reorganized. Every year, funding is the object of a negotiation round with the 5 regions. The negotiation includes incentive factors to induce regions to fight the rising costs of care and examinations. Public sector health care institutions are also "incentivized" to refer more patients to the private sector. In a matter of 10 years, the new system led to the closing of beds and hospitals in some locations and to the construction of new hospitals in other locations.

3. Taxes and Decentralization

Denmark is a highly decentralized country, while France remains a very centralized country 35 years after the 1983 decentralization Laws. Danes pay happily their taxes because they are realistic and know that their tax money will be used to give them free access to health care and higher education, among other things. For Americans it would look like a communist system. It's probably true, at least in part.

4. Skills assessment for nurses and doctors in Denmark

Health professionals are not assessed individually. They are assessed against the objectives set by public authorities in terms of patient health. The system is based on 8 major objectives and 29 indicators applied collectively. Doctors' compensation is 25% based on meeting national targets.

5. Digital connections

Danish doctors, nurses and paramedics are fully connected. The global connection system was made possible by a transition from 27 to 2 payroll systems. The connection of health-care professionals will soon be based on a single and totally digital compensation system. In a highly decentralized country, standardization is sometimes necessary to meet operational objectives in a pragmatic way. Finally, thanks to a broad partnership with private stakeholders, Denmark succeeded in developing a national tool to access health data.

USE OF PERSONAL HEALTH DATA: WHAT EUROPEAN SAFEGUARDS?

INTERVIEW

Giovanni Buttarelli, European Data Protection Advisor (UE)

with **Didier Bazzoichi**, Managing Director, Covéa Santé Prévoyance (FR)



1. GDPR protects citizens' dignity

Europe is playing its role when protecting citizens' fundamental rights. But what are the guarantees of GDPR? Until May 25, 2018, data protection was seen as a complement to freedom of movement, persons and capital. GDPR protects approved practices and ambitions to increase the effectiveness of firewalls. Users' dignity is at the heart of the regulation. Every citizen must be aware of the consequences of his on-line behavior. Until 24 May 2018, citizens' protection was a very complex issue.

2. Specifics of the health sector

The EU Commission identified various areas in which Member States have more autonomy and more specificities. Health is part of them. However, Europe must speak with one voice and set a perfectly clear framework. A common European health policy can't be rolled out based on fractional and heterogeneous data. It is necessary to set clear boundaries and enforce codes of conduct.

USE OF PERSONAL HEALTH DATA: WHAT EUROPEAN SAFEGUARDS? DÉBATE

Speakers:

Freddy Abnoui, Head of Healthcare & Research, Facebook, Interventional Cardiologist, Stanford Center for clinical research (US) - **Kathi Apostolidis**, Vice-President, European Cancer Patient Coalition (GR) - **David Gruson**, Founder, Ethik-IA (FR) - **Gaspard Koenig**, President, Génération Libre (FR) - **Eric Leandri**, President, QWANT (FR)

Led by **Didier Bazzocchi**, Managing Director, Covéa Santé Prévoyance (FR)



1. Data Protection versus access to data

GDPR is a positive step in the protection of personal data, but it will impact research if it becomes necessary to identify all patients and get their approval to use their data. The health sector has made great progress, but access to data is more important than ever to develop prevention tools. The data must be released and taken out of the silos where they are stored by various health and public stakeholders.

2. Personal data is part of our global assets

Health data is an individual priority, but it can also be part of a collective asset. In reality, if stakeholders can sell large amounts of data, people may not monetize their personal data. Finally, vis-a-vis GAFAs the user has little bargaining power. He donates his data in exchange for various services. Still, personal health data must be provided because citizens should contribute to collective good and to the development of new therapeutic treatments.

3. Qwant versus Google

The Qwant, search engine does not resell its users' personal data, unlike GAFAs. Its business model is simple and corresponds to Adwords. From 1999 to 2006, Google's business model was 100% based on Adwords. They still account for -it's important to know - 80 % of its revenue. The data is used by Qwant, but it is not useful to know who it is referring to.

4. GDPR versus Cloud Act (Clarifying lawful Overseas Use of Data Act)

The development of artificial intelligence is not at all impeded by GDPR. Europe must develop its own artificial intelligence, position its servers on its own territory and do so under the umbrella of the GDPR and not to comply with the Cloud Act. GDPR lets the health sector conduct its research and develop artificial intelligence while respecting citizens and patients. In the field of artificial intelligence, Europe cannot go back. It must go forward, while respecting users' confidentiality.

5. Facebook and the Cloud Act - the gap between the United States and Europe

Once the Cloud Act is signed, Facebook will not be able to fully protect its users' data. In that particular case, American and European policies are at odds with each other.

DRUGS: ASSESSMENT AND PRICE, A SINGLE EUROPEAN REGULATOR?

Speakers:

Frédéric Collet, President, Novartis France (FR) - **Philippe Lamoureux**, Vice-President, IFP-MA (FR) - **Nathalie Moll**, Director General, EFPIA (BE) - **Guido Rasi**, Executive Director, EMA (UE) - **Nicolas Revel**, Director, CNAM (FR)

Led by **Jean-David Zeitoun**, MD, Consultant (FR)



1. Europe is confronted to several emergencies and a revolution

It is urgent to give everyone, everywhere in Europe, a fair and quick access to medication and treatments. While, in some areas, Europe is moving slowly, some patients don't have time to wait. Patients want to have access to existing products, and also to the 7 000 products being currently developed.

In a context where the Brexit plays an important role, EU and Europe at large are losing their competitive edge.

Many innovative products are born from the tech revolution. There are so many products that each Member state alone can't develop the expertise needed. It is imperative therefore, to centralize evaluation and decision-making at the European level.

2. Europe must take charge of the evaluation, as it did for the AMM (drug marketing authorization)

Medical, scientific and clinical evaluation must be handled at the EU level. However, each country must be free to set its own prices based on the specifics of its treatment coverage. In this assessment, the risk/benefit approach is the first layer. The assessment must be conducted in an independent way. When Europe decided to put a centralized AMM in place, some stakeholders expressed their concerns. The concerns were swept away by EU's success and the same could happen with the assessment. Together with Germany, France must use its leadership to come out with a European evaluation system.

3. More dialog between Member States while negotiating with the industry

In France, it is the CNAM (National Sickness Insurance Fund) that will pay, and as such, they are interested in the price setting process. On this particular point, France and the other Member States are asking for more European dialog. At this point in time, no Member State really knows what the others negotiated for the same product. An extended dialog is needed to reduce current imbalances. It would not necessarily mean a fully centralized negotiation process with an integrated European body. However, Member States could take advantage of their critical mass to better negotiate with the industry.

4. European evaluation with national approvals - increasing inter-state cooperation without mandatory convergence?

European integration could potentially lead to a common assessment tool, but also to decisions made individually by each Member State based on the assessment. In the above scenario, Member States would benefit from the expertise pooling without losing any decision power. The European set up would provide a platform and assistance to decision making. As time is of the essence, Europe's support would make it possible to base the evaluation on a much larger sample. Instead of focusing on European convergence, France and Germany could lobby for the development of this form of cooperation.

HEALTH INNOVATION: FROM EUROPE TO AFRICA AND VICE VERSA

Speakers:

François-Xavier Albouy, Head of research, Chair in “Demographic Transitions, Economic Transitions” (FR) - **Diane Gashumba**, Minister of Health (RW) - **Charlie Graham-Brown**, CIO, Seedstars World (CH) - **Maimouna Ndour Mbaye**, Professor of Internal medicine at the University Cheikh Anta Diop of Dakar (SN)

Led by **Richard Villet**, President, French Surgical Academy (FR)



1. The “Be He@lthy, be Mobile” program in Senegal

Senegal is committed to deploy the “Be He@lthy, be Mobile” program of the WHO, to promote access to care via telemedicine. Market penetration rate is particularly high in Senegal, and that is a success factor. In Senegal, the program focused on diabetes, a critical illness in a country where 90% of the population is Muslim. Many among the faithful, are fasting despite medical contraindications. The program was a success and almost 100% of the participating volunteers said that they were ready to do it again. Duplication of the program elsewhere in Europe could contribute to reduce the cost of diabetes monitoring

2. Senegal “medicines exchange”

Senegal has developed an application to help patients to locate pharmacies where out-dated drugs can be dropped. The “exchange” makes it possible for patients to exchange drugs between them. Patients may also earn brownie points in bringing back counterfeit medicines. There again, this type of application could be very useful in Europe.

3. Senegal main priorities

Senegal has many priorities, but it would like for instance to keep the M-diabetes program, going. International organizations often experiment with new systems, but they don’t keep supporting them over time. Senegal should find ways to develop a stable economic and social model to make sure that experiments can be turned into actual development projects. The M-diabetes program was proven effective and deserves to go on.

4. The Rwandan model

Starting in the mid 1990s Rwanda mobilized its resources to build a health care system. That policy started with an action plan to fight malaria and diarrhea. In a second phase, the focus shifted to infrastructure refurbishing and the development of prevention policies. 91 % per cent of the Rwandan population is covered by health insurance. The new policy helped reducing maternal and infant mortality. Operators - public or private - are committed to meet health quality criteria under the terms of specific performance contracts. In 2018, the government devoted 16% of the country budget to the health care system. Thanks to this broad mobilization, life expectancy is now 66 years.

The country will be soon confronted with the issue of chronic diseases, like in rich countries.

5. African innovations

Africa can’t duplicate the solutions deployed in Europe. It does not have the required economic clout. Therefore, Africa must innovate and design its own solutions. Telemedicine for example is already used in various specialties, but it takes local specificities into account.

6. Building a health insurance system in Africa

Every year, Africans living in Europe send 15 billion euros to Africa. Most of that money is used to help relatives take care of their health. This financial inflow alone would suffice to support a project for the development of a social protection system. Senegal has a sickness insurance covering the cost of Medicines for children and elderly patients over 60 years of age. The other patients must pay for their medicines. Access to medicines is a problem and that creates opportunities for the sale of counterfeits.

SPEECH OF MISTER EDOUARD PHILIPPE PRIME MINISTER (FR)

With **Guy Vallancien**, President, CHAM (FR)

The National Health Strategy for 2018-2022 (My Health 2022) has just been released. A change in doctors training programs is a major focus of this strategy. The first impacts of the new strategy will not even be felt yet in 2022. The Prime Minister hopes that it will be easier to become a medical practitioner then.



1. Health care system where the doctor could focus on medical practice

Whatever the organizational and technological changes, the human interaction of the doctor with patients will remain key to practicing medicine. However, the Prime Minister wants the transformation plan to let doctors spend more time on medical tasks and less on administrative tasks and annexes.

2. Health care system where the grouping of independent doctors would be the standard solution

The Prime Minister would also like physicians to re-group in medical centers, in order to reduce the number of isolated doctors. It is a matter of helping independent doctors to get organized and regrouped to improve their collaboration with public hospitals to the benefit of their patients.



3. Gap between hospitals and city doctors

Access to doctors' surgeries becomes more and more difficult for unplanned care. At the same time, public emergencies are "embolized" by the deferral of unplanned care. The Embolization of Emergency care is the symptomatic result of all the problems afflicting the overall health system. To deal with such a systemic problem, a number of changes are needed. Problems must be dealt with, one by one and at the same time. The transformation plan of the health system is aimed at solving these issues.

4. Change in the role of the Regional Health Agencies (ARS) - from Regulation to coordination and support of local initiatives

The role of the ARS is deemed to change. They will increasingly need to play a coordination role and support the development of local organizations. A change of posture is necessary for the image of the health system as a whole. ARS will need to transform themselves to play a role as facilitators.

5. France position and public financial support

In the global competition, France is not lagging behind, but a change of scale is necessary. Strengthening relations and cooperation projects with Member States is a priority. Public funding will be important to free up energies, help businesses innovate and gain market shares. France will be in a better position to invest in a few key areas after turning around its public finances.

6. Attractiveness of the French economy

Development projects can also be managed by private investors. To attract foreign investors, France must increase its business appeal and create the conditions for a fast access to the markets. French expertise is attractive for investors, who must be convinced that they will be able to tap the markets at conditions that make it worth taking risks.

7. Keys to Success

The Prime Minister is convinced that it is possible to overcome the dysfunctions of the health system. France can rely on some remarkable skills. To succeed, French authorities must have a clear view of the situation and deploy action plans consistent with the released transformation plan. The transformation plan must be implemented for the long run.

HEALTH CRISIS: EUROPE SCATTERED!

Speakers:

Pierre Carli, Professor of Medicine, Chief, SAMU de Paris (FR) - **Philippe Juvin**, Member, European Parliament, Professor of Emergency Medicine, HEGP (UE) - **Isabel de la Mata Barranco**, Principal Adviser for Health and Crisis management, European Commission (UE)

Led by **Jean-François Lemoine**, MD, Journalist, Fréquence M (FR)



1. Does Europe need a health task force?

The number of health crises is increasing. If diseases cannot be stopped at the borders, Member States are not organized to fight them together with neighboring countries. With one health supervisory body for each Member State, Europe is not ready to face a health systemic crisis. Does Europe need a health task force? EU is currently operating under regulations clearly defined by the Treaties that create a framework for all the Member States.

2. What is a health crisis?

It is possible to consider that a health crisis is qualified by an impact on at least two Member States. However, that single transnational criterion may oversimplify the situation. How about the terrorist attacks in Paris? It could be seen as an exceptional health situation.

According to another definition, a health crisis is characterized by the destabilization of the social body. Paris attacks, Ebola epidemic or the crisis of the Spanish cucumber in Germany meet that definition.

Be that as it may, the legal framework applies to all Member States. If a serious health crisis occurs in Italy, France may not intervene if Italy does not ask for its assistance.

3. Media impact on public opinion

Media have an incredible power to produce anxiety. People's anxiety is often suggested by the media, who are turning a particular case into a general case. In that anxiety context created by media, people don't think at how they should react, but start looking for culprits instead.

Confronted to media-created crises, public authorities may be tempted to make striking decisions to respond to ad hoc situations. Decisions that may have a very negative impact over a period of time.

4. A "shared fund"

Member States do not individually have the means to support all the resources needed to deal with imaginary health crises. Therefore, the "shared fund" option makes sense.

5. Shared Resources are under used

In the operational set up of EU, Member States have all the resources needed to work together. When they do not use them, it is often by choice. Before criticizing EU, Member States - including France - must engage in self-criticism. The health crisis issue is highly symbolic of the current European debate. It is easy to point at EU's lack of impact while refusing to extend its powers. In health matters, a federal leap could help solving the problem of cross-border crises. EU would thus become a framework to ambitious projects conducted by Europeans acting together.

6. How about a European task force?

The creation of a European task force, meaning a centralized body with the power to strike without Member States' approval, would require amending the treaties. Setting up a health task force would be a new step towards a federal Europe, but it is not sure that all the Member States are ready to take that step.

PUBLIC HEALTH: PREVENTION AND EDUCATION, A EUROPEAN CHALLENGE?

Speakers:

Andrea Ammon, Director, European Centre for Disease Prevention and Control (UE) - **Antoine Flahault**, Director, Global health Institute at University of Geneva (CH) - **Olivier Véran**, French Deputy (FR)

Led by **Olivier Mariotte**, President, nile (FR)



1. Prevention must be protected against populism and fake news

The rise of populism breeds mistrust, especially on issues like vaccines. Vaccination coverage and the use of antibiotics differ widely from one Member State to another. National prevention campaigns remain rather heterogeneous. In that field Europe has a long way to go for convergence.

2. Mobilizing people against a threat that has become invisible

Vaccines are in some way victims of their success. They contributed to eradicate certain diseases in Europe. If we forget the past and disregard unquestionable scientific evidence, it is now possible to question the value of a vaccine against a disease that nobody knows any more.

3. From citizen concerns to personal concerns

Beyond scientific arguments, vaccination refers to personal concerns. But personal concerns are based on societal and cultural values, which differ from one Member State to another.

4. Specific approach for each disease

Today, France is focusing on vaccination against polio, a disease almost eradicated, with only 10 cases per year in the world. France could focus on other diseases. Its current posture is amazing, considering that approximately 6 000 people die of flu every winter. Furthermore, the flu vaccine is not very effective with the elderly, who are still a priority target.

5. Changing the vaccination policy?

Instead of targeting its vaccination policy at eradicated or almost eradicated diseases, France could focus on a number of emerging or re-emerging diseases. In terms of immunization, France has no plans to fight mental illnesses, while risks of dementia become really severe after the age of 65.

6. European prevention policy?

In investing in health and prevention, EU will move closer to its citizens and their concerns. In the deployment of a European health and prevention policy, patient groups and associations could become stakeholders.

7. Concrete actions for a European health and prevention policy

Diversity is an asset for Europe. It offers an opportunity to Member States to learn from each other. Still, Europe needs a central task force to convey a prevention message based on scientific evidence. Such a task force would act as a provider of scientific services to Member States, which could then deploy prevention policies based on shared expertise. In so doing, Europe could start targeting risks that are easily preventable.

MEDICAL DEVICES: HOW TO QUICKLY ACCESS INNOVATIONS?

Speakers:

Isabelle Adenot, President, CNEDiMITS, HAS (FR) - **Lucile Blaise**, President France and West Europe, Resmed (FR) - **David Caumartin**, CEO, Theraclion (FR) - **Stéphane Regnault**, President, Vygon, President, SNITEM (FR) - **Kerstin Wagner**, Senior Vice-President Diagnostics EMEA, Siemens Healthineers (DE)

Led by **Laurence Comte-Arassus**, President, Medtronic France (FR)



1. Controlling health spending versus access to innovations

Expense control is a limiting factor for a quick access to innovation. Controlling expenditure makes sense, but it is a hindrance to achieving certain health objectives. There is some sort of innovation phobia, as some people fear that innovation may trigger a spending inflation.

2. Can innovation be used as a budget balancing item?

In a context of expenditure control, innovation can be used as an adjustment variable. When companies, want to control or reduce their expenditures, they may be tempted to put pressure on their suppliers to lower their prices. Let's hope that innovative solution providers are not considered by health system stakeholders as mere suppliers.

3. Innovative evaluators as well?

Innovation is gathering momentum. To gain access to the market, innovation must be evaluated by the CNEDiMITS. With the acceleration of technology development, evaluation authorities have to follow suit. Innovation is a state of mind. While assessment procedures are getting more agile in the United States, which creates an appealing situation for young and innovative companies, Europe must send a clear message to fight the brain drain of innovative entrepreneurs.

4. Ongoing evaluation process made easier by digital technologies?

Real time examinations should facilitate - once the main principles have been assessed - the evaluation of new devices as they are being developed. Digital technologies will play a major role in that procedure.

5. Innovative entrepreneurs need a stable business environment

The French health system and patients, have a dire need for innovative partners. The HAS and CNEDiMITS are just links in the procurement chain and have no control over the business side. However, they are fully aware that innovative companies - especially the smallest ones - need a stable business environment. If the context does no change, large companies only will be able to innovate in France in the future.

6. Innovation - costly or increased productivity?

Innovative medical devices provide opportunities to increase efficiency and cut costs. They may free up time for more productive tasks. Even if the time saved is not measured, productivity gains have a very positive impact on the overall health system.

7. Evaluation makes it easier

To promote innovation and assist the health system in developing a smooth workflow, the Regulation must be based on a facilitation approach. Evaluation must be a facilitating process. It must be based on trust and simplicity. It will take a real co-construction effort and trusting relationship to let French and European stakeholders innovate for the benefit of patients.

INTERVIEW

AI AND EHEALTH AT THE BEDSIDE OF EUROPE

Frans Van Houten, CEO, Philips (NL)

With **Guy Vallancien**, President, CHAM



1. War for Digital Health

Philips is getting more and more interested in health and health technologies, i.e. IT based health. In the health digital war Europe lost the first battle to China and the United States. But the war is not lost yet. If it cannot mobilize its own forces Europe will not become an attractive market for the other blocks.

2. Alliance between health and digital tech

Europe has nurtured remarkable skills and resources in both health and digital sectors. It is therefore important to develop a mutual interaction between digital and health industries. We also need less talk and more action.

3. The real EU

Confronted to powerful challengers as China and the United States, EU must absolutely put an end to its silo based policy. Private companies and public institutions must unite to create a European network for health innovation.

4. GAFAs / impact of new technologies on health - impact on medical diagnosis

Data collected by Facebook and Google can have an impact on medical diagnosis. Algorithms also have an impact on diagnosing patients. Whatever the situation, health care always leads to be in touch and in contact with the patient.

5. Personal data and artificial intelligence

Europe is obsessed by individual data protection. Still, we all use the cloud and make online payments without worrying. It is also necessary to take magic out of artificial intelligence and dispel the fears. In many areas, including cardiovascular surgery, artificial intelligence is a great predictive tool that makes it possible to treat a patient before the occurrence of a heart attack. Ethics and regulations should not block innovation, otherwise Europe may lose the war.

THE WORD - BRUNO LE MAIRE MINISTER OF ECONOMY AND FINANCE (FR)



1. Fighting the omnipresence of GAFA and BATX

We must be able to compete with GA-FAs and BATXs. At the European level, our innovation policy must be as ambitious and proactive, as possible. Together with Germany and other European countries, France is working on various AI projects, some of them related to the health field.

2. Tax fairness

If we want to work on the same level playing field, tax systems must be fair. Currently, there are 14 points of difference between the GAFA's and BATX's tax systems on one side and our companies on the other side. This is not right. France is fighting, alongside EU, for a fair taxation of the digital giants.

3. French policy to support innovators

At the national level, we must be ambitious enough to develop a competitive health industry. We support an innovation-based economy and plan to create an environment that will boost the development of new technologies. For instance, smaller capital taxes should make it easier for companies to fund innovation investments. The tax credit for research cannot be repelled to ensure that France remains an attractive land for innovation.

4. European health policy supported by ambitious national policies

The creation of an EU health policy requires European decisions, as well as ambitious national policies for innovation. You can count on us to steady the course in years to come.

WHICH EUROPEAN GIANTS INSIDE THE WORLD HEALTHCARE INDUSTRY TOMORROW?

Speakers:

Olivier Charmeil, Executive Vice-President, General Medicines and Emerging Markets, Sanofi (FR) - **Maryvonne Hiance**, CEO, France Biotech (FR) - **Pierre Moustial**, CEO, URGO Group (FR) - **Diana Schillag**, CEO Healthcare Europe, Air Liquide Healthcare (FR)

Led by **Thierry Guerrier**, Journaliste (FR)



1. Europe - an old innovator that fell behind

We are walking while the rest of the world is speeding ahead. For decades France and Europe took part in all the innovation leaps. And yet European players fail to reach the critical size required to compete with the American and now Chinese giants.

2. Can France produce a health giant? Yes, it can do it

France, has the assets needed to create a giant. It has a strong research. Our entrepreneurs-researchers are motivated and 80% of the start-up entrepreneurs have a research background. France also offers a number of financial and legal options.

3. France is still lagging behind

France must react. If it does not react now, in 5 years it will be out of the race. France does not seem to be fully committed to innovation. Yet, there is no reason to be overcautious, as France and Europe currently play a major role in innovation.

4. Harmonizing patient management is a prerequisite

To foster the emergence of European giants, EU will have to seek a degree of harmonization in patient management. That includes the development of ambulatory care by Member States. The harmonization of national processes should contribute to the emergence of European giants that could make global proposals to the various health systems.

5. From innovation to entrepreneurship

Innovation does not create a market or a world leader. France has champions in all the industries, except in medical technologies. The country is not short of medical experts or technology specialists. France supports start-ups, but appears unable to create the right conditions to turn them into scale-ups. To assist innovative players, public authorities with a deep pocket, must convince private investors to use financial leverage.

6. A real sense of urgency

Collectively, French society does not realize that time is running out. We all know that the procedures are too long. The time to market for an innovation remains too long. It would be better to speed up the process - even if errors are made - to follow the pace of innovation. Innovation is often cumulative and exponential. An innovation that does not go quickly through the first phase, will be running late for the second phase and may never reach the third phase. A sense of urgency is ultimately a way to secure innovations.

7. Concrete proposals

To let innovators gain access to funding, EU should set up a European NASDAQ. But European leverage must not be financial only and Member States have to approve the creation of a European authority for evaluation. In France, some innovation stakeholders are calling for the deletion of the precautionary principle. Finally, the value of organizational innovation must be recognized. In a highly competitive environment, organizational innovation may become as important as scientific innovation.

HEALTH IN EUROPE: TO HARMONISE NATIONAL POLICIES?

Agnès Buzyn, Minister of Solidarities and Health (FR) and **Jens Spahn**, Federal Minister of Health (DE)

With **Guy Vallancien**, President, CHAM



1. European medical records

There is a European project on medical records (Connecting Europe Facility eHealth). Each practitioner will have access to a patient summary sheet and to the prescriptions of all European patients. This project, however, is planned for the mid term. In fact, it requires first the construction of national digital sites to create a European interoperability.

2. European training curriculum?

European cooperation must also focus on medical education. It is not relevant however, to look for a standard curriculum. Within the same Member State, different medical schools may focus on different topics, even if students pass the same exam at the end. European cooperation must therefore, focus on common standards of excellence.

3. European prevention policy?

The development of a European prevention policy is at the heart of our concerns. So far the weakness of European policies lied in the need for consensus, as health policies remain the prerogative of Member States. These reasons are often the sources of European failures.

4. European assessment?

Marketing approval is already centralized. That procedure is a success, but it cannot be duplicated for the assessment procedure. It seems unrealistic to consider the creation of a European Evaluation Agency. Conversely, Member States are expected to increase cooperation in this particular area

5. European policy on quality and relevance of the acts?

The evaluation policy on the quality and relevance of the acts plays a major role in the French health policy. The evaluation policy can ultimately be based on criteria set at the EU level. European criteria are currently focused on clinical quality. It is also important to consider their relevance. European criteria are useful, but the assessment of the quality and relevance of the acts must remain a national prerogative.

6. European crisis management?

At this point in time, it is unlikely that Member States will transfer crisis management to a European task force. That said, EU has a European medical task force available to any European country in case of emergency.

7. European protection

The stakes are shared by all Europeans. Resource pooling may be considered as an asset. Europe can thus deploy resources in addition to those of Member States, without replacing them.

That Europe is a Europe that protects.

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