Deputy Prime Minister and
Minister of Social Affairs and
Public Health

Frank Vandenbroucke

Conference 'Towards Establishing a RWE Generation Action Plan for Better Healthcare Systems & Patient Outcomes', 24 November 2021 : Key note speech

Ladies and Gentlemen,

I am very pleased to have the honor to open this event. In fact, I often repeat that I consider two principles particularly important for policymaking. These principles are scientific evidence and solidarity. The aim of the event today nicely combines these principles. We need real world evidence for our decisions on reimbursement, thus ultimately contributing to the financial accessibility of medicines in a spirit of solidarity.

Indeed, the basic objectives of drug policy are accessibility, availability and affordability. These form a trinity within the frame of solidarity, as it were. These elements are connected and must be the subject of a global approach and strategy. The European Pharmaceutical Strategy sets out a number of beacons in this regard. The increasingly expensive therapies are a particular point of attention and give rise to particular concern, testing the limits of solidarity we can sustain. The emerging directive on HTA is crucial in this regard. The conclusions of the council ministers of health of last June should also be taken into account.

The Covid crisis has taught us important lessons: the need to be well prepared and to anticipate where possible, the need to develop strong partnerships and finally also the need to use solidarity not only as a principle but made visible and tangible in concrete terms.

In all these endeavors, evidence is crucial to make informed decisions. Here the digital revolution offers enormous opportunities for healthcare. Healthcare has a gold mine of data. However, its exploitation takes effort and requires new investments.

Digitization is an important element in this context: it presents important possibilities to further simplify national procedures administratively and at the same time to create added value through the collection and analysis of data.

In Belgium for example, we have made electronic prescription and electronic authorization applications for reimbursement mandatory. This has led to an almost automatic reimbursement of medicines with an a priori reimbursement in 55% of cases. This is already an important step in terms of financial accessibility. But in addition, these electronic applications are an important source for the collection of health data. Ultimately, we would like to develop this further into a 'registration and evaluation system' that enables the generation of Real World Data (RWD) on a national scale.

Life Science Industries and others are strongly asking for Health Data to support research and development. That is to use Real World Data to collect Real World Evidence about the clinical effect of drugs or medical devices in clinical practice, in complement of robust clinical trials.

With the establishment of the Belgian Health Data Authority, which will integrate into the concept of the European Health Data Space, we are taking an important step in this direction. This authority will ensure that all conditions are met to make data available for all aspects of health and healthcare, such as population management, R&D, policy information, financing of healthcare, etc.

To this end, our federal administrations involved are already in advanced consultation. Furthermore this consultation will be expanded to other stakeholders such as the IMA, the federated entities, the health care providers and healthcare institutions, the industry, Europe and, last but not least, the citizens themselves.

There is no doubt that there is work to be done. Do we know sufficiently what data is available? Where it is located? Or whether it is of sufficient quality and is swiftly available? And how that data can be shared in a secure and privacy-respecting way? In fact, it seems obvious that we need to invest more and more in providing incentives for the sharing of qualitative data.

Furthermore, interoperability of systems, knowledge of the data, harmonization of processes and standards, good data governance, are essential elements to achieve this.

It is really important that all this is done with the consent of the citizen. The citizen has every right to know which data will be used, that this will be done in a secure manner and with full respect for the privacy, who will use the data and for which purpose. Building trust with citizens and ensuring transparency are essential to make this initiative a success.

While powerful data collection and evidence generation is absolutely essential, it is not enough. Data also needs to be analyzed and used to broaden the evidence base in order to gain insights into the value of the medicinal products in the clinical setting, in the real world.

In this regard, the current tools do not meet the needs. Challenges still remain in terms of data available vs data needed, delay in the availability of data, questions of cooperation of clinicians and patients, questions of trust… For a number of challenges an international approach at European level can offer a perspective and I hope today's conference will help to bring the discussions forward.

In fact, today's conference zooms in on the problems of Real World Data and Real World Evidence on the basis of an initiative that the National institute for sickness and disability insurance from Belgium, the Belgian reimbursement agency, launched about 5 years ago. It brought and brings together different parties to not only reflect on the different aspects, but above all to learn together on the basis of a practical approach and case studies. The initiative grew from the observation that the evidence base on which payers should rely with regard to the reimbursement of medicines is sometimes sub-optimal - especially for medicines for which virtually no valid comparators are available.

I believe that this initiative has already delivered important results and launched good debates in an international and multi-stakeholder setting. It allows to correct the information asymmetry. In addition, the project also shows that a better interaction between regulators on European level and payers on national level must be achieved so that payers' questions are also sufficiently addressed in an evidence generation plan. Finally, it is clear that information and evaluation of medicines is a continuous process. Ideally, it should be possible to come to an evidence generation plan that provides transparent data that responds to the needs of both: the regulators' needs regarding safety and efficacy, as well as the payers' needs regarding clinical and cost-effectiveness.

The elements discussed at today's conference are not just technical in nature. Essentially, it is a political debate about the correct allocation of scarce resources. It is also a question of ethics. For a society needs to make sure that the common resources invested yield sufficient return. To invest resources in drugs that are insufficiently proportionate to the clinical outcomes achieved seems simply unethical.

We can thus only welcome initiatives that contribute to strengthening the evidence base on which decisions are made. And I can only encourage everybody to use relevant building blocks and conclusions that emerge from this conference, to further discuss them where necessary and to make them concrete in terms of policy.

Thank you for your attention.

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