Role of Evidence in the Formulation of European Public Health Policies

Summary

This research aims to investigate the role of evidence in the formulation of European public health policies. Three case studies and a comparative analysis are undertaken to investigate (a) the kind of evidence sourced and used in the European Union's (EU) public health policymaking, (b) the perceptions of the use of evidence of key participants in the process and (c) the uptake of a specific type of evidence, namely research evidence. The aims of the research are further explained in *Chapter 1*. In particular, the study explores the similarities and differences in how the European Commission sourced and used the evidence in the formulation of legislation in the following areas: cross-border health care, information to patients on prescription medicines and food information to consumers.

The key concepts underpinning this research are presented in *Chapter 2*. They are mostly borrowed from knowledge-utilisation theories (Caplan1979; Weiss 1979; Lindblom 1990; Radaelli 1995; Boswell 2009). The complex dynamics of the evidence used in the EU policymaking are addressed looking at the demand–supply relationship between the policymakers seeking the evidence to inform their decision and gain legitimacy and consensus and policy networks of the affected stakeholders trying to shape the policy according to their beliefs. To better navigate the use of evidence in the formulation of policy, the Bowen and Zwi (2005) evidence-informed pathways model is used as the main framework for the analysis.

Chapter 3 describes the research methodology. This study is a descriptive and exploratory qualitative research that applies a multiple comparative case-study design. The main sources of information and data have been a study of the literature on evidence-based policies, EU health policies, impact assessment, EU policy-making process and knowledge utilisation, official and unofficial written documents from the European institutions, media, stakeholders, interviews with key informants and direct observations, courtesy of the researcher's privileged position as insider in the Brussels lobbying scene.

Chapter 4 analyses the case study on cross-border health care. The Commission funded various ad-hoc research projects on cross-border health care under the Public Health Programme and the 6th Framework Research Programme according to its specific policy needs. In addition, the Commission funded an independent expert analysis from the European Observatory on Health Systems and policies to support the impact assessment

accompanying the proposal. The Observatory acted as evidence broker. The views of the stakeholders and European citizens on the issue of cross-border health care were sought through a public consultation and a Eurobarometer survey respectively. There were no major opposing fronts among the stakeholders. Those who lobbied the European Commission the most were the Member States. Health care professionals, patients and the health care industry played a marginal role and focused their lobbying especially on the European Parliament. Some interviewees challenged the impact assessment because of the biased selection of the information gathered from the project results, the public consultation, and the questionability of the reliability of the figures on patient flows. Researchers, stakeholders and policymakers revealed that the evidence gathered only had a legitimizing role and was just a tool to justify a decision already taken at the political level. The impact assessment was considered a communication exercise, a lobbying tool with limited or no added value in providing a solid evidence base to the Commission's Proposal. According to the interviews and on the basis of participant observations, the research evidence sourced was not useful because it didn't produce reliable data on the main issue, namely patient flows, and didn't have the EU-wide coverage needed by the European Commission. This was also one of the main hindering factors for the uptake of evidence. While the main factors facilitating the use of evidence were policymakers' information needs, the available research provided in a policymakers' friendly format and the direct relationship between the European Observatory and the officials in charge of the dossier in the European Commission.

Chapter 5 investigates the case study on information to patients. As for the sourcing of evidence, the analysis shows a common pattern in the way the European Commission approached the evidence generation in the adoption of the pharmaceutical review in 2001 and 2008, namely with the creation of parallel stakeholder fora used to generate consensus and ideas about the issue but formally detached from the legislative policymaking process. The types of evidence used by the European Commission to formulate the Proposal also included a limited literature review conducted by a consultancy that prepared an independent study report to support the impact assessment. They also included ad-hoc working groups with the Member States and stakeholders, in addition to horizontal EU fora such as the EU Health Policy Forum, public consultations and the economic and political arguments gathered from the stakeholders and Member States. Over the years, the Commission demonstrated at least a commitment to improve the use of

scientific evidence and involvement of the stakeholders in the formulation of policy, but the actual impact on the legislation proposed remains unclear. The selective choice of research evidence and the way the stakeholders were consulted (the number of public consultations, wording of the questions, presentation of the consultation results, imbalance in the composition of working groups such as the High-Level Pharmaceutical Forum) - as they emerged from the analysis of documents, from the interviews and from participant observation -, confirm that the use of evidence by the European Commission was a sort of cosmetic exercise to increase legitimacy and consensus around a Proposal already decided upon at the political level.

The lack of clear-cut research evidence on the possibility to make a clear distinction between information and advertising, the selective use of the available literature on Direct To Consumer Advertising used as upper-bound evidence and the lack of interest, training and skills to assess the research evidence on the public health of the policymakers who drafted the Proposal, emerged as the key hindering factors for the uptake of evidence. The decisive factor that influenced both the use of evidence and the overall Proposal was the personal will of Commissioner Verheugen. Overall, the perception of the interviewees is that in the EU policymaking process, evidence doesn't play a strong role. Despite several attempts to build consensus, the Commission Proposal was not accepted and never became an EU law.

Chapter 6 presents the case study on food information to consumers. Food labelling is a key public health policy tool in the fight against obesity and overweight, as it allows consumers to better understand the nutritional value of their food and make healthy choices. In preparation of the draft legislation, the European Commission actively sought different sources of evidence on the costs and benefits of bringing a change in the legislation. The two impact assessment reports that accompanied the Proposal were the results of the three studies commissioned to external consultancies and various forms of consultations with the stakeholders. While measuring the administrative costs of the industry was relatively easy – even if the Commission admitted that the industry figures were overestimated – deciding on what kind of information consumers were entitled to and in which format the information should be provided were considered to be the more "societal issues" that had to be discussed with the stakeholders. The research findings of studies by academics and reports from national authorities were among the main sources of information referred to in the impact assessment. However, from the analysis, it emerged that the Commission largely relied on the inputs from the

stakeholders. The key stakeholders in relation to the draft legislation were, on the one side, the food and drinks industry and, on the other side, health NGOs and consumer associations. The stakeholders were consulted in different ways, including closed consultations addressed to some constituencies only, public consultations, surveys and interviews conducted as part of the external studies commissioned to consultancies, via consultation made by the Member States at the national level as well as via the various European Commission stakeholder fora (e.g., Diet platform on nutrition and health). "Good enough evidence" on food labelling was not fully available when the Commission was preparing the draft legislation, and information gaps existed that the Commission and the consultancies that worked on the topic tried to fill in consulting the stakeholders. The main facilitating factor for the uptake of evidence were policymakers' information need to make the impact assessment while the main hindering factors were the lack of relevant and timely research, the lack of policymakers' skills to assess the available evidence and policymakers' personal beliefs.

Chapter 7 made a comparative analysis of the three case studies. The legislative proposals are similar with regard to the policy instruments used and the policy goals that the European Commission wanted to achieve, and they followed very similar legislative pathways within the well-defined procedures set out in the Treaty. The European Commission's internal procedures influenced the way decision makers seek, analyse and uptake both the research evidence and the evidence provided by stakeholders via the European Commission expert groups and public consultations. More specifically, it is possible to conclude that the European Commission placed equal efforts in gathering research evidence for the three proposals. Interviewees perceived that often the available research evidence is inconclusive or biased or not relevant and that several factors (e.g. lack of time, lack of training and so on) hinder its proper uptake in the formulation of EU policies. For the three proposals, the European Commission gathered knowledge and information via polls but conducted further surveys for the proposal on food information. The stakeholders' views had more weight for the proposal on information to patients and food information as they were organised around two opposing advocacy coalitions while they were more dispersed and voiced less strongly for the proposal on cross-border health care. Evidence about costs played a more important role in the proposal on information to patients and food information than for the proposal on cross-border health care while politics was more relevant for the proposal on cross-border health care due to disputes over the limited EU competence on health

care. Overall politics, including the political saleability of a legislative proposal as well as the need to adopt a balanced legislation with the consensus of all interested parties, is the element that seems to have influenced most the formulation of the three legislative proposals.

Chapter 8 provides the main conclusion of the research, its strengths and limitations and some recommendations for policy makers and researchers. From the three case studies and comparative analysis, it emerged that for the European Commission, evidence goes beyond what is commonly understood as evidence in relation to evidence-based policies and it includes research evidence usually gathered indirectly through the filter of stakeholders or consultancies conducting external studies to support the European Commission impact assessments. Policymakers consider research evidence not only the research produced by academic institutions and published in peer-reviewed journals but also the research by think tanks and governmental bodies. Other types of evidence used include Eurobarometer surveys, statistics stakeholders' views economic and political interests of the Member States. The way evidence is sourced largely depends on the organisational procedures put in place by the European Commission itself and that EU officials have a limited margin of manoeuvre.

The participants in the process believe that the European Commission selects evidence by choosing data and information in line with its political agenda and decisions already taken. They consider that the collection of evidence is just a cosmetic exercise to gain legitimacy and consensus.

Overall it is possible to conclude that the formulation of EU public health policies can be defined as evidence-based only if evidence is considered in a very broad sense as to include not only research evidence but also other types of evidence such as information, interests and ideas of stakeholders, politics and economics.

The most important methodological strength of the research regarding both data collection and analysis also represents the main limitation: the direct involvement of the researcher in the EU debates on public health policies offered a privileged observational perspective, valuable insider knowledge as well as easy access to official and confidential documents. It also allowed the researcher to undertake in-depth and open conversations with the interviewees. At the same time, this position increased the risk of bias. Such risk has been mitigated mostly by triangulating results with other information sources and with the existing literature.

The most important recommendations for EU policy makers is to be clearer with themselves, with citizens and stakeholders about what they consider as evidence and to update the European Commission guidelines for the commissioning of external studies and for the drafting of the impact assessments. It is also important to ensure that EU officials have the necessary training, time and resources not only to collect the evidence but also to assess it critically and to use it appropriately. The most important recommendation for future researchers willing to investigate the role of evidence in policymaking is to clearly identify what they mean by the term "evidence" and use a consistent definition throughout their study. This research study also shows that it would be useful for researchers who wish their work to be used in the EU policymaking process to know more about how the process works and to tailor their research to policymakers needs, however without compromising their scientific integrity.