THE TOP 4 ISSUES IN MEDICINES POLICY 2020:THE SNEAK PREVIEW YEAR

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2020 is a special year for the EU policy world. During the second half of last year, we heard a lot about the overarching themes of the von der Leyen Commission. For the next eleven months, there will be a lot of pushing and turning – and lobbying money spent- to zoom in on the big themes and narrow down the priorities and initiatives for possible new legislation. 2020 could therefore be branded as the sneak preview, preparatory year which comes around every five years at the start of each Commission mandate. Practically speaking, by December, we will have a much better idea of what will keep us busy until Ursula von der Leyen's first term in office comes to an end.

Generally, the new Commission will be equally sceptical and hesitant as its predecessor in launching new pieces of legislation especially in health. Nonetheless, medicines' policies are expected to dominate the Commission's health agenda, as they did under Juncker, fuelled by the systemic problem of excessive prices. It is very important that the Directorate-General for Health and Food Safety (DG Santé) finally will have, for the first time ever, a clear mandate on access and affordability. That says a lot about the problem but is it enough?

Here is a snapshot of the themes and trends which will dominate the EU pharmaceutical policy in 2020:

1. WILL DG SANTÉ STAND ITS GROUND?

Although the issue of high medicines prices will continue to give Health Ministers sleepless nights, the lack of coordination among Member States, is a more fundamental obstacle, which does not get the attention it deserves. Since the June 2016 Council Conclusions on pharmaceuticals, there have been attempts to reinforce the collaboration and most importantly, the coordination amongst Member States, predominantly amongst those who wish to push the access and affordability agenda forward. Several fora (such as the directors of pharma, the roundtable discussions between pharma heads of Europe and Health Ministers to name but a few) have been tested but to no avail. The efforts to use the June 2016 Council Conclusions as an inventory for action, to draw a clear roadmap with an allocation of tasks and timelines have also not been a fruitful exercise.

Last December, the Netherlands, the most diligent access to medicines champion in the Council

suggested boosting the role of the Council Working Party on Health as the main forum to agree a cross-Presidency roadmap to advance the pharmaceutical agenda at the core of the Council's work. The Dutch will still have to do some internal lobbying in the Council to rally Member States' support for their latest proposal, not least due to the opposition by countries spearheaded by but not limited to Germany. The latter would not mind discussing pharmaceutical policy but do not favour doing so with access and affordability headlining the agenda.

DG Santé has in the meantime put forward the revival of its Pharmaceutical Committee as a counter-proposal. Fearing being sidelined in the pharmaceuticals debate, the EC will phase out the Expert Group on Safe and Timely Access to Medicines for Patients ("STAMP") and (re)politisize the long, underwhelming pharmaceutical committee. The ambition is high, but this committee does have regulatory issues at the core of its mandate. Moreover, it remains to be seen what level of national representation it will attract from the capitals and whether it will eventually prove to be a reliable coordination body.

Many Member States are not keen on having the Commission in the driving seat on medicines policies, particularly the access, affordability and availability aspects. It is not that they do not trust DG Santé but in the face of powerful industries banding together on the "innovation" principle and given the dynamics and competing interests within the different Commission Directorates (specifically DG RTD, GROW, Trade, COMP and Santé), there are doubts as to whether the arguments for access and affordability will be seriously taken on board by the Commission as a whole.

DG Santé will not only have to stand its ground internally but also prove to the majority of Member States concerned about excessive medicines' prices that they genuinely share their concerns and priorities. To this end, DG Santé will firstly have to overcome its own diachronic identity crisis and convince the sceptics that the top priority listed in President von der Leyen's mission letter to Health Commissioner Kyriakides namely the supply of affordable medicines is compatible with the second one i.e. "to support the European pharmaceutical industry to ensure that it remains an innovator and world leader".

For example, strengthening the ties between DG Santé and the payers, an integral part of healthcare systems in Europe on one hand, along with forging an ever closer collaboration between DG Santé and the European Commission Directorate-General for Competition (DG COMP) will certainly help alleviate Member States' fears and will boost DG Santé's leverage within the Commission's decision-making balance of power in relation to the design of pharmaceutical policy. DG Santé would strengthen its position further if it were to build on its cooperation with the Organisation for Economic Cooperation and Development (OECD) in providing technical assistance to Member States on key issues such as price transparency for the implementation of the landmark transparency resolution of the WHO.

WHY DOES IT MATTER?

All this constitutes a real barrier to substantial progress as the political momentum cannot be translated into concrete policy initiatives and legislative reform without coordination and concerted action. As 2020 is the preparatory year for the rest of the Commission's term, it is crucial that the messages from the Council to Berlaymont as to which initiatives should be prioritized by the Commission are loud and clear. Irrespective of what happens to the recent Dutch proposal, fortunately, the Slovenian and Portuguese Presidencies (in 2021) are likely to keep the access and affordability issues high on the agenda of the Council. Although there are not many other access to medicines champions in the Council, whatever happens in the coming year, the regionals such as the Beneluxa partnership will have a spillover effect onto the discussions in Brussels.

2. CONNECTING HEALTHCARE: A NEW UNITED LOBBYING FRONT

Many pharmaceutical executives are not oblivious to the hostility against them in Europe. Some of them admit that the reputational damage is self-inflicted; most understand that the hostility is here to stay and it will make it harder for them to land favourable pieces of European legislation similar to what they achieved in the early 2000s. Pharma is after all paying the price for the aggressive business and marketing strategies they pursued over the past decade. Notwithstanding, the industry is not standing still. It is on the defensive, if not on the attack.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) is increasing its lobbying budget. Behind the game-changing pharma-tech dynamic and the undisputed convergence of technologies which is reshaping the pharmaceutical landscape worldwide, "Connecting healthcare" is the latest EFPIA mantra, a new lobbying alliance and strategy. It highlights one of pharma's favourite lobbying methods - the promotion of multi-stakeholder platforms, which while bringing stakeholders together, can also be a diversion from the real questions and problems and act as satellites and message amplifiers. They tend to repeat in an orchestrated manner complimentary message aligned with the pharma narrative while, "omitting", or "forgetting" issues which the industry does not wish to talk about.

The impact of the "Connecting Healthcare" coalition is most felt in the shaping of the successor of the Innovative Medicines Initiative (IMI), the multi-annual, multi-billion public-private partnership (PPP). What is new, however, is that whilst IMI was a partnership solely between the European Commission and EFPIA, in "Connecting Healthcare" pharma joins forces -and lobbying power- with other business sectors such as the medical devices, diagnostics, digital and others. It was only a few years ago when the medical devices lobby group distanced itself and preferred to operate alone. Fast forward to today,

Med Tech and the others realise that there is more that unites than divides them, even if the pie will most likely have to be split among more partners, leaving less money per trade association and their members.

WHY DOES IT MATTER?

Discussions are ongoing both regarding the successor of the Innovative Medicines Initiative, the future Partnership between the European Commission and the healthcare sector industries (tentatively called Innovative Health Initiative, IHI) as well as the future of the EU's research framework programme, Horizon Europe. Huge amounts of public funds are at stake in both endeavours, thus the high industry interest.

There is nothing wrong with PPPs as long as the first P which stands for public, and is this case represents the European Commission, is properly represented and defended over the second P in the partnership. It is up to them and particularly the powerful Directorate-General for Research and Innovation (DG RTD) to learn from the mistakes made during the IMI, to guarantee public oversight, ownership, balanced representation. They need to ensure that IHI and Horizon Europe do not become industrial strategy vehicles in disguise. DG RTD needs to become an ambassador of the public health and affordability arguments most usually championed by their colleagues in DG Santé.

This is a test for the Commission's clusters approach whereby various DGs are expected to work together. In doing so, the Commission as a whole needs to take seriously, calls by a wide spectrum of stakeholders for the European Partnership on Health to be driven by the public interest, not narrow commercial priorities. This is particularly pertinent as far as the priority setting and the establishment of the legal and governance frameworks of the new Health PPP are concerned.

In the words of the recent Finnish Presidency of the EU "there is an urgent need to focus on incorporating health objectives into all policies that have relevance for access to medicines, including research, innovation, trade and competition policies, and on efforts to find new ways to strengthen the strategic cooperation between Member States. It is equally important to monitor whether EU measures have the intended impact and to evaluate pharmaceutical policy at EU level and its objectives". The above should not be overshadowed by pro-business arguments nor by the innovation principle school of thought. The same should -obviously and hopefully- apply to the highly publicized EU Cancer plan, the Cancer Mission and the planned Pharmaceutical Strategy of the Commission.

3. ANTIBIOTICS: A TROJAN HORSE FOR MORE INCENTIVES?

The consensus over the abuse, misuse or overuse by the pharmaceutical manufacturers of the incentives generously granted by the EU legislator in the field of orphan drugs (medicines developed to treat rare diseases) has been growing steadily across Europe not least due to their paralyzing and headline-making price tags. The pharmaceutical lobby is still recovering from the June 2016 groundbreaking Council Conclusions on pharmaceuticals which triggered among others an unprecedented political debate over the impact and suitability of intellectual property (IP)-related incentives and exclusivities in biomedical research and development (R&D). This is ongoing, together with an evaluation of the respective EU legislation for orphan and paediatric medicines.

The Commission has been dragging its feet in releasing the respective staff working document which distills the various pieces of work commissioned and published in recent years on the role of incentives. This is a telling sign of the external pressure as well as the internal workings of the Commission. The pro-business, more powerful and influential –than DG Santé- Directorates General such as DG Trade and Grow attempt to water down any recommendations to fix the shortcomings and scale back the patent-based monopolies and exclusivities. Such an outcome would set a dangerous precedent for the industry. It understandably triggers an alarm in these DGs and beyond, all the way to pharma's business allies on the other side of the Atlantic. The likelihood of a scale back should nevertheless not be discounted as the originators' surprising defeat over the SPC manufacturing waiver showed last year. Besides, the budget impact and the sustainability threat posed by orphan drugs are too big to ignore, even in the eyes of the staunchest proponents of the pharmaceutical companies.

Pharma is not content with the negative turn the incentives-related discussion has taken. Having failed to prevent this from happening, EFPIA has raised the profile of antimicrobial resistance (AMR) as a policy priority. AMR is a platform which allows the industry to talk about incentives in a positive light (as opposed to orphans). Everyone agrees – the industry included- that the current antibiotic pharmaceutical market is "broken" as very few antibiotics have been produced in the past decades. What is the industry's solution to the conundrum? More incentives. Although the European pharmaceutical lobby has not been forthcoming about what sort of incentives mechanisms they would be happy with, what they are aiming at is higher prices for new antibiotics, more unconditional public funding and market-based exclusivities in return for new antibiotics.

WHY DOES IT MATTER?

The pharmaceutical business sector, the pharmaceutical giants mainly, has for decades ignored –and continues to do so- the problem in antibiotics development and has invested in more profitable disease areas. Instead of complimenting pharma for having acknowledged their own failure to deliver, the

approach should be one of recognising that pharma companies have dropped the ball and should be held accountable rather than be rewarded with billions more in public funds.

The European Commission is right to prioritize AMR as it undeniably is an urgent global public health threat. The pharmaceutical sector, while acknowledging this threat also sees a new substantial profit-making opportunity and has not hidden its preference for a new EU legislative initiative specifically on incentives for AMR. Meanwhile, in most EU capitals, AMR does not figure prominently on the national agenda, making it even more appealing and necessary for the European Commission to take action.

Should the European Commission decide to go down the path of introducing new legislation on AMR incentives, it should do so keeping in mind the principles of affordability, accessibility and availability of any new products. Heavy industry influence and lobbying, propagating market-based solutions should be counter-balanced with public-interest conditionalities (such as transparency and affordability provisions) attached to any new or existing funding streams and types of incentives. It is worth remembering that in the field of antibiotics and vaccines development, non-market based mechanisms have been very successful in addressing market failures caused by profit-driven market fundamentalism. Hence, it is high time we questioned the general hypothesis that only the private sector can advance drug & vaccine development. The Commission should seize the momentum to learn from and explore synergies with models such as Global Antibiotic Research and Development Partnership (GARDP) and the Drugs for Neglected Diseases Initiative (DNDi) and look at non-profit PDPs.

In the face of pharma's inaction and continuous failure to address drug-resistant infections, even former Goldman Sachs economist and top AMR advisor to the UK government, Lord Jim O' Neill changed his mind about offering the pharma industry market entry rewards and has favoured public-purpose ownership and manufacturing instead.

The industry's strategy is clear: by mixing and grouping the incentives discussion under AMR, they aim to prevent any critical amendment of the European orphan drugs legislation and increase their chances of getting a diverse set of new incentives. Member States should therefore empower DG Santé to make sure that the public health, access and affordability arguments do not get overlooked nor sidelined during the Commission's intra-service filtering, be it on the orphans review or the likelihood of new AMR incentives-specific legislation. Here are some recommendations on how to amend the orphan drugs legislation.

4. HTA: THE END OF A NOT SO LONG JOURNEY

A compromise will be found and the negotiations on the proposed regulation on Health Technology Assessment (HTA) will be concluded during the influential German Presidency of the European Union (second half of 2020), almost three years since the launch of the proposal. Due to the upcoming Presidency, Germany will have to play a more neutral role but rest assured, there will be others eager to fill their critical shoes. In an unusual turn of events, the (new) European Parliament is expected to be the intermediary between the Council and the Commission while the latter will do its best to meet the former half way. Commissioner Kyriakides and the Commission as a whole will welcome any plaudits from the resolution of this thorny file at the end of its first year in office.

Nobody can foresee how the final text will look like. For the moment, political tensions aside, it seems that on the technical level, there is at least some consensus among HTA bodies, especially those with limited capacity and know-how, that they will be better off once this regulation comes into force. Pharma will not get what they hoped for i.e. an easier market access pathway but they will get a one-stop shop, despite the fact that Member States will retain their right to conduct their own clinical assessments – however, will they really make use of that option?

The joint clinical assessments will not be binding and they will not assess whether product (a) is better than product (b). Put simply, they will be merely inconclusive evaluations providing Member States with plenty of flexibility, exactly what governments need if they are to accept this regulation. In the coming months, negotiations will delve more deeply into the role of the European Commission in the final set up of the new EU-wide HTA system. The Commission will continue to demonstrate its spirit of compromise, but ultimately it cannot agree to something which they cannot legally defend. In other words, the Commission is ready to agree to much of what the Council is asking but not to everything and not at all costs. Pharma is expected to continue pushing on the mandatory uptake of the joint clinical assessments and the non-duplication of data requests from national competent authorities but they will not get very far.

WHY DOES IT MATTER?

Our predictions over the thorny issues and then non-speedy conclusion of the negotiations proved to be accurate. Let us just hope that the end product will not resemble the highly dysfunctional medical devices regulation with hundreds of confusing delegated and implementing acts. The new EU-wide HTA system should strengthen the role and capacity of HTA agencies in Europe. It should equip HTA authorities with "more teeth" towards pharmaceutical manufacturers so that they can do their job properly: rationalize pharmaceutical expenditure, enable meaningful innovation, and serve all patients'

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needs. Additionally, the new system should be shielded against any legal attacks, as it is certain that the business sector will not shy away from challenging in court any unfavorable joint EU clinical assessments, the basis of subsequent HTA appraisals.

Furthermore, medicines shortages, an old new problem will be high on the political agenda -even without clear direction but with certain tension between parallel traders and big pharma as well as between East and West. Another highlight for the year will be the election of the new Executive Director of the European Medicines Agency (EMA) by the Agency's Management Board sometime before summer. The approval pathways and their impact on access and affordability will be under further political scrutiny.

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