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Pharmaceutical regulation, policy and access to medicines in the European Union

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INTRODUCTION

European health systems have traditionally aimed at the provision of high-quality care and equity of access. This has become increasingly challenging over the past decades, with unabated pressure to deliver more and better services with insufficient resources[1].

In the pharmaceutical arena, there is growing concern and interest in the area of access to medicines in the European Union. Whilst member states are bound by a legislative infrastructure which addresses quality, safety and efficacy of medicinal products on the market, patients in these territories experience disparate levels of access to medicines[3].
Paradigms for improvements in this field most often focus on the individual barrier and do not relate to the wider perspective[2].

AIMS

To investigate stakeholders' perceptions of barriers to medicines' access and to examine the influence of pharmaceutical policy and regulation in this area.

METHOD

A systematic mixed-method approach was adopted, primarily comprising qualitative techniques. The research incorporated 4 stages:

Phase 1: Unstructured interviews with doctors and nurses, questionnaires to pharmacists and to prescribers to obtain the viewpoint of practitioners directly engaged in patient care.

Phase 2: Semi-structured interviews with policy-makers and experts exploring their perceptions on health care provision, payer advocacy, health economics and pharmaceutical policy.

Phase 3: Semi-structured interviews with regulators seeking their perspectives on the impact of pharmaceutical regulation in this field.

Phase 4: A focus group was conducted with the aim of consolidating and validating the findings and proposals of the study.

Directed content analysis was used to evaluate and interpret the results. The coding guide was developed through the literature review.

RESULTS

Member State Level: Medicines Access

Deterrents to medicines' access are entrenched, and sometimes replicated, at various strata of the health systems of the member states. The advantages that a documented national medicines policy may bring in this context are not fully understood or implemented. The multiplicity of factors impacting access are also over-arching at a pan-European level.

E.U. Level: Policy

It would be difficult for a pan-European policy targeting access to medicines to accommodate the wide spectrum of divergences between the member states. Additionally the consensus in the member states is that Europeanisation of the pharmaceutical arena should not be further developed at this time.

Pan-European Potential

The European Union's potential for providing technical support, networking and co-operation, establishing scientific norms, capacity building and the co-ordination and dissemination of information, should be exploited. The current initiative to revise the legislation should strategise access to medicines as a focal point.

CONCLUSION

Measures to mitigate the challenge of medicines' access are best taken conjointly at European Union level and in the member states. The latter should adopt a transparent, cohesive and documented national policy which explicitly upholds access to medicines, provides clear direction and serves as a platform towards fostering this goal.

To be fit for purpose, such a policy must be participative and inclusive of all actors and must be developed in accordance to each country's needs and resources. The Commission has a role in supporting and complementing the member states by developing generic facilitating frameworks.

REFERENCES

[1]Michalopoulos S. Pharma Industry Cannot Escape Drug Price Talks. Brussels: 2016.
[2]Report on EU options for improving access to medicines (2016/2057(INI)), available at: http://www.europarl.europa.eu/doceo/document/A-8-2017-0040_EN.html
[3]Verheugen, G. (29/09/2006), Delivering better information, better access and better prices, published by the European Commission, available at: http://europa.eu/rapid/press-release_SPEECH-06-547_en.htm cited: 22nd Oct 2017