Enferm Infecc Microbiol Clin. 2019;37(10):656–660

Enfermedades Infecciosas y Microbiología Clínica

www.elsevier.es/eimc

Review article

HIV pre-exposure prophylaxis (PrEP) in Spain: Political and administrative situation☆

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ARTICLE INFO

Article history:
Received 19 April 2018
Accepted 8 May 2018
Available online 15 July 2019

Keywords:
Pre-exposure prophylaxis
Public policy
Politics
Policy-making

ABSTRACT

This study focuses on actions at the political and administrative level in Spain in relation to the implementation of pre-exposure prophylaxis (PrEP). We analysed a whole range of different formal initiatives taken by the political and administrative actors involved. The information was obtained from official public data sources. As of February 2018, PrEP had not been implemented. The decision is dependent on both state and regional governments. The Ministry of Health and some Autonomous Regions are working on different interventions, but without providing an implementation timetable. The political parties have kept a very low profile in terms of initiatives related to the implementation of PrEP. From a legal point of view, proceedings are passing back and forth with the extension of the patent. The role of intergovernmental and interdepartmental institutions is very important for the implementation of PrEP in Spain.

Profilaxis preexposición al VIH en España: situación política y administrativa

Palabras clave:
Profilaxis preexposición
Política pública
Políticas
Elaboración de políticas

RESUMEN

Este estudio se ha centrado en las actuaciones a nivel político y administrativo que se han realizado en España en relación con la implementación de la profilaxis preexposición (PrEP) al VIH. Se ha analizado todo tipo de iniciativas formales por parte de los actores políticos y administrativos implicados. Las fuentes utilizadas son las fuentes oficiales públicas. Hasta febrero de 2018, la PrEP no ha sido implementada. La

DOI of original article: https://doi.org/10.1016/j.eimc.2018.05.012
☆ Please cite this article as: García LM, Iniesta C, Garrido J, Fuster MJ, Pujol F, Meulbroek M, et al. Profilaxis preexposición al VIH en España: situación política y administrativa. Enferm Infecc Microbiol Clin. 2019. https://doi.org/10.1016/j.eimc.2018.05.012
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decisión depende de los niveles estatal y autonómico. El Ministerio de Sanidad y algunas Comunidades Autónomas trabajan en diversas intervenciones sin establecer un calendario de implementación. Los partidos políticos por su parte han promovido escasas iniciativas relacionadas con la implementación de la PrEP. En el terreno jurídico, se han producido vaivenes legales relacionados con la extensión de la patente. El papel de los órganos intergubernamentales e interdepartamentales es vital para la implementación de la PrEP.

Introduction

HIV pre-exposure prophylaxis (PrEP) is a biomedical intervention for the prevention of HIV infection which is recommended by the World Health Organisation[1] and was authorised by the European Commission after the recommendation of the European Medicines Agency in August 2016.[2] It is an indication of a medicinal product called Truvada® from the company Gilead, composed of tenofovir disoproxil fumarate and emtricitabine. Following the adherence regimen, it prevents an HIV-negative individual from being infected with HIV,[3,4] demonstrating that it is an efficient and cost-effective prevention measure.

In 2016, the overall rate of new HIV infections in Spain was higher than the European Union and Western Europe average (7.22 per 100,000 population without correcting for delayed notification).[5] In this context, the Spanish AIDS study group (GeSIDA) issued a document[6] adapting the international recommendations to the Spanish case for groups with an incidence of higher than 2/100 person-years. Unlike in some European countries, and despite being registered in the Spanish Agency of Medicines and Medical Devices, PrEP is not currently available within the Spanish National Health System (SNS). However, Truvada® is available[7] for the treatment of HIV infection. It is a medicinal product which follows a hospital use classification and is dispensed exclusively with a medical prescription by a doctor specialising in HIV.[8]

For its part, the SNS is one of the products of decentralisation of the Spanish political and administrative system, with different levels of government required by the regulation[9] to cooperate in order to achieve their goals. This investigation had the objective of analysing the PrEP implementation process in Spain at the state and autonomous region level. Furthermore, the legal status of the medicinal product Truvada® and its generic drugs has been reviewed.

Methods

An analysis of the formal relationships of the political and administrative actors was carried out. The data sources were official public sources: official bulletins, jurisprudence, the online portal of the Ministry of Health, Social Services and Equality (MSSSI) and the Right of Access to Public Information. Within the policy actions, the set of initiatives that the Spanish Constitution and the Autonomy Statutes grant to the Legislative Chambers and their Regulations for carrying out their activity were studied. They were classified into legislative initiatives, control of Government action, impulse to Government action and other types of initiatives without particular classification, such as institutional declarations. Within the administrative actions, documents issued by Public Administrations (resolutions, collaboration agreements, consensus documents, reports and information notes) were analysed. Legal resolutions related to the patent and its extension, as well as the responses given to the Right of Access to Public Information (Law 19/2013, of 9 December, on transparency, access to public information and good government) were also reviewed. A content analysis was carried out with the help of the tool Open Code, segmenting the information in order to be able to interpret the content of it. The temporary approach was set within the period from 2008 with the IX Legislation to the XII Legislation on a state level and in the respective legislation in the autonomous regions which started in 2015, with the exceptions of the Basque Country and Galicia (2016). The date 28/02/2018 was set as the end of information collection. The terms used for the parliamentary activity searches were “HIV”, “AIDS”, “PrEP” and “prophylaxis”.

Results

Administrative situation

On a state administration level, the MSSSI published a consensus document[10] in January 2018 on PrEP in which it collected scientific evidence and set the selection, eligibility, dispensation and monitoring criteria. It was drafted by a group of experts composed of administrations, professionals, scientific societies and civil society organisations. Likewise, the MSSSI promoted a feasibility study (DIR-TRU-2017-01) thanks to a collaboration agreement[11] signed with the pharmaceutical company Gilead, which involves the free provision of the medicinal product Truvada®. This study sought to evaluate the economic and organisational impact, as well as possible interferences in the cascades of care in the face of a hypothetical implementation of PrEP in Spain. The study was developed for the participation of the Autonomous Regions (AR). AA.). In the end, two of the four proposed ARs (Catalonia and Basque Country) participated, as the incorporation of the other two ARs (Autonomous Region of Madrid and Andalusia) was not agreed in the end. Similarly, the MSSSI, in the framework of the call for 2017 of intended grants, funded HIV prevention programmes and grants were awarded to two programmes relating to PrEP[12] carried out by social entities.

There are pending updates in the face of a real implementation of PrEP in Spain. Once registered and authorised by the European Medicines Agency and the Spanish Agency of Medicines and Medical Devices, the PrEP introduction process had to pass through two procedures: price fixing,[13] coordinated by the MSSSI through the Interministerial Board on Medicine Prices,[14] which is an interdepartmental and intergovernmental body responsible for fixing the maximum producer price of medicinal products that are candidates to enter the SNS Services Portfolio; and the updating of the common services portfolio.[15] Up to the date of the study, the process was halted at the fixing of prices, without it being possible to determine the specific status of the procedure, according to Article 14 of Law 19/2013, of 9 December, on transparency. The medication for PrEP was not included among the new favourable indications for public funding up to February 2018,[19] and it was not included either in the public Consultation for updating the SNS Basic Service Portfolio.[20] A Therapeutic Positioning Report[21] regarding PrEP has not been issued either, a report which is drafted during the price fixing process and that is taken into account by the Interministerial Board on Medicine Prices. The maximum producer prices (the

Table 1
Maximum producer prices and salt used for the generic medicines of tenofovir disoproxil/emtricitabine.

Pharmaceutical company	Salt used	Maximum producer price agreed (€) (monthly)
Gilead Sciences	Fumarate	432.73 (2005)
Mylan Pharmaceuticals	Maleate	246.82
Teva Pharma	Phosphate	251.85
Krka Farmaceútica	Succinate	187.39
Sandoz Farmacéutica	Succinate	187.39
Accord Healthcare	-	187.39
Kern Pharma	Phosphate	187.39
Viso Farmacéutica	Phosphate	187.39
Lupin Europe	Phosphate	Not fixed on 28/02/2018
Aristo Pharma	Phosphate	187.39

Sources: AEMPS[16,17] and MSSSI.[18]

pharmaceutical company selling price) of generic versions have been published (Table 1).[22]

Political situation

On a state political level, PrEP did not enter the political debate until the end of 2016, with initiatives of the *Partido Socialista Obrero Español* [Spanish Socialist Workers' Party] (PSOE) and the *Partido Demócrata Europeo Catalán* [Catalan European Democratic Party] (PDeCAT) on a state and autonomous level, in Catalonia (Table 2).

The non-legislative proposal on the PrEP prevention of HIV strategy presented by the PSOE in January 2017 (161/001191) stands out among the content of the initiatives. In addition, on a state level, there are two questions to the Government presented by PDeCAT (184/005117) and PSOE (184/006151) where the intention regarding the implementation of the measure was questioned. In separate responses, the Government listed the actions that it was carrying out through the MSSSI.

With regard to autonomous activity, Catalonia is the AR in which the most initiatives have been promoted both from a political and administrative aspect. Thus, PrEP is established as one of the actions to be developed within the objective of reducing new HIV infections of the *Plan de Acción contra el VIH y otras ITS* [Action Plan against HIV and other STIs] 2016–2020.[23] It is a specific objective within the general prevention strategy against HIV. In line with this, the participation in process in 2018 along with the Basque Country in the feasibility study proposed by the MSSSI, as well as the PrEP-Ara 2017–2019 programme in the framework of the *Plan Estratégico de investigación e Innovación en Salud* [Strategic Health Research and Innovation Plan] 2016–2020 (PERIS),[24] can be cited. PrEP-Ara is an implementation study promoted by the Catalan Department of Health. On a parliamentary level, the Motion for a Resolution 250-00469/11 of the *Partido Socialista de Catalunya* [Socialist Party of Catalonia] (PSC) in which, among other matters, the Catalan Government was urged to implement PrEP should be highlighted, as well as the invitation (356-00293/11) of the Catalan Government of *Junts pel Sí* [Together for Yes] to an NGO to tackle the HIV epidemic situation in Catalonia, with PrEP being one of the key subjects of the debate. Lastly, it should be mentioned that amendment 641 to the Draft 2017 Budget of the *Generalitat* [Catalan Regional Government] requested to incorporate PrEP as a preventive treatment. In the end, this amendment was not approved. With regard to the Autonomous Region of Madrid, PrEP has been addressed in various initiatives: in the question to the Government with a written response PE-711/2017 (X) asked by the party *Podemos* [We Can] regarding access to HIV pre-exposure medications in non-medical centres as well as in questions with an oral response in a plenary session PCOP 853/2016 (X) and PCOP 1066/2017 (X), promoted by *Ciudadanos* [Citizens], in which parliamentary interventions which mentioned PrEP were compiled. In general, the response of the Madrid Government, which can be extrapolated to the rest of the autonomous regions, mentions the scientific evidence and the recommendations and coordination given by the MSSSI and its National AIDS Plan, meaning that PrEP does not feature among the actions performed regarding prevention (written question 1274/2017, from the PSOE). As in Catalonia, the invitations to social entities in which the need to implement PrEP was mentioned (C-164/2016, from Ciudadanos) stand out. With regard to the Autonomous Region of Valencia, PNL 739/69332 promoted by the party *Compromís* [Compromise] regarding the implementation of PrEP, as well as the PrEP implementation pilot programme in sex workers advertised and conducted at the Hospital General de Valencia, should be pointed out. As a result of the intergovernmental conflict, the administrative reasons of the Autonomous Region of Madrid and the lack of agreement between the Regional Ministry of Health of Andalusia and the MSSSI to coordinate the participation of both autonomous regions in the aforementioned feasibility study coordinated by the MSSSI can be mentioned. In the case of Andalusia, reference is also made to the adaptation of the feasibility study to the characteristics of the Andalusian Health System and to bioethics problems in the formulation of the study to guarantee the dispensation of the medicine only during the study as well as the conflict of interests on the part of the pharmaceutical company which provides the medicine free of charge. Furthermore, it is worth highlighting a position opposing PrEP in August 2017 by the Administration of the Autonomous Region of Navarre, which denied the suitability of implementing PrEP stating that scientific evidence is insufficient to incorporate it into the preventive measures arsenal. For more information on the administrative actions and positions of the Administrations involved, extracts from all the responses given to the Right of Access to Public Information regarding PrEP are gathered in the appendix (supplementary material in electronic version).

Table 2
Number of initiatives presented by political parties in which reference is made to PrEP on 28/02/2017.

	Status	AR AA.
Partido Popular (PP)	0	0
Partido Socialista Obrero Español (PSOE)	2	3
Podemos	0	1
Ciudadanos	0	3
Esquerra Republicana de Catalunya (ERC)	0	1
Partido Nacionalista Vasco (PNV)	0	0
Partido Demócrata Europeo Catalán (PDeCAT) (Mixed Congress Group)	1	1
Compromís (Mixed Congress Group)	0	1

Source: Search engines for initiatives of the *Cortes Generales* [Spanish Parliament] and Parliaments of the autonomous regions.

Legal status of the drug Truvada® and its generic forms

Regarding the legal status, after being rejected in the first instance by the *Oficina Española de Patentes y Marcas* [Spanish Patent and Trademark Office], the Supplementary Protection Certificate was awarded to Gilead by a court ruling which granted it a patent extension following a judicial process. This figure would extend the patent protection for up to a maximum of five years,[25] i.e. up to 24 February 2020.[26] The implementation process for generic medicines is proving to be complex due to the judicial appeals that Gilead started against the marketing of generic products by the companies Teva[27] and Mylan.[28] Under the protection of the aforementioned certificate, in May 2017 Gilead's request to

prevent the marketing of generic medicines was granted provisionally by a court order. However, this decision was revoked in October 2017,[29] meaning that the marketing of generic medicines is possible.

Discussion

The PrEP implementation process in Spain has been open since September 2016, the date on which the MSSSI made the proposal for approval in the meeting of the Public Health Committee of the SNS Interterritorial Board.[30] In the political arena, the entire spectrum has indicated that they are in favour, or at least not explicitly in opposition, to its implementation. However, there has been limited political activity related to the promotion of the measure, and the activity that there has been either does not have the timely transmission with regard to real actions, or is pending for a prolonged period of time. As a prime example of the latter point, we can cite PNL 161/001191 which the PSOE presented in the Congress of Deputies, an initiative for which there was no fixed processing time legally, depending on the priority given to each of them by the proposing parliamentary group. This initiative is not relevant in terms of its regulatory significance, but rather due to its explicit demand to implement the measure and fund it publicly, allowing the parliamentary groups to present the amendments and debate it, and, ultimately, allowing them a political position. In addition to the PSOE, the activity of PdeCAT, Compromís and Podemos, as parties which have presented specific political initiatives, stands out. Ciudadanos has indicated that it is in favour of putting the study of its implementation on the table, especially in the area of the Autonomous Community of Madrid. The *Partido Popular* [People's Party] (PP), as the party in State Government during the years when PrEP was approved at European level, has promoted the administrative actions carried out in the MSSSI. Turning to concepts of the Analysis of Public Policies,[31] it can be established that not taking decisions or that these do not occupy high-level positions in the agenda, is one of the possible courses of actions that policymakers can take in the face of dealing with public problems.

With regard to the legal status of the medicine and its patent, judicial processes similar to that which has taken place in Spain are also occurring in other European countries. To this effect, and due to their direct influence on the status of the Supplementary Protection Certificate in Spain, the preliminary ruling C – 121/17[32] proposed at the start of 2017 by the High Court of Justice (Chancery Division) to the Court of Justice of the European Union in relation to the duration of the patent should be mentioned. The pronouncement of the Court will allow a unified interpretation in the European Union with regard to the patent of the medicine. With that in mind, the opinion[33] of the Advocate General Mr M. Wathelet on the preliminary ruling was published on 25 April 2018. In summary, justification is given for the complaints of companies producing generic medicines against Gilead's claims with the Supplementary Protection Certificate. It is therefore anticipated that the Court of Justice of the European Union will consider the conclusions of the Advocate General, despite the fact that these conclusions are not binding. In this manner, the response would be binding for all jurisdictional bodies of the European Union, including Spanish courts.

In any case, it seems necessary to improve transparency in the price fixing process, and, related to this, to establish a clear situation of the patent's legal status. Changes in the validity of the patent have been able to influence the price fixing process, as the cost of new indications is one of the basic criteria from which medicines are studied by the Interministerial Board on Prices, even if it is not possible to establish a casual relationship between the two. In any event, in the aforementioned regulation, the cost and budgetary impact for the SNS of the medicines which are subject to evaluation for their inclusion in the service portfolio (Article 92 of Royal Legislative Decree 1/2015) is cited explicitly. Similarly, the "bottom-up" concept[34] is interesting in the sense that the agents which are most in contact with the problem to resolve are those that propose the solutions to adopt to the decision makers. In this case, just as in a significant proportion of public policies related to Health, there is a large number of agents involved with the implementation of PrEP, which is testified in the public documents issued. There is consensus on the need to slow down the constant number of new HIV infections, but not in the response to give, as there is a claim for urgent implementation of the measure based on the existing evidence from scientific and social agents, and by the political-administrative actors there has been a proposal for the conduct of new local studies which adapt the international conclusions to the situation in Spain and, ultimately, to actions leading to its implementation, but not in the short term, in contrast to the situation in other European countries.

Furthermore, one limitation of this investigation is the circumscription of the study objective to the area of the formal actions. Other qualitative research techniques, such as in-depth interviews, would make it possible to tackle the problem of implementing PrEP from the non-formalised dimension of the relationships which would make it possible to obtain an integrated approach.

In conclusion, the implementation of PrEP in Spain is a process which started mid-2016 resulting from a contained political interest combined with certain administrative actions which are being promoted from the Administration, split over an interdepartmental (several Ministries), intergovernmental (two levels of Government) and interorganisational (Administrations, scientific societies, clinical centres and community centres) level. In any case, it is an unfinished process in which further action in the short- and mid-term are awaited in Spain.

Conflicts of interest

The authors declare that they have no conflicts of interest.

Acknowledgements

To the Autonomous Region of Madrid (File EPY-100/17 [PEJ16/SAL/AI-0867]). Grants for hiring Research Assistants and Laboratory Technicians.

To the AIDS Research Network (RD16CIII/0002/0006).

To the Biomedical Research Networking Centre for Epidemiology and Public Health (CIBERESP).

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.eimce.2018.05.019.

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