



Dara Calleary, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

6th April 2023

PQ: 14941/23

To ask the Minister for Health have made efforts since 2017 in procuring versatis at a better rate; and if he will make a statement on the matter. -Dara Calleary

Dear Deputy Calleary,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 14941/23), which you submitted to the Minister for Health for response.

The HSE is mandated to deliver the maximum savings possible when making decisions in relation to pricing of medicines and optimise the use of the limited resources available to it commensurate with maintaining continuity of supply in the market place to meet patient needs.

In accordance with the Health (Pricing and Supply of Medical Goods) Act 2013, the HSE is required to consider the following criteria when it is making decisions in relation to pricing of Medicines:

- (a) the equivalent relevant prices (if practicably available) of the item in all other Member States where the item is marketed,
- (b) the relevant prices of therapeutically similar listed items,
- (c) the potential therapeutic benefits of the item for patients likely to use the item if it were to become a listed item,
- (d) the potential budget impact of the item if it were to become a listed item,
- (e) the ability of suppliers of the item to meet patient demand for the item if it were to become a listed item,
- (f) the resources available to the Executive, and
- (g) the terms of any agreement in place (whether entered into before, on or after the commencement of this section) between the Executive and any representative body of the suppliers of drugs, medicines or medicinal or surgical appliances where the agreement relates, whether directly or indirectly, to the price of the item.

Lidocaine 5% medicated plaster (Versatis®) is licensed and approved for reimbursement for the symptomatic relief of neuropathic pain associated with previous herpes zoster (shingles) infection known as post-herpetic neuralgia (PHN) in adults.

The HSE Medicines Management Programme (MMP) has reviewed the evidence available to support the use of lidocaine 5% medicated plaster (Versatis®). A further review was conducted in 2021 to update clinical evidence relevant to the use of lidocaine medicated plaster. Following this review and based on best practice recommendations, the Primary Care Reimbursement Service (PCRS) introduced changes to the reimbursement of lidocaine 5% medicated plaster from 1 September 2017. This process supports appropriate use of this medication while ensuring those with an indication of post-herpetic neuralgia (PHN) continue to have access to this treatment. <https://www.hse.ie/eng/about/who/cspd/ncps/medicines-management/lidocaine-plaster/>

A four year Framework Agreement on the Supply and Pricing of Medicines (i.e., '2016 IPHA Agreement') was agreed between the Irish Pharmaceutical Healthcare Association (IPHA) and the State in 2016. This incorporated a number of new cost saving measures, including an annual price realignment exercise which was operationalised as per Clause 5 of the 2016 Agreement:

- The ex-factory price of all patent protected medicines to be annually realigned (downwards only) to the average of the relevant price in the nominated states on the 1st August 2016 and the 1st July 2017, 2018 and 2019 respectively.

In December 2021 the State agreed two new multiannual agreements with the Irish Pharmaceutical Healthcare Association (IPHA) and Medicines for Ireland (MFI):

- Framework Agreement on the Supply and Pricing of Medicines (i.e., the 2021 IPHA Agreement)
- Framework Agreement on the Supply and Pricing of Generic, Biosimilar, and Hybrid medicines (i.e., the 2021 MFI Agreement)

The Framework Agreement on the Supply and Pricing of Medicines is an agreement between the State and Industry, and it is the responsibility of the HSE to manage the implementation of same, in compliance with the Health (Pricing and Supply of Medical Goods) Act 2013. These framework agreements on the supply and pricing of medicines contribute to the sustainable funding of new and existing medicines and are estimated to deliver additional savings to the State. The savings achieved are via a number of measures outlined in the agreements including enhanced price reductions for off-patent medicines and increased rebate contributions for on-patent medicines. The HSE works diligently to harvest the maximum possible value of the Industry Framework Agreements. The Industry Agreements also generally provide for clear direction to all parties in relation to the requirements of the State for the supply and pricing of medicines.

With specific regard to the 2021 IPHA Agreement, the following is ensured:

- Each Supplier shall rebate to the HSE: [X]% of the value, at the Price or relevant ex-factory price, of all Medicines reimbursed by the HSE in the Relevant Schemes and of all Medicines supplied by the Supplier to the HSE or Relevant Agencies from 1st of October 2021 to 30th of September 2025 (Clause 10):

- The following rebate percentages will apply, as denoted by “X%” in clause 10.1.1:
 - Year 1a: 1st of October 2021 – 31st of December 2021 (3 months) = 5.5%
 - Year 1b: 1st of January 2022 – 31st of December 2022 (12 months) = 7.75%
 - Year 2: 1st of January 2023 – 30th of September 2023 (9 months) = 8.25%
 - Year 3: 1st of October 2023 – 30th of September 2024 (12 months) = 8.50%
 - Year 4: 1st of October 2024 – 30th of September 2025 (12 months) = 9.00%

- The Price of all Medicines will be realigned, downwards only, in accordance with the following provisions:

The Price of a Medicine shall be calculated and set at the average of the relevant price (being the ex-factory price or equivalent thereof) in the Nominated States in Euro on the following dates: (i) 1st March 2022 (ii) 1st March in each of 2023, 2024, and 2025 (Clause 5.2 2021 IPHA Agreement) (<https://www.hse.ie/eng/about/who/cpu/ipha-price-reduction-2022/>)

The Marketing Authorisation holder (Grunenthal Pharma Ltd) of Lidocaine 5% medicated plasters (Versatis®), have engaged in the Annual Price Realignment Process in the years 2017, 2018, 2019, 2020, 2021 & 2022.

Lidocaine 5% medicated plasters (Versatis®) have not been subject to a downward price realignment as per Clause 5 of the Industry Framework Agreements in the years 2017, 2018, 2019, 2020, 2021, 2022. The current Irish Ex-Factory Price, which was negotiated by the Corporate Pharmaceutical Unit (CPU) in 2016, has remained below the average of the relevant price (being the ex-factory price or equivalent thereof) in the Nominated States (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the UK) in each of the years 2017, 2018, 2019, 2020, 2021 & 2022.

With specific regard to patent-expired non-exclusive medicines the 2021 framework agreements ensure:

- The price of each medicine that becomes a patent-expired non-exclusive medicine after 1st January 2022 shall reduce to 40% of the ex-factory price of that medicine as of the 1st October 2021 (Clause 7.2.2 of the IPHA Agreement).
- A new generic medicine for which an application is made to be priced at no greater than 40% of the 1st October 2021 price of the equivalent branded original medicine (Clause 7.2.1 of the MFI Agreement).

Yours sincerely,



Suzanne Doyle
Primary Care Eligibility & Reimbursement Service