UNDERSTANDING PRICING REGULATIONS AND SEP

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health
Department:
Health
REPUBLIC OF SOUTH AFRICA

OVERVIEW

- Enabling legislation to the SEP
- SEP implementation process
- Annual SEP Adjustments
- Exceptional SEP increase
- Role of the Pricing Committee
- Section 36 (2) of the Medicines Act
- Pricing of Section 21 Medicines

ENABLING LEGISLATION

- National Drug Policy_ Chapter 4

- Medicines and Related Substances Act 101 of 1965
  - Section 22G
  - Section 18A
  - Section 36(2)
  - Regulation 38

- Medicines Pricing Regulations

  - SEPU Guidelines
  - SEPA Guidelines

SEP IMPLEMENTATION

- **Process**
  - Scheduled medicines must have an official SEP prior to marketing.
  - The PEE directorate within NDoH processes launch submissions and register SEP's on the Database.
  - Documents required when listing an SEP for the first time
    - Medicine Registration certificate
    - Licence to manufacture
    - Template D (Excel spreadsheet)
    - Package Insert
    - Signed Declaration form and Cover letter
    - Regulation 19 Form
- SEP information cannot be amended without notifying NDoH.
- Registration of the SEP is the responsibility of the manufacturer.
- The nappi code cannot be amended once listed at NDoH.

REGULATORY ROUTE TO SALE OF AN SEP ALLOCATED MEDICINE

Step 1

SAHPRA

- Registration
- Section 21 listings

Step 2

NDoH

- SEP allocation
- Publication on database

Step 3

Launch and marketing

- Sale in South Africa
- Public sector excluded

SEP COMPONENTS

- The SEP is the sum of the following components:
  - Ex- manufacturer Price
  - Logistics Fee
  - VAT

- **SEP = Ex –Manufacturer Price + Logistics Fee + 15% VAT**

- The Unit price is another important component of the SEP and it is calculated as follows:
  - SEP ÷ Quantity ÷Pack Size = Unit Price

SEP COMPONENTS AND RELATED INFORMATION

- Related pack sizes of a medicine must always have the same Unit Price.
- Injections with the same concentration must always have the same Unit Price.
- Medicines allocated an SEP must have the following information which gets reflected on the NDOH database.

Applicants MCC\SAHPRA Licence No	Applicant Name as Registered with MCC\SAHPRA	MCC\SAHPRA Medicine Reg. No.	Nappi Code	ATC 4	Medicine Schedule	Medicine Proprietary Name	Active Ingredients	Strength	Unit	Dosage Form	Pack Size	Quantity	Manufacturer Price	Logistics Fee	VAT	SEP	Unit Price	Effective Date	Status	Originator or Generic
0000001154	3M South Africa (Pty) Ltd	U/4/104	703312001	N01BA	S4	Xylestesin-A	Lidocaine hydrochloride	20	mg/ml	INJ	50	1	204,94	33,59	35,78	274,32	5,49	12 March 2021		Originator

EXCERPT OF THE DATABASE

Applicants MCC\SAHPRA Licence No	Applicant Name as Registered with MCC\SAHPRA	MCC\SAHPRA Medicine Reg. No.	Nappi Code	ATC 4	Medicine Schedule	Medicine Proprietary Name	Active Ingredients	Strength	Unit	Dosage Form	Pack Size	Quantity	Manufacturer Price	Logistics Fee	VAT	SEP	Unit Price	Effective Date	Status	Originator or Generic
0000001154	3M South Africa (Pty) Ltd	U/4/104	703312001	N01BA	S4	Xylestesin-A	Lidocaine hydrochloride	20	mg/ml	INJ	50	1	204,34	33,53	35,78	274,32	5,43	12 March 2021		Originator
							Adrenaline	0,012	mg/ml											
0000001154	3M South Africa (Pty) Ltd	A38/4/0430	710488001	N01BB	S4	Ubistesin	Articaine hydrochloride	40	mg/ml	INJ	50	1	249,16	40,86	43,50	333,53	6,67	12 March 2021		Originator
							Adrenaline	0,01	mg/ml											
0000001154	3M South Africa (Pty) Ltd	A38/4/0431	710497001	N01BB	S4	Ubistesin Forte	Articaine hydrochloride	40	mg/ml	INJ	50	1	249,16	40,86	43,50	333,53	6,67	12 March 2021		Originator
							Adrenaline	0,01	mg/ml											
0000000125	Abbott Laboratories SA (Pty) Ltd	47/21.8.2/0347	3004321001	G03FA	S4	Femoston Conti 0,5mg/2,5mg	Estradiol Hemihydrate equivalent to Estradiol	0,5	mg	TAB	28	1	174,18	19,01	28,38	222,17	7,93	15 June 2022		Originator
							Dydrogesterone	2,5	mg											
0000000125	Abbott Laboratories SA (Pty) Ltd	52/30.1/0094	3002734001	J07BB	S2	Influvac Tetra	A/Victoria/2570/2019 (H1N1)pdm09-like strain	15	mcg	INJ	0,5	1	87,55	7,09	14,20	108,84	108,84	18 February 2022		Originator
							A/Hong Kong/2671/2019 (H3N2)-like strain	15	mcg											
							B/Washington/02/2019-like strain (B/Washington/02/2019, wild type)	15	mcg											
							B/Phuket/3073/2013-like strain (B/Phuket/3073/2013, wild type)	15	mcg											
0000000125	Abbott Laboratories SA (Pty) Ltd	35/7.1/0372	701855001	C09CA	S3	Teveten 600	Eprosartan	600	mg	TAB	28	1	252,78	25,09	41,68	319,55	11,41	18 February 2022		Originator
0000000125	Abbott Laboratories SA (Pty) Ltd	36/21.8.2/0330	703107001	G03FA	S4	Femoston-Conti	Dydrogesterone	50	mg	TAB	28	1	211,11	23,04	35,12	269,28	9,62	18 February 2022		Originator

TYPES OF TEMPLATES FOR SEP MANAGEMENT

- Single Exit Price Descriptors
- Template A - Permanent SEP reduction
  - Template B - Non Permanent SEP reduction
  - Template C - SEP increase post Non Permanent SEP reduction
  - Template D - SEP of a new medicine
  - Template E - Introduction of a New Pack Size
  - Template F - Discontinuation
  - Template G - Medicine details amendments
  - Template H - Reintroduction of a previously discontinued medicine
  - Template I - SEP increase post Reg 9 approval
- Timelines – Processing timelines range from 02 - 30 working days

IMPORTANT INFORMATION TO NOTE

- A template B price should be in the market for no less than six weeks post approval.
- The SEP submitted in Template H should be the same as what was approved in Template F.
- A discontinued medicine (Template F) is always retained on the database.
- SEP approvals are communicated to industry via sepupdates@health.gov.za: NB: to update company contact details.
- Only two email addresses per company are accommodated.

ANNUAL SEP ADJUSTMENTS

- The annual SEPA – Single Exit Price Adjustment is announced and where applicable implemented at the beginning of each financial year.

- Pricing Committee; Interested stakeholders and Minister and the Pharmaceutical supply chain are involved in the determination process.

- SEPA determination is done at PC and Minister level whereas implementation is by DG and PEE.

- The database of medicines; international and local economic dynamics are crucial in the SEPA determination and implementation.

PREVIOUS SEPA ADJUSTMENTS

YEAR	ADJUSTMENT QUANTUM	SEP REFERENCE DATE	FIRST SUBMISSIONS	FINAL SUBMISSION
2012	2,14%	09 December 2011	03 January 2012-30 March 2012	30 March 2012
2013	5,80%	21 December 2012	02 January 2013-30 September 2013	30 September 2013
2014	5,82%	20 December 2013	31 January 2014-01 April 2014	19 May 2014
2015	7,50%	23 December 2014	12 January 2015-13 March 2015	30 April 2015
2016	4,80% 2,90%	22 December 2015 20 May 2016	11 January 2016-11 March 2016	28 April 2016
2017	7,50%	21 December 2016	06 January 2017- 06 March 2017	20 March 2017
2018	1,26%	22 December 2017	02 January 2018-19 February 2018	01 March 2018
2019	3,78%	21 December 2018	11 January 2019-22 February 2020	03 April 2020
2020	4,5%	20 December 2019	10 January 2020-28 February 2020	03 April 2020
2021	3,68%	21 December 2020	11 January 2021-22 February 2021	08 March 2021
2022	3,5%	24 December 2022	07 January 2022-04 March 2022	25 March 2022

IMPORTANT SEPA MATTERS TO NOTE

- Non permanent SEP reductions become permanent reductions after the database is locked.

- Resubmissions are applicable to submissions which did not received 100% approval.

- The SEP on the locked up schedule is the only reference SEP used for SEPA purposes.

- Commercial transfers of applicancy are not the same as regulatory transfers.

EXCEPTIONAL SEP INCREASES

- SEP increases are only possible through Regulations 8 and 9 of the Medicines pricing regulations.

- Regulation 8 may allow SEP increases and Regulation 9 is for exceptional SEP increases.

- Approval of exceptional SEP increases is dependent of provision of evidence which matches the motivation submitted in the application.

- Only the Minister makes the final decision on SEP increases made in terms of Regulation 9.

ROLE OF THE PRICING COMMITTEE

- The PC makes recommendations to Minister on the following areas:
  - Dispensing Fees
  - SEPA
  - Exceptional Price Increases
  - SEP Implementation disputes
  - Schedule Zero medicines
  - Exclusion of certain medicines from compliance with SEP provisions

- PC members engage various stakeholders on pricing matters, upon request by a particular stakeholder.

- PC regularly liaises with other regulatory bodies such as SAHPRA, CMS, DTI and Treasury.

- PC is involved in the investigations conducted by the Competition Commission on the conduct of stakeholders in the pharmaceutical industry

SECTION 36 (2) OF THE MEDICINES ACT

- In terms of Section 36(2) allows for certain medicines to be excluded, under certain conditions, from being compliant with the provisions stipulated under Section 22G and 18A.

- The PC has previously applied this section to allow access to medicines after completion of a clinical trial and to allow NGO's to purchase medicines at tender price instead of SEP.

- Section 36(2) is sometimes used to exempt all Schedule Zero, Veterinary and Complementary medicines from the provisions of Sections 22G and 18 A.

- The Minister makes the final decision on Section 36(2) applications.

- All Section 36(2) applications and approvals will be published on the NDoH database, in the near future.

SECTION 21 MEDICINES

- Section 21 approval is SAHPRA's responsibility whereas the pricing of these medicines is the mandate of the Pricing Committee.

- After conducting numerous investigations, and after liaising with SAHPRA, PC found Section 21 medicines prices to be far less than what later gets listed at NDoH as SEP for the same medicine.

- Discussions are currently underway to ensure transparency in the prices of medicines approved under Section 21.

CONCLUSION

- Whilst SEPs are determined at NDoH in terms of the Medicines Act, its important to note that re-imbursements fall under Council for Medical Schemes and the Medical Schemes Act.

- The NHI Bill has indicated the need to continue applying SEP under the Universal Healthcare regime in South Africa.

- Key to the SEP legislation is the need for transparency in medicines prices.

- In the event a company contravenes any of the pricing legislation, the Responsible pharmacist is always deemed liable.

THANK YOU !!

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