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Fee Regulations Review – Reponses to Public Comments Received

Index

- Background
- Overall comments and responses
- Priority Reviews
- Category A_Human
- Category D_Human
- Fees for clinical trials
- Fees for Licences (incl. MD/CAMS)
- Inspectorate
- Permits and certificates
- Amendment, transfer and appeal

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Background

- The revised Fee Regulations were published for comments on 4 August 2023 and closed on 3 November 2023.
- Comments received within the specified timeframe were from 21 industry representative bodies and individuals.
- Based on the comments received some changes were implemented, including re-analysis of cost recovery calculations and removal of some fees
- The presentation will only address fee categories where comments were received and received within the required timeframe
- Due to the Medical Device Regulation not being finalised and revised planning for call up of products intended to commence in 2025 the new fees for Medical devices will be withdrawn from the revised fee regulations. A separate process will be initiated following the pilot process to introduce new fees for Medical Devices.

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Overall Comments and Responses

The following comments and responses cuts across multiple fee areas:

- Fees should only be in line with inflation

✓ *Majority of fees were increased by an average of 4.1%. It should be noted that this is significantly lower than the average inflation rates of 2023. Higher or lower % did occur due to the rounding up or down of amounts. It should also be noted that no inflationary adjustments were made since December 2020. This will effectively be more than 3 years without increases*

✓ *Some fees appear to be significantly higher due to adding the screening fee charged for to the initial application amount. The screening fees have been removed from the revised Gazette.*

✓ *New fees introduced could not be aligned to inflation, new cost recovery calculations were done to justify the fees.*

✓ *Certain fees with a significant year on year increase is justified based on the re-evaluation of the time and effort taken for the related regulatory activity. The current fee regulations did not consider all review processes within the workstream, and adjustments needed to be made to enable a justified cost recovery*

- New revenue lines previously not charged for now being implemented

✓ *During the review of the fee regulations SAHPRA noted that various workstreams which takes considerable time and effort does not have a fee associated with the regulatory activity. In line with the cost recovery model, it is justifiable to charge a fee for these activities*

- Timelines should be included in the regulation or agreed upon upfront. Credits/discounts to be provided if timelines are not met

✓ *SAHPRA is a regulator, not a service provider. It operates within the legal framework provided and cannot accelerate processes due to industry pressure that may compromise regulatory processes. SAHPRA has significant funding challenges that is prohibiting it from operating at 100% capacity. SAHPRA does however communicate regulatory timelines and its performance against this in its annual performance plan and in its annual report. Requirements and regulations changes and performance targets are reviewed annually*

- Lower fee for SMME/Local Manufacturing

✓ SAHPRA is considering a mechanism for SMME/Local Manufactures on a strategic level and will be communicated in the near future

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Overall Comments and Responses

The following comments and responses cuts across multiple fee areas:

- The use of milestone payments instead of upfront payment at application, i.e. payment upon completion of certain activities:

✓ *Milestone payments cannot be applied until the regulatory process is fully digitised and integration with the finance system. Up front payment being applied is the same model followed by other regulators. Milestone payments may be considered after the digitisation strategy has been implemented however assessment of the impact on timelines due to administering partial payments need to be considered.*

- Reliance fee vs full review fee to be included

✓ *Majority of fees impacted by reliance is only inflationary based. Reliance already benefits the applicant in terms of reduced timelines, the processes followed are same, verification of sameness and access of reports sourced by SAHPRA are time consuming and resource intensive. Failure to retrieve reports will result in defaulting to full review.*

- Guidelines are not updated or finalised

✓ *Guidelines are living documents and would be updated as required to align with regulatory best practices. However, there is always guidance (existing guidelines in place) whilst review of guidelines are undertaken. Follow existing guidelines until implementation date or communication thereto is shared. Any concerns with regards to guideline updates should be communicated through the appropriate channels*

- Suggestion of mirroring the EMA in terms of allowing for certain valid criteria for fee determination, considering application status (SME,NPC), product type (advanced therapy, rare conditions, small patient population) and product status (1st year after registration)

✓ *It is important to note that SAHPRA is a small regulatory agency compared to EMA, such requests may be entertained once SAHPRA processes are established and part of wider AMA which will have a centralised approach. Further matters of advanced therapy requires mandate for SAHPRA and corresponding expertise to avail services which are costly and cannot be carried by a small regulator. It will be investigated to mirror approaches which EMA has adopted such as limiting the number of applications admitted per cycle to enable better management of applications to resources ratio.*

- Response review General:

✓ All application fees will include the 1st round of response reviews. 2nd round of response reviews will attract fees as per the different categories in the revised fee gazette

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Priority Review

DESCRIPTION	IMPLEMENTED FEES	PROPOSED FEES	REVISED FEES	Industry Comments	SAHPRA Responses
	Gazetted 22 Dec 2020	4 Aug 2023 Gazetted for public comment	To be gazetted	Summary of comments	
(a) Application for all priority review assessment: Fee charged for a priority review application	-	11 500	11 500	Is this for Pharma? Include definition and criteria. Price should be inflation related increase. Application fee inclusive. Lower fee for variation priority (R4 500). Same as fast-track applications. Guideline?	The priority review policy applies to New Chemical Entities (NCE s), New Biological medicines, interchangeable multi[1]source (generic) medicines and Biosimilars for both new registrations and only Type II variation applications. The communication on the request for priority review is available on the SAHPRA website and clearly describes the criteria and process to be followed. There is no priority review request guideline available at this time . The cost of processing the requests for priority is the same irrespective of the outcome or type of application. The administrative fee will be charged for the initial request for priority review of an application (new medicine or variation). This administrative fee will not be waived if the approval is successful (i) The administrative fee is based on our current Priority review request policy and process

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Priority Review

(b) For approved priority pre-registration evaluations: (i) Generic products (pharmaceutical, analytical and bioavailability evaluated) including generic dental and radio-pharmaceutical products {first strength, first dosage form) including 2 API's and1 BE study Additional API's and BE studies will be charged for in line with the Fee Regulation par. 3 (e)	-	475 000	192 000	Fee is significant and excludes additional API and BE, re-consider pricing. Generic pricing (with less evaluation time) cost more than NCE/Biological. A fee for reliance vs full review to be considered. Breakdown of cost is required. Fee proposed is R273 500. Inclusive of master and duplicates/multiple strengths. Timelines to be communicated, milestone payments with forfeiture if not met. Fees per dossier or per strength per dosage form. Different fees for Generics backed by clinical data/bioequivalence/biowaiver as per regulation 3(a). Lower fee for only one API/BE?	Cost recovery reperformed and duplication of BE studies were noted and removed and fees were adjusted accordingly. In case of other costs a breakdown of the added resources, closer timelines and additional meeting frequency costs were factored into priority costing. 60% (R192k/R120k) higher than normal application
Generic products (pharmaceutical and analytical evaluated) including generic dental and radio-pharmaceutical products {first strength, first dosage form). 2 API's. Additional API's will be charged for in line with the Fee Regulation par. 3 (e)	-	-	132 400	Lower fee for only one API/BE?	New fee introduced to align non priority application descriptions. Generic applications without bioavailability. 53% (R132 400/R86 700) higher than normal application
(ix) All Generic products with clinical data			188 000		New fee introduced to address priority generics with clinical data. It is significantly higher than the normal review pathway. During re-evaluation it was noted that the current fee is not recovering the costs fully.

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Priority Review

New Chemical Entities, new biotherapeutics other than vaccines (first strength, first dosage form), including 2 API's and Final Finished Product,. Additional API's and BE studies will be charged for in line with the revised fee regulation Par. 3 (e)	-	300 000	300 000	It is untenable that application for generic medicine cost more than a New Chemical Entity / Biological as there is less evaluation required for the generic medicine.	The evaluation based on the current cost of review. It must be noted that in case of NCE, no BE studies included as it is innovator and is dependent on clinical study reviews. 38% (R300k/R217 200) higher than normal application Generic fee reviewed and is lower than a NCE application
Biological products e.g. vaccines (excluding new biotherapeutics)	-	322 000	282 300	Same as above and: Lower fee for only one API/BE? All biological applications are priority, new criteria	The timelines are indicated in the Priority communication. 53% (R282 300/R184 400) higher than normal application. Not all biological applications are considered priority as a separate normal application fee can also be charged. Biological studies do not include BE reviews
(c) For approved priority post-registration evaluations relating to quality variations, including biologicals: (i) Priority Quality Type II , minor amendment	-	6 500	-	Clarify what is minor/major. Levels to be indicated. Should include response review. Reliance vs full review pricing. Pricing based on inflation. Timelines (3-4 months). Cost breakdown required	Classifications of minor/major is included in the applicable guideline. The fee will be removed as Type II amendments are considered major amendments as per the fee of R23 000 below. The cost includes 1st response review
Priority Quality Type II , major amendment	-	23 000	23 000	Clarify what is minor/major. Levels to be indicated. Should include response review. Reliance vs full review pricing. Pricing based on inflation. Timelines (3-4 months). Cost breakdown required	There is type II that involves e.g. widening/change in specifications as opposed to more extensive API source change involving full review of APIMF. Refer to guidelines and explanatory notes. Includes 1st response review

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Priority Review

(d) For approved priority post-registration evaluations relating to safety variations, including biologicals: (i) Priority Safety Type II , safety amendment	-	29 500	29 500	Safety not quality. Timelines required (3-4 months). Breakdown of costing. What is meant by the term quality. Minor and Major. Include response review.	Corrected to safety. All applications includes 1st response There is however consideration of quality, clinical, inspectorate variations only for Type II on priority as Type I priority is too short for priority consideration
(ii) Priority Safety Type II, safety and efficacy amendment	-	44 900	44 900		
(iii) Priority Clinical 2nd responses with clinical data per application	-	24 700	-	Remove-fee should form part of request for clinical updates/part of Type II safety and efficacy amendments. Cost breakdown required. Minor and Major. Include response review.	Moved to Category A Fees. CEM response reviews included under Cat A, split between major and minor included. Extra clinical data will require additional expert evaluation
(e) Request for an application number	-	2 000	-	Will the no be valid indefinitely and only applicable to the applicant who paid for it. Bears not cost for SAHPRA and should be removed. Post registration Type II variation - reason for additional payment and for priority. R1 000 per dossier.	The fee was charged for the administrative process involved in allocating an application number and the applicable fee. With the implementation of the new portal, application numbers will be generated by the system and notifications to the applicant will be automated. We may consider removal of this fee.
(e) Request for a borderline product status review	-	15 000	15 000	Clarity on which borderline products are included here. Breakdown of the costs. Its only a simple evaluation and not costly. Clarification of the process involved guideline not finalised	The fee covers all Borderline Products. The processing of the request is the same irrespective of the outcome i.e.. whether it will be classified as a medical device, medicine or other. Borderline committee primary and peer reviewed, administration and screening. Some applications require significant deliberation due to the impact of the classification

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Category A_Medicine – New applications

(a) In respect of the submission of an application for registration of: (i) New Chemical Entities, new biotherapeutics other than vaccines (first strength, first dosage form)	208 400	217 200	217 200	NCE's are less complex than new biotherapeutics (R85k to R217 200) increase not justifiable. R115 400 (12 months) R217 200 (6 months). Milestone payments. Timeline for review. Lower fees for reliance and risk basked reviews. Should be inclusive of response reviews.	Current fee is R208 400. The R111 000 referred to in the previous gazetted has been removed This fee is based on cost of review. Reliance already benefits the applicant in terms of reduced timelines, the processes followed are the same, verification of sameness and access of reports are time consuming and resource intensive. The increase is only 4.2%.
(ii) Strengths and dosage forms other than those referred to in sub-paragraph (i)	82 000	85 400	85 400	94% increase not justified, very little review is required (inflation based increase). Cost breakdown required/Benchmark done. Inflation increase only. R45 760 (12 months) R85 400 (6 months). Milestone payments.	The current fee is R82 000. The increase is only 4.1%. The R44 000 referred to in the previous gazetted has been removed together with the fee amounting to R111 000. Same principle applies. The cost of review per study and time of review is higher, cost of reviewers fees increased and the process followed requires added resources
(iii) Biological products e.g. vaccines (excluding new biotherapeutics)	177 000	184 400	184 400	Timelines (12 months) to be indicated. Milestone payments.	Not a generic application. Falls under NCE category/timelines
(iv) Biological products e.g. biosimilars {excluding new biotherapeutics)	173 000	180 300	180 300		
(v) Strengths and dosage forms other than those referred to in sub-paragraph (iv)	55 000	57 300	57 300		

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Category A Medicine – New (Generic)

(vi) Generic products (**pharmaceutical and analytical evaluated**) including generic dental and radio-pharmaceutical products {first strength, first dosage form) Including 2 API's. Additional API's will be charged for in line with the Fee Regulation par. 3	84 000	87 600	87 600	Which generic products does this relate to. Breakdown of cost calc. Increase should be inflation based. Timelines	The generic product it relates to is as per the fee description. Price increase is only 4.3%. The fee includes 2 API' and no BE studies
(vii) Generic products (**pharmaceutical, analytical and bioavailability evaluated**) including generic dental and radio-pharmaceutical products {first strength, first dosage form), including 2 API's and 1 BE study Additional API's and BE studies will be charged for in line with the Fee Regulation par. 3	-	120 000	120 000	Cost breakdown required. Timelines. Bioavailability study is a clinical study, why so much higher than generic backed by clinical data (reg 3aix)	The cost includes quality, bioavailability, 2 API's and 1 BE study.
(viii) Strengths and dosage forms other than those referred to in subparagraph (vi,vii)	27 000	28 100	28 100	Include (vii)	Updated
(ix) All Generic products with clinical data (vi,vii)	84 000	87 600	87 600	Why does bioavailability costs more than clinical applications. Timelines. For all generic products with clinical data (vi and vii)	BE evaluations takes more time and effort to review. Current fee is subsidised and will be reviewed with the next fee regulation update. Subsidised due to clinical information being mostly literature and not actual studies
(x) Strengths and dosage forms other than those referred to in sub-paragraph (ix)	27 000	28 100	28 100	Correct to par. Ix	Updated

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Category A Medicine – (Response)

(b) For the 2nd response review of the evaluation outcome of New Chemical Entities, New Biological Products other than vaccines (first strength, first dosage form), per evaluation outcome: (i) Response review of major queries	-	45 000	45 000	Possible incentive for evaluators - evaluations must be consistent, against standards and timelines. Define major, moderate and minor. Needs to be capped ito variation types submitted in one application. Increase based on inflation. To be incorporated into application fee (admin burden). Breakdown of cost required. Already a substantial fee on application. Timelines required. Process for disputing a query. Will this apply to generic applications. Sharing of evaluator templates/checklists. Training sessions required. Queries from SAHPRA that are not scientific/inconsistent	The first response round is included in the initial application cost however second and subsequent response round must be paid for. It is expected that applicants submit applications conforming with guideline requirements to avoid large number of queries and where the first query round is not adequately addressed results in more response rounds which have added cost of review. This will encourage applicants to ensure that their submissions and responses are addressed adequately to avoid many response rounds. Guidelines will be developed for classification of responses and response query and timelines. Content available in the guidelines ICH and IPRP can also be utilised. Training/workshop on guidelines will be undertaken. Queries cannot be raised outside guideline requirements and such instances should be reported through the correct channels. Capping is not applicable
(ii) Response review of moderate queries	-	22 500	22 500		
(iii) Response review of minor queries	-	9 000	9 000		
Clinical 2nd response reviews with clinical data per application		24 700	24 700	Remove-fee should form part of request for clinical updates/part of Type II safety and efficacy amendments. Cost breakdown required. Minor and Major. Include response review.	Moved from Priority Moved to Category A Fees. Extra clinical data will require additional expert evaluation.
2nd Response review of the evaluation outcome of safety and efficacy variations per application number per variation queried: 2nd Response review of Type II and multiple submissions (Type IB and IA)	-	6 800	6 800	Paying for each query per variation. Is the overall variation Type II, IB or IA that the fee will be required, appears that a fee per variation will be required. Fee be charged for Typ. e IB and IA. Possible incentive for evaluators - evaluations must be consistent, against standards and timelines. Define major, moderate and minor. Needs to be capped ito variation types submitted in one application. Increase based on inflation. To be incorporated into application fee (admin burden). Breakdown of cost required. Will this be applicable to queries/clarity required. Will it only be required for the highest classification per application no considering only PI/PIL of dossier is effected. Timelines required. Applicable to quality variations only (Reg 3fvii already includes) Sharing of evaluator templates/checklists. Training sessions required. Queries from SAHPRA that are not scientific/inconsistent. Fee should be per dossier/application not per application no. How will the rejection be controlled to ensure system is not abused.	The rationale is about the cost recovery . If the applicant has met the criteria of submission (new & variation), there will not be queries raised. Note that the evaluation process is to establish, quality, safety and efficacy and hence the applications must meet this criteria and is not about finding something to raise a query. The industry is aware that both Industry and Regulators have collectively established ICH guidelines and these criteria for Q,S,E is met. Note that the applicants take time to respond and always request extensions and advice, limited resources to address queries, the added resources for additional responses has not been accounted for in the initial fee. Fee is to ensure funding for resources and that the timelines can be met. Note that revenue is not recognized until review is done. The matter of having to have the same review for multiple submissions have been addressed when Industry agreed to have grouping of amendments and not to have a range.
(ii) Response review of Type IB	-	2 400	-		The fee for standing type I response removed, however if it is part of multiple submission response then as per response review of Type II
(iii) Response review of Type IA	-	1 300	-		

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Category A_Medicine – (Response/Consult)

2nd Response review of the evaluation outcome of clinical variations per application number: (i) Response review for the evaluation outcome of Type IB, clinical variation application substantiated with data	-	-	7 200	Remove fee as clinical data is provided for safety and efficacy amendments. Fee should form part of the request for clinical updates. What is the process to appeal query. No fee should be charged for response review for variations. Fee should only be applicable if the data was not submitted in the original application.	Refers to new data in response to an evaluation query. Fee is only applicable if data was not submitted in original application. Split fee introduced. Fee re-allocated under responses section
(ii) Response review of Type IB	-	-	3 000		
(iii) Response review of Type IA	-	-	1 900		
(d) Pre- Registration Consultation Meeting for Biological Medicines Under Developments and with the intention to submit for registration (Pre-I ND), per application: (i) Type A - meetings conducted before finalisation of non-clinical tests	-	43 200	43 200	Breakdown of cost calculation. Meetings mostly only 1 hour long.	Cost of 6 experts preparing (5 hours) and attending committee meeting (3 hours) at a rate of R900 per hour (DPSA aligned). The review of the information shared and time taken for such review, hence sub classification of different types of meetings. Administration and related activities incur cost
(ii) Type B - meetings conducted when non-clinical development is complete and Ph-I trials are ready for submission	-	32 400	32 400		
(iii) Type C - meetings conducted during the clinical development phase and prior to final registration application	-	21 600	21 600		

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Category A_Medicine – (Additional API/BE)

(e) Fees for additional API sources and FDC's (excluding CEP's and CPQ's) and additional BE studies: (i) New Generic and NCE Applications with more than 2 API's, for each additional API and API source	-	18 600	18 600	Fees applicable for pre- or post registration variations. Why only for Generic. APIMF reliance was introduced, hence no fee required for additional API's similar to the exclusions in place. Confirm if applicable per application/dossier (not application no) as the AMPIMF/BE study is only reviewed once and not separately per strength/duplicate Double billing. Fee already payable for variations. Breakdown required.	Cost recovery on initial application only includes 2 API's. In order to meet service timelines there should be payment commensurate to the resources and service used for review of additional API's submitted. Reduced time/cost was incorporated for additional API cost recovery. Charge will be per application number as previously consulted with industry. Only applicable to new applications
(ii) New Generic and NCE Application with more than 1 BE study, for each additional BE study	-	26 200	26 200	Same as above When more than 2 BE studies are required only as it is a requirement already for many applications.	Cost recovery on initial application only includes 1 BE study where indicated. In order to meet service timelines there should be payment commensurate to the resources and service used for review of additional BE study's submitted. Reduced time/cost was incorporated for additional BE cost recovery

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Category A_Medicine – (Post registration)

(f) Any medicine, the registration of which has been approved by the Authority in terms of Section 15(3) of the Act: (i) In respect of registration of any medicine, the registration of which has been approved by the Authority in terms of Section 15(3) of the Act (in the case of medicines in minute-dose form; the fee encompasses different dilutions and different volumes, when submitted simultaneously for the same indication or intended use) and in respect of which an application fee has been paid	2 000	2 100	2 100	Fee for Type II variations not included? Clinical fee for Type II variation (where clinical data is not required) Fee for duplicate/clones ito the prescribed fee is a clone dependent on the parent dossier.	(f) iii iv. If no clinical data then it is not a Type II. Charge is per dossier. A fee for clones and duplicates will be separately charged for. This fee relate to certificate variations
(ii) Evaluation of request for rescheduling or reclassification of a product	16 000	16 600	16 600	Does the fee incl clinical package insert evaluation submitted as part of the rescheduling application	No, it is not possible. N/S evaluation and then to clinical evaluation. Evaluations are also considered by the various expert committees
(iii) Evaluation of request to amend Professional Information and Patient Information Leaflets in respect of which data relating to safety must be evaluated (post registration) per application	15 600	16 200	16 200	Timelines (6 months). If not adhered to fees be credited back to the applicant. R3 300 applicable to Type II variations? Fee for Clone/Duplicates. Is the clone dependent on the parent dossier.	N/S evaluation and then to clinical evaluation. Evaluations are also considered by the various expert committees. The R3 300 is only applicable to Type I evaluations. A fee for clones and duplicates will be separately charged for
(iv) Evaluation of request to amend Professional Information and Patient Information Leaflets in respect of which clinical data relating to safety and efficacy must be evaluated (post registration)	15 600	32 800	32 800	100% increase. What new work is required. Breakdown required. Timelines (6 months).	Reviewer fees not the same as several year ago and previous fees did not adequately consider total time and effort. 21 hours Level 3 primary review, 7 hours peer review and 8 hours adjudication (QA) at R900 per hour
(v) Evaluation of request to amend the Innovator or Generic medicine Professional and Patient Information Leaflet where clinical data is not required (post registration)	2 600	3 300	3 300	Ref 3f(v)(vi). Wording is the same, does (v) refer to Type IA changes. Is this applicable to Type IA variations. What is the difference between v,vi,vii	Not the same. Type IA and Type IB applications is based on alignment with P&A and EMA Fees. However, Clinical variations are charged per application and not per variation. Refers to Type IA

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Category A_Medicine – (Post registration)

(vi) Evaluation of request to amend the innovator or Generic medicine professional information and Patient Information Leaflet where clinical data is not required (post registration): Type IB	-	6 000	-	Same as above and: Significant increase as clinical data is not required. Cost breakdown required. Type IB is currently R2 600, what is the difference between (v)(vi)	Fee removed
(vii) Response to clinical variation application substantiated with data	-	7 200	-		Moved to responses section
(g) For quality variations, the fees are applicable per application number: (i) Type II Level 1 (post registration) - Evaluation of request for major technical amendments in respect of which data relating to quality must be evaluated for the **first two variations in the same application: R29 700 per variation**	28 500	29 700	29 700	Fees should be per application/dossier not per number as the variation is only reviewed once and not separately per strength/duplicate	Groupings with industry consulted and will remain
(vii) Evaluation of requests for exemption from registered post-importation testing requirements per product per product per year the exemption is valid for	5 300	5 500	5 500	Duplicate wording	Duplicate wording removed

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Category A_Medicine – (Retention and Renewal)

(viii) Annually, in respect of the retention of the registration of a medicine, the registration of which has been approved by the Authority in terms of Section 15(3): R5 200: Provided that this provision shall come into effect one year after the date on which the registration of the said medicine was approved by the Authority in terms of Section 15(3); Provided further that the said fees payable during a particular calendar year shall be payable on or before the last working day of June that year, failing which the registration may be cancelled in terms of Section 16(4)	5 000	5 200	5 200	Retention fees be waived in year of renewal	Management has explored the possibility, however the Medicines act does not allow non payment during the year of renewal. Fees are due because of the listing obtained after registration. Retention fees funds various regulatory compliance activities (investigations, border control, PV)
(ix) Every 5 years, in respect of the renewal of a New Chemical Entity Health Product/Medicine, the registration of which has been approved by the Authority in terms of Section 15(3): **R50 000 per Master application**	-	50 000	34 000	Excessive (cost breakdown to be provided) will inhibit access to affordable medicines in RSA	Costing revised based on pilot actual time and effort spent per application for master and line extensions
(ix) Every 5 years, in respect of the renewal of a New Chemical Entity Health Product/Medicine, the registration of which has been approved by the Authority in terms of Section 15(3): **R20 000 per Line Extension up to a maximum of two line extensions**	-	20 000	13 500		
(x) Every 5 years, in respect of the renewal of a Generic Health Product/Medicine, the registration of which has been approved by the Authority in terms of Section 15(3): **R40 000 per Master application**	-	40 000	31 600		Costing revised based on pilot actual time and effort spent per application for master and line extensions
(x) Every 5 years, in respect of the renewal of a Generic Health Product/Medicine, the registration of which has been approved by the Authority in terms of Section 15(3): **R12 000 per Line Extension up to a maximum of two line extensions**	-	12 000	9 600		

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Category A Medicine – (Auth Presc/Lot Release)

(xii) Authorised Prescribers Amendment per application	-	35 800	35 800	Fee appears high (Breakdown). What is Authorised Prescribers Amendment and why does it attract a fee.	The review of "authorised prescribers and authorised use/prescribing of scheduled substances" applications. The N&S unit and committee review (8 – 7 members, 2-1 hours) these applications submitted by generally association's e.g., HPCSA/ SAPC/ AHPCSA/ Podiatry associations and is then referred to the Clinical Committee for comment before referral to the RC for finalisation and approval.
(h) In respect of the testing of a human vaccine for purposes of batch release by the National Control Laboratory *(per batch)* (i) New applications per batch: **R70 000 for the first 12 months** of this Gazette and R146 500 thereafter	23 100	70 000	70 000	Excessive Breakdown required. Inhibit access to meds in RSA. DOH impacted on introduction of new vaccines ito expanded vac programme. Pricing should be based on inflation. High fees should exempt repeat PIT by NCL	Refer to 2022/23 SAHPRA annual report. Cost of NCL Laboratory Services R22.6 million (pg130). Revenue generated R3.9 mil (pg170 - biological medicine). Cost to operate NCL for 2024/25 is R26 million. Revenue projections based on average annual volumes over the past 5 years (173 lots, incl. re-release (35)) will amount to only R10.9 million. with an under recovery of more than 50% in year 1 of application. No further reduction in fees can be afforded. Lot release is not the same as PIT by applicant.
(i) New applications per batch: R70 000 for the first 12 months of this Gazette and **R146 500 thereafter**	-	146 500	-		This fee is required to fully recover the cost of laboratory services in South Africa. Will be removed and reviewed after 12 months
(ii) Re-release per batch (previously tested): **R35 000 for the first 12 months** of this Gazette and R75 500 thereafter	-	35 000	35 000	Same as above and: High fees should exempt repeat PIT by NCL. Regarding PIT exemption, is it per patch/not product per year. Emergency Measles vac was per product. Applicants are also doing additional PIT testing and exemption is requested.	Refer to 2022/23 SAHPRA annual report. Cost of NCL Laboratory Services R22.6 million (pg130). Revenue generated R3.9 mil (pg170 - biological medicine). Cost to operate NCL for 2024/25 is R26 million. Revenue projections based on average annual volumes over the past 5 years (173 lots, incl. re-release (35)) will amount to only R10.9 million. with an under recovery of more than 50% in year 1 of application. No further reduction in fees can be afforded. Re-release is not PIT. Testing is per lot not per product.
(ii) Re-release per batch (previously tested): R35 000 for the first 12 months of this Gazette and **R75 500 thereafter**	-	75 500	-		This fee is required to fully recover the cost of laboratory services in South Africa. Will be removed and reviewed after 12 months

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Category D_Human (Registrations)

DESCRIPTION	IMPLEMENTED FEES Gazetted 22 Dec 2020	PROPOSED FEES 4 Aug 2023 Gazetted for public comment	REVISED FEES To be gazetted	Industry Comments Summary of comments	SAHPRA Responses
(a) In respect of the submission of an application for registration of: (i) Products submitted with clinical and or toxicological data (first strength, first dosage form)	14 300	16 700	16 700	How does this impact any updates to the 30 CAM's license applications that may be pending finalization	Registrations are not the same as licenses. This is inflation adjustment only including R1 800 screening fee
(iv) Strengths and dosage forms other than those referred to in sub-paragraph (iii).	2 100	4 000	4 000	Double the cost, breakdown required.	Fees in section a includes the previous screening fee of R1 800 (now removed from the draft regulation as a separate charge) with an inflationary adjustment +-4%
(b) Any medicine, the registration of which has been approved by the Authority in terms of Section 15(3) of the Act: (i) In respect of registration of any medicine, the registration of which has been approved by the Authority in terms of Section 15(3) of the Act and in respect of which an application fee has been paid:	1 800	1 900	1 900	How does this impact any updates to the 30 CAM's license applications that my be pending finalization	Registrations are not the same as licenses. This is inflation adjustment only

SAHPRA
South African Health Products Regulatory Authority

Fees for clinical trials

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(b) In respect of clinical trials amendments and other S21 applications: (iii) Any other application except for the purpose of performing a clinical trial	350	400	400	Does this include RUO's clinical evaluation/Submissions	This is for S21 only

SAHPRA
South African Health Products Regulatory Authority

Fees for Licences (incl. MD/CAMS)

DESCRIPTION	IMPLEMENTED FEES Gazetted 22 Dec 2020	PROPOSED FEES 4 Aug 2023 Gazetted for public comment	REVISED FEES To be gazetted	Industry Comments Summary of comments	SAHPRA Responses
(a) An application for a new, licence, incl. CAM's, in terms of Section 22C (1)(b) of the Act: (i) Manufacture	25 200	26 200	26 200	The definition of Manufacturer, Distributor and Wholesaler needs complete review in line with the operations of the medical device industry. Current definitions will entail one company to register and hold Manufacturer, Distributor and Wholesaler licenses, which is nonsensical and will attract exorbitant fees as well as an administrative burden. Reduced fees for Local Manufacturer and SME's. inconsistent application of the fees where some HCRs would pay one fee, and others must pay per activity. Remove import/export and align to Regulation 9b	The licensing guidelines provide clarity as to what applicants are applying for ito the different categories for medicines and scheduled substances which include elements of different activities applied for i.e.. To minimize multiple licenses. Fees are based on cost recovery and reductions will not be affordable, however local is already paying less than importing/exporting companies which will incur addition costs, including inspection fees. Fees are charged based on the activity and applied consistently. Regulation 9B does not apply to medicines and scheduled substances. Removed HCR wording for distribute license
(ii) Distribute [Holder of certificate of registration (HCR)]	15 000	15 600	15 600		
(iii) Wholesale	15 000	15 600	15 600		
(iv) Import (Holder of certificate of registration)	15 000	15 600	15 600	Same as above and: License for example allows a company to import/export That would entail Manufacture having to pay: R 26 200 R 15 600 import R 15 600 export	Local manufacturing does not attract import and export and only R26 200 will apply. HRC's with no local manufacturing will only pay R15 600 for import and R15 600 for export
(v) Export (Holder of certificate of registration)	15 000	15 600	15 600		
(b) An application for a new medical device establishment licence in terms of Section 22C (1) (b) of the Act: (i) a manufacturer licence to manufacture, import or export medical devices or IVDs	25 200	26 200	26 200	Duplication/remove as MD is covered above. Same comments apply as above	New separate description added for MD and IVD's "Refer to the Medical device Regulations and The Medicines and Related Substances Act 22C & H) on establishments related to Medical devices including IVDs", Definition of Manufacturer, Distributor and Wholesaler is indicated under the Medical Device Regulation published version of 2016.
(ii) a distributor licence to import, export and distribute medical devices or IVDs	15 000	15 600	15 600		
(iii) a wholesale licence to act as wholesaler of medical devices or IVDs	15 000	15 600	15 600		

SAHPRA
South African Health Products Regulatory Authority

Fees for Licences (incl. MD/CAMS)

(c) An application for the renewal of a licence, incl. CAMS, in terms of Section 22D of the Act, the licensing of which has been approved by the Authority in terms of Section 22C(1)(b) of the Act: (i) Manufacture	22 000	22 900	22 900	Clarify if a license holder should pay the annual retention fee as well as the renewal fee on the year of renewal. inconsistent application of the fees where some HCRs would pay one fee, and others must pay per activity.	Retention fee will be applicable in the year of renewal made as the Medicines Act does not allow for an exemption on renewal Licensing unit does not charge for amendment during renewal. HCR wording to be removed for distributor
(ii) Distribute (Holder of certificate of registration)	12 600	13 100	13 100		
(iii) Wholesale	12 600	13 100	13 100		
(iv) Import (Holder of certificate of registration)	9 200	9 600	9 600		
(v) Export (Holder of certificate of registration)	9 200	9 600	9 600		
(d) An application for the renewal of a medical device establishment licence in terms of Section 22D of the Act, the licensing of which has been approved by the Authority in terms of Section 22C(1)(b) of the Act: (i) a manufacturer licence to manufacture, import or export medical devices or IVDs	22 000	22 900	22 900	Duplicate to above fees?. if no changes are made when it is time to renew a license , why is it proposed to have a renewal fee that is inline with the fee applied to a new registration. All significant changes will already have seen documented and fees applied as a significant update to a license. Consider a different fee structure depending on changes to made upon renewal. This fee may be inline with the annual fee as the same activities will be applied. Finally , consider fee reduction for SME and local manufacturers	Not a duplication, category for MD's for renewals. The document will have to be reviewed during renewal. Annual fee and renewal fees are not the same and allocation of funds does not serve the same purpose During the process of application screening, review and evaluation a similar process is followed, Fees reduction for the SME's does not cover the fact the similar process is followed for evaluation of the product whether is submitted by SME's or not.
(ii) a distributor licence to import, export and distribute medical devices or IVDs	12 600	13 100	13 100		
(iii) a wholesale licence to act as wholesaler of medical devices or IVDs	12 600	13 100	13 100		

SAHPRA
South African Health Products Regulatory Authority

Fees for Licences (incl. MD/CAMS)

(e) Annually, in respect of the retention of a licence issued in terms of Section 22C(1)(b) of the Act: R4 400, and this fee is payable on or before the last working day of June that year, failing which the license may be revoked	4 200	4 400	4 400	Clarify the time when this fee is payable. "on or before the last working day of June that first year", failing which the license may be revoked. There is no evaluation or review required. The fee levied is too high in relation to what is required to simply retain an Establishment on a register. Align fees to SADC countries. Fee to be waived in the year of renewal	Fees are due from 30 June each year. SAHPRA allows 30 day payment and communication is sent out each year regarding this. Retention fee will be applicable in the year of renewal made as the Medicines Act does not allow for an exemption on renewal Licensing unit does not charge for amendment during renewal. Fee increase is based on inflation only. Funds pharma co-vigilance and regulatory inspection (law enforcement) activities and is not the same compared to SADC countries. As per the guidelines products/licenses listed at 31 December of the preceding calendar year will have fees due by June the following year.
(f) Licensing for any manufacturer, distributor, wholesale, import or export, the license of which has been approved by the Authority in terms of Section 22(1)(b) of the Act including medical devices	3 400	3 500	3 500	The fee proposed for issuance of a certificate is similar to the fee to register a class A low risk device. The documentation and administration and time required by these activities are not comparable and it is proposed that this be reduced - R1 750	2 activities are not comparable as indicated and not done at the same level by same person. Licensing and Registration are 2 separate activities,
(g) Application for the amendment to an existing licence to manufacture, distribute, wholesale, import or export including medical devices	5 300	5 500	5 500	R1500 (single significant amendment), R3000 (2-3 significant amendments), R4500 (more than three si0nificant amendments) Define amendment.	The amount is less than for applying for a new license, which would be applicable for most of these type of applications, however this fee was introduced to ensure that trade continues and does not disrupt the applicants operations. Please note that this fee is not new and the Increase is inflation based only. The work involved and fee remains the same regardless of the number of amendments due to regulatory oversight requirements. The significance of the amendment does not effect the technical and administrative part of licensing Amendments that will attract a fee are listed in the Licensing Guideline for Amendments.

SAHPRA
South African Health Products Regulatory Authority

Inspectorate

DESCRIPTION	IMPLEMENTED FEES Gazetted 22 Dec 2020	PROPOSED FEES 4 Aug 2023 Gazetted for public comment	REVISED FEES To be gazetted	Industry Comments Summary of comments	SAHPRA Responses
10. Fees for inspections to assess the quality, safety and efficacy of medicines, scheduled substances and medical devices					Remove MD
Payable fees are:					
(a) The charge out rate per inspector will amount to R1 660 per hour per inspector for all scheduled inspections conducted. Inspection hours and travel time will be charged for in accordance with the applicable guideline.	1 600	1 660	1 660	Should not be applicable to MD. IS013485 certification in place by 16 January 2024 . ISO certification includes an onsite "inspection" as part of the stage two audit requirements t at is implemented internationally.	MD removed
(b) Desktop inspection to assess quality, safety and efficacy of medicines or scheduled substances, review of GxP compliance status after license amendments and medical devices: R2 200 per day per inspector	2 100	2 200	2 200	Desktop cost more than physical.	Amount stated is R2 200 per day per inspector, not per hour

SAHPRA
South African Health Products Regulatory Authority

Permits and certificates

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11. Fees for Permits and Certificates					
Payable fees are as follows:				Please clarify what these fees pertain to Since they are already referred to above and the activities are encapsulated in a Manufacturer/ Distributor License	Comments refer to Licences. This section refers to permits/certificates which are different to Licences.. Please refer to the Inspectorate and Regulatory Compliance guidelines
(a) In respect of the issuing of a permit or a certificate: (i) Certificate [Certificate of a Pharmaceutical Product (WHO), Good Manufacturing Practice (GMP) Certificate, Certificate of Free Sale]	1 400	1 460	1 460		
(ii) Import permit (holder of certificate of registration)	950	990	990		
(iii) Export permit (holder of certificate of registration)	925	960	960		
(iv) Any other permit or certificate	950	990	990		
v) Permits issued by the Director-General in terms of Section 22A of the Act, excluding government departments	950	990	990		
vi) Review of port health and or border detainment products	Not included	400	-	remove. This is a compliance assessment (not at the behest of the company) and should not be subject to a fee. Criteria for detainment. How will detained products be controlled so as not to abuse the system of charging a cost for their review by SAHPRA? Our members are concerned as Complementary Medicines that are listed on the member's licence on the SAHPRA CM portal are continuously being detained even though they were received multiple times through the ports previously. AHPRA to please clarify if this payment needs to be provided before the sat release of stock.	Fee not applicable. Cost recovered under retention fees

SAHPRA
South African Health Products Regulatory Authority

Amendment, transfer and appeal

In respect of all applications for amendments in terms of Section 15A, the name of the medicine approved by the Authority under Section 15(5), which shall be the proprietary name, the approved name of each active ingredient of the medicine and the quantity thereof contained in a dosage unit or per suitable mass or volume or unit of the medicine, the conditions of registration, the name of the applicant, the name and address of the manufacturer, packer, final product release control, final product release responsibility	800	850	850	No fees should be charged for an "Amendment of information in the register" where the error that requires to be amended was caused by the Authority. This should not be required if the amendment is due to SAHPRA's error	Correct. No fee will be charged due to a SAHPRA error.
Payable fee in respect of an application in terms of Section 158	1 050	1 100	1 100	Is this is the same as 8(a)xiv	This fee is applicable to only TOA of medicines. 8(a)xiv refers to a fee applicable to a proprietary name change or site change or TOA for medical devices
Payable fee in respect of an application in terms of Section 24 (3)	50 000	52 500	52 500	This needs to be reduced. The DoH and SAHPRA need to understand contextually that an internal appeal is a legal pre-requisite to judicial review in terms of the Promotion of Administrative Justice Act 3 of 2000. Internal appeals must be exhausted. Appeal fees must be reasonable (or removed altogether) to ensure that any company, regardless of turnover or means, is able to utilise the appeal process to challenge a decision taken or not taken when aggrieved. The fee proposed to appeal a decision by the regulator is exorbitant and far beyond the actual cost to register a product. The affect this will have is that most companies will not appeal and thus the options available to market for a particular product will be reduced and will reduce competitiveness. The exorbitant fee is not explanatory in what the additional activities will be to justify the cost. There needs to be consistency in the review and application of guidelines and regulations if inconsistent on SAHPRA evaluation then the fee should be waived.	Cost of appeal exceed fees being charged. Current rates are averaging R2 500 per hour for SAHPRA appointed legal representatives and R900 per hour for committee appointed representatives. Increase is only inflationary.

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Questions

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