NATIONAL ASSEMBLY

FOR WRITTEN REPLY

QUESTION NO. 2095

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Ms H Ismail (DA) to ask the Minister of Health:

(1) With regard to the SA Health Products Regulatory Authority (SAHPRA), what (a) is the full breakdown of section 21 applications that his department has received for the use of Ivermectin to date and (b) are the full, relevant details of all donors to SAHPRA for the past three years;

(2) whether he can confirm that an amount of R70 million was donated to SAHPRA by the Bill & Melinda Gates Foundation in 2019 and 2020; if not, why not; if so, what are the relevant details;

(3) (a) has his department received any applications from manufacturing facilities from abroad, (b) how long will it take for a certificate for analysis to be done, (c) how are senior management of SAHRPA recruited and (d) for what total number of years on average are senior management in their positions;

(4) what are the full, relevant details of all donor research and other programmes funded for vaccines in the Republic?

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REPLY:

(1) (a) The full breakdown of Section 21 applications received by the South African Health Products Regulatory Authority (SAHPRA) for the use of Ivermectin (ivermectin controlled compassion use program) as at 13 August 2021 is as follows:

Description	Approved	Rejected	Pending	Duplicate
Section 22C(1)(b) licence holder	8	3	0	0
Healthcare facility Stock	334	45	17	4
Named Patient	496	19	21	1
Total Applications - 948	838	67	38	5

(b) The full and relevant details of all donors to SAHPRA for the past three years are as follows:

Description	Clinton Health Access Innitiative	Centers for Disease Control	Public Health Enhancement Fund	Right to care	Bill and Melinda Gates Foundation	National Treasury
1. Type of Fund	Direct Donation	Direct Donation through NDOH	Services in Kind	Services in Kind (Office Accommodation)	Services in Kind	Conditional Grant
2. Purpose of Fund	Backlog reduction project	Backlog reduction project	Crisis support during strike	Backlog reduction project	Backlog reduction project	Backlog reduction project
3. Period Received	Jan-19	April '19 - Nov '20	Sep '18 - Feb '19	Nov '18 - Dec '18	April '18 - current	April '19 - March '21
4. FY 2018-19	R1 441 170	-	R2 580 000	R94 204	R27 600 000	-
5. FY 2019-20	-	R14 634 131	-	-	R45 400 000	R40 000 000
6. FY 2020-21	-	R2 104 925		-	R7 411 346	R20 000 000
7. Total Funds/Services received to date	R1 441 170	R16 739 056	R2 580 000	R94 204	R80 411 346	R60 000 000
8. Total Funds/Services used FY 2019/20	R1 441 170	R14 634 131	R2 580 000	R94 204	R45 484 335	R17 409 082
9. Total Funds/Services used to date FY 2020/21	R1 441 170	R16 739 056	R2 580 000	R94 204	R65 448 457	R35 807 189

(2) SAHPRA did not receive direct funding from the Bill and Melinda Gates Foundation (BMGF). However, SAHPRA received support through the Wits Health Consortium which received funding from BMGF with the purpose to project manage, remuneration of international evaluators and the development of guidelines and procedures in support of the SAHPRA Backlog Reduction Programme. Refer to the response to 1(b) above for the financial details as at the end of 31 March 2021.

(3) (a) Yes, the majority of medicine registration applications from local applicants have foreign manufacturing sites included in their dossier submissions. Medical Devices and IVDs section authorised a total of 107 Section 21 applications to date, for Multinational companies.

(b) SAHPRA does not generate certificate for analysis (COAs) for imported or local products, this includes Medical Devices and IVDs. COAs for Medicines are generated by the manufacturers (foreign or local), their contracted laboratories (if applicable), or local laboratories in the case of post-importation testing conducted locally. Timelines are dependent on Service Level Agreement (SLAs) between applicants and manufacturers/laboratories.

(c) SAHPRA has a Recruitment and Selection Policy that guides the Authority in Sourcing employees. In addition, Psychometric Assessments and Case Studies are utilized in the Selection Process to determine the best candidate for the position.

(d) Senior Management are appointed for a period of 5 years fixed term contract. The general years of experience required for Senior Managers is five (5) to seven (7) years.

(4) According to the South African Medical Research Council, the table below provides the relevant details of all donor research and other programmes funded for vaccines in the Republic:

Project Title	**Institution**	**Funded period**	**Funded Amount**	**Funder**	**R&D Stage**
Maintenance and Optimization of the SHIV/Rhesus Monkey Model and Colony	UCT/ SAMRC	2018-2021	R15.59M	SAMRC and SHIP DSI funds	Preclinical testing of HIV vaccine candidates
Novel HIV vaccine candidates for South Africa	UCT	2018-2021	R14.30M	SHIP DSI funds	Development of novel HIV vaccine candidates
Production of Novel HIV Vaccine Candidates in Plants	UCT	2018-2021	R4.32M	SHIP DSI funds	Vaccine production platforms
CAPRISA 012: Phase I/II trial of Subcutaneous Administration of Monoclonal Broadly-neutralizing Antibodies (SAMBA Trial)	CAPRISA	2019-2021	R21.33M	SHIP DSI funds	Clinical trial on monoclonal antibodies for passive immunization
Broadly neutralizing HIV antibodies, adjuvants and immunogens	NICD	2018-2021	R16.44M	SAMRC and SHIP DSI funds	Development of novel HIV vaccine candidates
Evaluation of the Protective Efficacy of Plant-Based CAP256 in Rhesus Monkeys	CSIR	2020-2021	R3.80M	SHIP DSI funds	Preclinical testing of HIV monoclonal antibodies
Defining the immunological capacity of novel vaccine variants to prevent against infection by 501Y.V2	NICD	2021	R3.77M	SHIP DSI funds	Immunogenicity of COVID vaccines
Antibody correlates of vaccine-induced immunity to SARS-CoV-2 501Y.V2	UCT/NICD	2020-2021	R0.979M	SAMRC funds	Immunogenicity of COVID vaccines
Neutralization escape of 501Y.V2 from antibodies elicited by vaccines	UKZN	2021	R2.53M	SHIP DSI funds	Immunogenicity of COVID vaccines
Development of an Autologous Human Dendritic Cell Vaccine to Treat SARS-COV-2 501Y.V2: A Preclinical Trial	UCT	2021	R0.654	SAMRC funds	Novel COVID candidate
An adaptive phase I/II randomized placebo-controlled trial to determine safety, immunogenicity and efficacy of non-replicating ChAdOx1 SARS-CoV-2 vaccine in South African	Wits	2020-2021	R10M	SAMRC and SHIP DSI funds	Clinical trial on COVID vaccine

adults living without HIV; and safety and immunogenicity in adults living with HIV					
Sisonke: Open-label, single-arm phase 3B implementation study to monitor the effectiveness of the single shot Ad26.COV2.S COVID-19 vaccine among health care workers in South Africa	40 sites	2021	R170M	Treasury, Solidarity Fund, Elma Foundation, Michael and Susan Dell Foundation, Bill & Melinda Gates Foundation	Clinical trial on COVID vaccine
Total				**R263.7M**	

END.