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| MEMORANDUM FROM THE PARLIAMENTARY OFFICE |

**NATIONAL ASSEMBLY**

**FOR WRITTEN REPLY**

**QUESTION 835**

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**INTERNAL QUESTION PAPER NO 8 OF 2021**

**Ms C V King (DA) to ask the Minister of Higher Education, Science and Innovation:**

Whether the state-owned pharmaceutical company known as Ketlaphela has been established; if not, what are the reasons that it has not been established; if so, what (a) is the latest relevant information regarding the development of the company and (b) total amount has been spent in the (i) planning and (ii) development processes of establishing the company?

**NW995E**

**REPLY:**

1. (a) The Ketlaphela SOC was established as a subsidiary of Pelchem SOC, a subsidiary of South African Nuclear Energy Corporation (NECSA). The establishment of Ketlaphela was part of the vision to manufacture Active Pharmaceutical Ingredients (APIs) for drugs against the most problematic diseases in South Africa, in particular HIV/AIDS. This was part in a process of many other activities and investigations into the sustainability of such an entity which included a number of studies, establishment of public private partnerships seeking expert and legal opinions. Much work in this regard was done between 2011 and 2014. In total, the process was done in three phases. The first phase entailed a partnership with Lonza, from which Lonza withdrew citing the new management team’s global “Focus and Deliver” strategy, which they said would not align with the partnership on Ketlaphela.

Following Lonza’s withdrawal, Cabinet approved a process to find a new technology partner. This was referred to as Phase 2 of Ketlaphela. The need for finding yet another partner was based on the fact that all APIs used in drug formulations in South Africa are imported and as such, a technology partner would facilitate technology and skills transfer. This phase was implemented through open calls for Expressions of Interest. Unfortunately, no bidder could meet the minimum qualifying criteria. The collapse of this phase ushered the process into the third phase.

The third phase entailed a more pragmatic approach, where Ketlaphela branded anti-retroviral tablets (ARVs) would be introduced into the national health care system through a collaboration with local ARV producers, whilst a small-scale manufacturing plant for APIs for selected niche products, including new ARV APIs would be established. The rationale for this phase was to tap into existing contracts between the Department of Health (DoH) and ARV suppliers to produce and supply Ketlaphela-branded ARV tablets to the DoH. In order to incentivise ARV suppliers to collaborate with Ketlaphela, there was a need for a letter of intent between DoH and Ketlaphela on long-term supply agreement. The Request for Proposal was therefore drafted for existing ARV suppliers who want to partner to allocate current supply of their volumes to Ketlaphela in exchange of a long -term contract. In this regard, the Department of Science and Technology (at the time) was to provide financial support for the development of new manufacturing approaches through research and development.

The third phase could not proceed as the letter of intent for long-term supply contract could not be secured. However, the research, development and innovation aspect under the Department of Science and Technology continued and the small-scale manufacturing plant for API manufacturing has been established. As from 2017, the Pelchem Board decided to take the process forward by finding an international technology partner to provide finished products under the Ketlaphela Brand. The Department of Science and Innovation is not part of this process as it does not follow the original aspect of local development and manufacturing of APIs.

(b) It is important to note that for the period 2011 to 2015, all activities for the three phases were funded by the then Department of Science and Technology to an amount of R13 747 152 to support the establishment of Ketlaphela. The funds were utilised as per the breakdown below:

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| Financial year | Amount | Institution | Reason |
| 2011/12 | R2 964 617 | Pelchem SOC | * KPMG Economic Impact Analyses of Ketlaphela * Frost & Sullivan Commercial viability, Socio-economic benefits * Study on the formulation, fill and finishing operations in the SA pharmaceutical sector |
| 2012/13 – 2013/14 | R1 500 000 | Cliff Dekker Hofmeyr | * At National Treasury’s request to obtain a legal opinion on validity of the process of engaging with Lonza by Pelchem and the IDC * Assist with the development of draft contracts and evaluation of Expression on Interest |
| 2013/14 | R4 082 535 | Pelchem SOC | * Development of New Business plan to find new technology partner * Development of all legal agreements needed to engage with new technology partner * Issuing and evaluation of the Expression of Interest * Some direct management and operational expenses * Development of blue prints for the pilot plant at Pelindaba |
| 2015/16 - 2016/17 | R5 200 000 | Pelchem SOC | * Some direct management and operational expenses * Development of Ketlaphela 3 business plan * Initial synthesis of 2 drug molecules (Tenefovir and Dalutegravir) at the University of Pretoria and the University of Kwazulu-Natal |

It is important to note that the services as procured in this regard during the three phases were rendered and as such, funds were utilised for specific deliverables. At the end of the contract between Pelchem and the Department of Science and Technology in March 2017, the unspent amount of R4 836 272.29 was refunded. Ketlaphela was therefore left existing just in name, without assets and no funding was inherited from the establishment process. The process currently being pursued by Pelchem and the Department of Energy and Mineral Resources to take the process forward in a different format seem to have stalled. With the Department of Science and Innovation not being part of that, the Department is therefore not in a position to provide an update on the latest developments.