The National Pharmaceutical Pricing Authority (NPPA), the regulator of medicine prices, has said the attempt to fix the prices of all 354 medicines mentioned in the health ministry’s National List of Essential Medicines (NLEM) could be difficult under the existing rules.

NPPA was responding to the fresh initiatives of the Ministry of Chemicals and Fertilizers to see if all NLEM drugs could be brought under price control. NPPA is an independent body that functions under the administrative control of the ministry.

A recent analysis carried out by NPPA indicates that only 8 of the 354 bulk drugs (basic raw material) may qualify for such price control. While 114 drugs got excluded due to the non-availability of exact market-size, competition and turnover, most of the remaining ones did not satisfy the conditions laid down under the current rules to bring a medicine under price control.

The Drug Policy, 1994, says a medicine should be considered for price regulation only if it has a minimum annual turnover of Rs.4 crore or a turnover of Rs.1 crore with a 90% monopoly market share. Of the 17 medicines shortlisted by NPPA as probable candidates for price control, the prices of 9 are already fixed by the government under the existing rules.

The ministry move comes after Chemicals and Fertilisers Minister M K Alagiri wanted to see if the “public interest” clause enshrined in the existing drug law could be invoked to put all essential medicines (NLEM) under price control.

NPPA currently fixes the price of 20% of the Rs.60,000 crore worth of medicines sold in the country annually. The industry is free to fix the prices of the remaining 80%, even as there is a cap of 10% increase in a year.

Introduction of all 354 NLEM drugs under direct price control would have seen NPA having say on the prices of about 17,000 specific packs of medicines, worth approximately Rs.7,000 crore.

The analysis, however indicated that apart from eight drugs manufactured by companies such as Piramal (products are now part of Abbot’s portfolio), Zydus Cadila and GlaxoSmithKline, etc, all other products might fail to pass the “inclusion” criteria. Even in the case of these eight drugs, more studies would be necessary before a final decision is taken.

A senior ministry official said the exercise was meant to understand the seriousness of the issue and the government could, if it wanted, bring all medicines under price control.