The mandate the Member States had given was limited to a system that would enable those Member States without an adequate domestic pharmaceutical sector to acquire help in exercising their compulsory license from abroad. The mandate did not authorise Member States to extend the scope to other sectors where Member States have no domestic manufacturing facilities. Further, the mandate did not call into question the application of patent rights for Member States without a domestic manufacturing sector. Despite the recognition that a problem exists in the TRIPS Agreement, the mandate in no way detracts from the basic tenet that implementation of an adequate and effective patent system, inclusive of the grant and limitation of rights, remains a principal obligation of each and every Member State.

## II. Manufacturing capacity

In order to be able to determine when a Member State has an insufficient or no manufacturing capacity, there must be a common understanding on what 'manufacturing capacities' can encompass. The text of the Public Health Declaration permits two views: either there is a lack of production facilities or there is an inability to produce. The former refers to the physical absence of a pharmaceutical manufacturing facility and does not include the manufacture of components or chemical compounds used in the final production. If the Member States were to limit their interpretation to a portion of the pharmaceutical production process (i.e. the lack of one chain in the production process) it would effectively defeat the purpose of paragraph 4 of the Public Health Declaration by limiting the Member States right to take comprehensive measures to protect the public health.[772] Further, any attempt to identify which stages of the production process would have to be absent would ensure that such a solution would drown in bureaucratic regulation.

The latter however, the inability to produce, is broader in scope and refers to the inability to domestically produce any/all elements at any/all stages of production of a pharmaceutical product. This would therefore include all operations commencing at the purchase of materials and products, production, quality control, release, storage and distribution of pharmaceutical products and the related controls. It would also mean that any if any one stage could not be produced domestically that this stage alone could be fulfilled by a compulsory license. This approach would thus better reflect the object and context of the Public Health Declaration as it would allow the Member State ultimately to elect which portions of the manufacturing process it wishes to undertake and/or if it would rather import the finished pharmaceutical.[773]

772 *Correa*, Implications of the Doha Declaration in the TRIPS Agreement and Public Health (WHO Geneva 2002).

773 The WHO also takes this expansive view of 'production'. Cf. *WHO*, WHO Expert Committee on Specifications for Pharmaceutical Preparations Technical (WHO Geneva 2005) p. 63.

### III. Insufficient or no capacities

Once it has been determined what manufacturing capacities encompass, it is necessary to determine when they are insufficient or absent. Like the manufacturing capacity, absence or insufficiency can be determined in two ways: the absolute non-existence of a pharmaceutical sector or, where such exist, the unwillingness of domestic producers to produce the compulsory license for the licensee. The Public Health Declaration, in particular the inclusion of the word 'insufficient', appears to require the Member States to find a solution to both, i.e. the problem exists not only where there is no production facilities but also where the existing facilities are unable (or unwilling) to assist in the production. This would imply that although there could be an ability to produce, factors prevent this from occurring. These factors are neither limited by paragraph 6 nor by the Public Health Declaration. Accordingly, there does not appear to be a limitation as to what causes the insufficiency. Provided the reason is a reasonable and justifiable ground and not a means to circumvent the protection of intellectual property rights.

### IV. Pharmaceutical sector

The reference to the 'pharmaceutical sector' is relevant in that it reflects the context of the Public Health Declaration and ensures that the solution should not extend beyond this scope. One of the goals of the Public Health Declaration was to ensure that Member States were able to afford healthcare treatment. Limiting the solution to the pharmaceutical sector reflects this goal and ensures the solution is tailored to meet this goal and not to be misused for other purposes.

The ordinary meaning of 'pharmaceutical sector' implies that only that sector that prepares, preserves, compounds or dispenses drugs will be considered.[774] This would imply that instruments, testing machinery and other non-medicinal measures used to counter epidemics and other extreme urgencies would not be included.[775] This is, to some extent, reflected by the reference to access to medicines in paragraph 4 of the Public Health Declaration. Notwithstanding this, limiting the meaning to industries producing medicines would not reflect the general context of the Public Health Declaration, i.e. taking measures to protect the public health. Non-medicine products such as diagnostic kits for HIV/AIDS play a crucial role in the treatment of diseases. A narrow interpretation of the concept 'pharmaceutical product' would rule out

774 Webster's Third New International Dictionary (Merriam Chicago 1971) p. 1694.

775 *Correa* makes another proposal. He suggests that the 'pharmaceutical sector' may be interpreted to extend to all those products sold by a pharmacy. Cf. *Correa*, Implications of the Doha Declaration in the TRIPS Agreement and Public Health (WHO Geneva 2002) p. 21.