multilateral trade agreements since their adoption in 1994. The System has already been available for use since the 2003 waiver decision and will become a permanent feature of the TRIPS Agreement once two thirds of WTO members formally notify their acceptance. A wide cross-section of the WTO membership has already taken this step, with many notices of acceptance received from developing countries, including several LDCs, and virtually all developed countries.[1] Accepting the Protocol is distinct from incorporating the System into national law or choosing to make use of the System. It expresses legal consent that all WTO members should be permitted to use this additional flexibility if they so choose.

Intended by WTO members to contribute to global efforts to strengthen the legal framework for access to medicines, the new System has been endorsed in a number of multilateral forums:

> The 2008 WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI) identified the use of the System as a specific action.
>
> The Ministerial Declaration – 2009 High-

further use, and a multi-stakeholder workshop is needed in order to discuss the operation of the System. It is essential to clarify whether constraints on its use were built into the System, thus necessitating its reform, or whether such constraints were a consequence of how individual countries chose to implement it.

Potential users of the System may be deterred by concerns about political or trade ramifications associated with the use of compulsory licensing.

The CAMR was successfully utilized, and only a very small portion of the three-year time period was taken up with procedures associated with the System. Much of the time that elapsed between the regulatory review of the medicine in question and the actual shipments was attributable to other factors.

The limited use of the System is not an appropriate measure of its success, as no delegation demonstrated evidence of obstacles to its use when such use was required. A single case demonstrated that the System could work when necessary, and that it could play a supportive role in the wider effort to improve access to essential medicines, given that alternative ways of procuring the needed medicines are often available.

The System is not a panacea to solve all public health-related problems. Rather, it is part of a broader picture which includes other important aspects that have an impact on innovation and access, such as infrastructure, tariffs, innovative financing mechanisms, partnerships and cooperation (including at the regional level), and regulatory frameworks.

Implementation of full patent protection for pharmaceutical products in India, coupled with the approaching expiry of transition periods in LDCs, could make it more difficult in the future to procure generic versions of new medicines. Under such circumstances, the Paragraph 6 System might assume a greater significance.

… while its full operational context is still being mapped …

While the System provides an avenue to respond to demand for medicines in a specific procurement scenario, there has been negligible notification of demand from potential beneficiaries who are faced with this particular scenario. This is against a backdrop of widespread expressions of concern about affordable access to medicines. No developing country has notified the WTO that it has a general intention to use the System, although LDCs need not take this step and other countries could also do so at the same time they notify details of the needed product. Countries

In the future – for example, in response to a pandemic or some other health security event – effective treatments are more likely to be patented in established major supplier countries. In such a scenario, the System could well assume greater importance and be used more extensively. The availability of the System provides a more credible basis for effective use of compulsory licensing for countries with either no production capacity or limited capacity, thus strengthening their hand in negotiations on price. Past experience with procurement processes (such as Brazil's threat to use compulsory licensing for the ARV drug nelfinavir in 2001) shows how effective use of compulsory licensing can succeed in inducing lower prices without the actual final grant of a licence. The limited role of the System thus far may also partly be due to the fact that many countries procure needed medicines through international procurement programmes which may