

TABLE 17.—TOTAL ANNUAL COST OF NEW REPORTING BURDEN

Type of report	Number of affected reports	Per report cost of new burden	Annual cost (\$ mil)
<i>Expedited:</i>			
Serious and unexpected SADR	53,350	\$104.23	\$5.6
Always expedited reports	1,650	612.44	1.0
Unexpected SADR with unknown outcome	983	918.65	0.9
Information sufficient to consider product administration changes	309	\$347.46	0.1
Medication errors	111,000	612.44	68.0
30-day followup	46,340	366.99	17.0
Serious SARs—blood products	7,000	612.44	4.3
<i>IND Safety:</i>			
Information sufficient to consider product administration changes	600	158.54	0.1
Bioavailability/bioequivalence safety report	200	508.21	0.1
<i>Periodic:</i>			
TPSR	1,435	603.76	0.9
PSUR	2,535	1,563.66	4.0
IPSR	353	1,172.75	0.4
Individual case safety reports—semiannual submission	5,206	1,042.28	5.4
<i>Other:</i>			
Reports of nonserious SADR and certain medication errors to manufacturer or applicant	4,652	36.92	0.2
Submit safety records to FDA upon request	21	217.24	0.0
Annual reports	2,432	¹ (530.99)	(1.3)
Total Annual Cost of New Reporting Burden			\$106.60

¹ Values in parentheses represent an estimate of cost savings.

V.D.2. Costs of MedDRA

FDA contracted with ERG to estimate the industry cost of using MedDRA terms to code individual case safety reports. In the fall of 1999, ERG and FDA staff visited three drug companies and conducted telephone interviews with several more companies and industry consultants. The purpose of the interviews was to collect information to assist in estimating the major cost components of implementing MedDRA. ERG's complete report is on file with the hearing clerk (Ref. 25).

Companies were asked to describe costs incurred or projected based on company experiences. Companies identified major cost elements that include one-time implementation costs such as planning and coordination of the conversion, converting existing data and information systems, and training. Recurring costs include MedDRA subscription and maintenance costs.

ERG applied estimates of cost by category and firm size to the number of affected firms within each industry. Estimates of affected drug and biologic product manufacturers are derived by applying data from 1998 FDA Adverse Drug Event Reports and Vaccine Adverse Event Reports to aggregate firm data from the Small Business Administration, Census of Manufactures and the National Science Foundation. Estimates of affected blood facilities are derived from the FDA Center for Biologics Evaluation and Research database of licensed and/or registered

establishments, the National Blood Data Research Center and the Census Bureau.

Limitations on ERG cost estimation include the complexities associated with firms' abilities to separate incremental costs from factors that substantially influence expenditures, such as integrating operations of one or more newly merged corporations, isolating U.S. corporate policies and operations from global corporate policies and operations, and reaching consensus on the extent and timing of the conversion of historical SADR and data.

V.D.2.a. One-time costs

V.D.2.a.i. *Planning and coordination.* Companies will need to allocate time to plan and coordinate the conversion of MedDRA across their affected operations. Planning costs are affected by the extent of decentralization of coding and pharmacovigilance work within the corporate structure. Managers for drug and biologics firms are expected to spend from 240 hours for very small firms to 1,400 hours for very large firms (greater than 750 or 500 employees respectively for drug and biologics firms) for planning and coordination. Costs per company ranged from \$10,800 to \$64,500 for drug and biologics firms. In contrast to drug and biologics firms, blood facilities have a limited range of products, do not need to convert legacy data, and typically operate only in the United States. Therefore, ERG judged that compliance

costs for blood facilities would be 4 to 5 percent of equivalent-sized drug and biologics firms. Estimated costs per firm range from \$450 to \$2,260 for very small and very large firms, respectively.

V.D.2.a.ii. *Development of information technology support structure.* Companies reported that information technology (IT) personnel will need to modify existing database systems to:

- Accommodate adding a new medical dictionary,
- Allow for MedDRA's complex hierarchical structure and wider field widths,
- Reconcile the comparability of existing dictionaries with MedDRA (in the short term),
- Integrate a Web browser, and
- Install or modify an autoencoder system.

IT personnel are estimated to need from 720 hours for very small firms to 1,920 hours for very large firms to develop and validate computer data systems that will accommodate MedDRA. Costs are estimated to range from \$25,850 to \$68,900 for drug and biologics firms. No costs were forecast for blood facilities.

V.D.2.a.iii. *Purchase or development of an autoencoder.* Companies reported that they currently use an existing database such as COSTART or WHOART and supplement these dictionaries with their own medical vocabulary. Autoencoders assist with the automated conversion of existing medical terms to MedDRA. Companies